

Compilation of Responses to Office of Science and Technology Policy (OSTP) Request for Information (RFI) To Improve Federal Scientific Integrity Policies

This document compiles the responses to the RFI (<https://www.federalregister.gov/d/2021-13640>), issued by OSTP on June 28, 2021. Of the 225 total responses, 159 were determined broadly relevant to scientific integrity. Of these responses, 66 (42%) were submitted on behalf of organizations¹ and 93 (58%) were from individuals. In most cases, (72% of individuals) identified themselves as a part of a group or occupation and 16 of those self-identified as retired members of a group or occupation. The majority of organizations represented (from organizational submissions and individual, self-reported affiliations) were Academic, Industry or Disciplinary Consortia (e.g., professional societies and trade organizations), or Research Organizations (including publishing companies, consulting firms).

Respondents were invited to provide information for as many topics below as they chose:

1. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science:

Information about the strengths and weaknesses of Federal scientific integrity policies, including where additional efforts are needed to meet the broad ambition to establish trust in Federal science by protecting against: political or other improper interference in the conduct of scientific research, the collection of scientific or technological data, and the utilization of science in decision-making; suppression or distortion of scientific or technological findings, data, information, conclusions, or technical results; disproportionate harm to Federal scientists and researchers from groups that are historically underrepresented in science, technology, and related fields; or equitable delivery of the Federal Government's programs. Of interest was information about how perceived shortfalls in scientific integrity affect public trust in science and about mechanisms Federal agencies could use to detect or deter potential violations of scientific integrity policies before they occur. [Please note: The RFI did not seek reports on alleged offenses that are in violation of Federal scientific integrity policies, noting that specific allegations should be handled through other appropriate channels].

2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information:

Practices related but not limited to: Engagement of Federal scientists and contractors working on scientific matters with news media and on social media; protection of scientific independence during clearance and review processes; avoidance of political or other improper interference in research or data collection; differentiation in official government communications of references to scientific publications and peer-reviewed research versus science-based or science-informed policy statements and determinations.

3. Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce:

Practices related but not limited to: Handling scientific disagreements about research methods and conclusions; addressing gaps in current scientific integrity policies related to emerging technologies, such as artificial intelligence and machine-learning, and evolving scientific practices, such as citizen science and community-engaged research; supporting the professional development of Federal scientists;

supporting scientists and researchers of all genders, races, ethnicities, and backgrounds and advance the equitable delivery of the Federal Government's programs; and Ensuring the independence, autonomy, and effectiveness of scientific integrity officials and chief science officers.

4. Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices:

Practices related but not limited to: Educating and informing employees, contractors, and grantees in scientific and technical positions, as well as those who manage, communicate, or make decisions based on science and technology, of their rights and responsibilities related to agency scientific integrity policies; reporting practices that promote transparency in the implementation of agency scientific integrity policies and in the handling of any allegations of misconduct; communicating to the public about alleged lapses in scientific integrity, substantiated violations of scientific integrity policies, and remedial actions taken; and minimizing conflicts of interest in Federal science and research misconduct.

5. Other important aspects of scientific integrity and effective approaches to improving trust in Federal science:

Other elements that should be included and addressed in the scientific integrity policies of Federal agencies, beyond those specified in the 2009 Presidential Memorandum, 2010 OSTP Memorandum, and 2021 Presidential Memorandum, including effective practices, in addition to those specified above, that Federal agencies could put in place to improve scientific integrity and public trust in Federal science (e.g. proactively promoting rigorous, objective scientific research and streamlining implementation within and across Federal departments and agencies).

¹ Only responses that explicitly stated they were being submitted on behalf of an organization were counted as organizational responses; all others were considered individual responses.

TABLE OF CONTENTS

Submitted By	Page Number
Public Employees for Environmental Responsibility (PEER)	3
Richard Vance	10
Eric Geimer	11
Marlo Barnett	12
Jackie	13
Marcia McNutt	14
Orlando Auciello, University of Texas-Dallas	16
George Smith, Oxford University	17
Frank Carrillo, State Farm Correctional Complex	18
S Stanley Young	19
Joe Shelby Cecil and Eugene Griffin	21
Veronica Brooks	22
Livia Dinu, Engineering Custom Solutions, Inc.	23
Sherman W Braithwaite	24
Ken Snider	28
David M Richman (dmr0313)	29
Michele Triplett	35
Mallory Suzanne Graydon	39
honu20061	45
Rangaswamy Muniappan, Virginia Tech	46
Avi Ornstein	47
Patricia Pinto da Silva	48
David Duncan Dow	49
John Richard Schrock	55
Melinda Gormley, University of California, Irvine	59
Cheryl Gross	61
Anne Millbrooke	63
Center for Open Science	67
Tom Rogers, The Atomic Biology Institute	73
Eileen Graessle	75
David Gump	76
Richard Solomon	79
Betsy Webster	80
Bill Vaughan	81
Craig Stephens	82
Jim Morrow, National Marine Fisheries Service	84
Benjamin Hassan	85
William Gorham	86
Lorin Peters	88
Ivan Graff, US Department of Energy	89
Jacob Carter, Andrew Rosenberg, Genna Reed, Anita Desikan, Taryn MacKinney, Union of Concerned Scientists (UCS)	91
Union of Concerned Scientists (UCS) - signed by 9,700+ names	99
John W Hunt, University of California, Davis	100

TABLE OF CONTENTS

Corinne Ann Dale, Small Diverse Research Institute	101
Susan Von Struensee	105
Dyne Immune Institute for Translational Medicine and Research	117
Jerald E Jones, EnergynTech, Inc.	118
Han Naung Tun	119
Ashwani K Gupta, University of Maryland	120
Maureen Fairbrother	122
Daniel J and Julie J C H Ryan	123
The MITRE Corporation	128
Sandra Scholar	136
List of 25 organizations representing thousands of journalists	137
Randy k Rannow	140
Andrew Hartley	143
Jeff Angers, Center for Sportfishing Policy	144
Jason Borenstein, et al. (14 names), Association for Practical and Professional Ethics Research Integrity Scholars and Educators (APPE RISE) Consortium	145
American Association for the Advancement of Science (AAAS), Association of American Medical Colleges (AAMC), Association of American Universities (AAU), Association of Public and Land-grant Universities (APLU), and Council on Governmental Relations (COGR)	149
Rizwan A Siddiqi, EBA Engineering, Inc.	155
Christopher Lish	157
Michael D Rich, RAND Corporation	158
Dan Dumbacher, American Institute of Aeronautics and Astronautics (AIAA)	162
Paige C Magness, Altria Client Services Inc.	166
Matthew Tenan	173
Richard Nadler	174
Carlos Carroll, et al. (11 names), Journal article in <i>Conservation Biology</i>	176
Research Data Access & Preservation (RDAP)	185
Phillip Worts	188
Elizabeth R Cantwell, University of Arizona	189
Gregory G Guthrie, National Technical Information Service (NTIS) US Department of Commerce	191
Marcia McNutt, National Academy of Sciences	192
Jodi Schneider, University of Illinois at Urbana-Champaign	194
Virginia Zaunbrecher	197
Adrienne Wootten	201
Kathryn Foxhall	204
Laurie Costello	207
Phoebe Woodworth-Jefcoats and Donald Kobayashi, Pacific Islands Fisheries Science Center, NMFS/NOAA	210
Harry Hochheiser, University of Pittsburgh School of Medicine Department of Biomedical Informatics	212
Michael Mummert	214
Priya Madina, Taylor & Francis Group	217

TABLE OF CONTENTS

Adrien Treves, University of Wisconsin-Madison	224
Ron Kavanagh	230
Teresa Gerton, National Academy of Public Administration	237
Sheryan Epperly Chester	245
American Society of Agronomy (ASA), Crop Science Society of America (CSSA), and Soil Science Society of America (SSSA)	247
Basil Hassan and Nedra Bonal, Sandia National Laboratories	252
Robert Hummer and Sara Curran, Population Association of America (PAA) and Association of Population Centers (APC)	256
Barbara D Alexander and Rajesh T Gandhi, Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA)	258
Springer Nature	262
Ted Steichen, American Petroleum Institute	268
Cochrane and the Cochrane US Network	275
William J Wiatrowski, Bureau of Labor Statistics	280
Charles Gasparovic, The Mind Research Network	281
American Society for Biochemistry and Molecular Biology (ASBMB)	284
Matthew Barblan, Association of American Publishers (AAP)	287
Steve Hensley and Beau Greenwood, Pesticide Policy Coalition (PPC)	292
Aatif Hayat	297
Glenn Hampson, Science Communication Institute (SCI)	298
James Worron, Elsevier	300
Steve Milloy, <i>JunkScience.com</i>	307
Daniel Sepulveda, Wiley	308
Nancy Amato and Alec Yasinsac, Computing Research Association and the Association for Computing Machinery (ACM)	312
Dan Stanzione, Texas Advanced Computing Center (TACC) at the University of Texas at Austin	318
Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Centers (EPCs) – 9 universities/organizations	320
Theresa Defino, <i>Report on Research Compliance, Report on Patient Privacy</i>	323
Philip Carpenter, STM (The International Association of Scientific, Technical and Medical Publishers)	324
David Parsons, Project Coyote and The Rewilding Institute	331
Caitlin Bergstrom, et al. (8 names), American Geophysical Union (AGU)	334
Martha Kinsella, Brennan Center for Justice at NYU School of Law	341
Scott Glisson, American Institute of Biological Sciences (AIBS)	348
Sandra A Brown, University of California San Diego– Office of Research Affairs	352
Jacobs Institute of Women’s Health – The George Washington University	358
Kathryn Ubl	365
Gretchen Gehrke, Alejandro Paz, Marcy Beck, and Shannan Lenke, Environmental Data & Governance Initiative (EDGI)	366
Marian Keegan	373
Jeanne Blankenship and Pepin Andrew Tuma, Academy of Nutrition and Dietetics	375

TABLE OF CONTENTS

Chris Novak and Megan Provost, CropLife America (CLA) and Responsible Industry for a Sound Environment (RISE)	382
Katherine J Duncan, IEEE-USA (Institute of Electrical and Electronics Engineers)	386
Phyllis Blumberg	392
American Geophysical Union, Climate Science Legal Defense Fund, Free Government Information, Government Accountability Project, Government Information Watch, Jacobs Institute for Women's Health, National Nurses United, Open The Government, and Union of Concerned Scientists	394
Mary Lee Kennedy, Association of Research Libraries (ARL)	398
Peter Corkeron	404
P Courtney Gaine, The Sugar Association Inc. (SAI)	406
Karen A. Robinson, Johns Hopkins University, on behalf of the Evidence-Based Research Network (an international organization)	410
Juliane Baron, Federation of Associations in Behavioral and Brain Sciences (FABBS)	412
Charles J Rothwell	416
Elizabeth Daniel Vasquez and Clinton Hughes, Brooklyn Defender Services (BDS)	420
Stacey Schultz-Cherry, American Society for Microbiology (ASM)	427
Eric Brazer, Gulf of Mexico Reef Fish Shareholders' Alliance	433
University Corporation for Atmospheric Research (UCAR)	437
Tara L Pickens and Sierra M Hicks, Pennsylvania State University Science Policy Society	440
Heather Joseph, Katie Steen, and Nick Shockey, SPARC (Scholarly Publishing and Academic Resources Coalition)	447
David T. Ozar and Donald E. Pattthoff	453
David Sampson, <i>The New England Journal of Medicine (NEJM)</i> Group	459
Meredith McCarthy Moore, Elizabeth Cerny-Chipman, and Amy Trice, Ocean Conservancy	463
The Climate Science Legal Defense Fund (CSLDF) and the Sabin Center for Climate Change Law at Columbia Law School	470
Emily Trunnell and Katherine Roe, People for the Ethical Treatment of Animals	477
Brian D. Marshall	484
Amanda Stanley and Laura Lindenfeld, COMPASS and The Alan Alda Center for Communicating Science	489
Redge B Johnson, The State of Utah Office of the Governor	492
Elizabeth Geltman, CUNY Graduate School of Public Health & Health Policy	498
Lars Vilhuber, American Economic Association	500
Richard W Briggs	505
Felice J Levine, American Educational Research Association (AERA)	506
Julian Herszage	511
Jeanine Botta, Committee on Noise and Health, Environment Section, American Public Health Association	512
Frederick Duhring	513
Kate Adamala and Carlise Sorenson, Build-a-Cell	517

TABLE OF CONTENTS

Dana Gold and Anne Polansky, Government Accountability Project	521
Steve Pierson, American Statistical Association (ASA)	526
Terri L Hill, Maryland District 12	527
Kit Kubitz	528
Leslie D McIntosh, Ripeta	530
Thomas Gulbransen	533
John Haltiwanger and Kenneth Troske, American Economic Association (AEA)	534
Jennifer Brown	535
Bohdan A Oryshkevich	536
Patricia L Morris, Federation of American Societies for Experimental Biology (FASEB)	540
Venkatesan Thimmakondur Samy	543
Elizabeth de Laperouse	545
David E Ortman	546
Zach McKinney	548
Frederick B Wood	549
Randy (AG) Randol, VA Scientists and Engineers for Energy and Environment	552
Bevin Wathen	555
J Kenneth Wickiser, Academic Research Division, West Point, NY	558
Barbara Stauffer, Smithsonian Institution National Museum of Natural History	560
Dawn Davey	562
Maureen	563
Danny Wake	564
Daniel Adams	565
(UNIDENTIFIED LANGUAGE)	567
Lilian Castro	568
Kimberly Kahl	569
Cynthia Bowen	571
Lucas Hollela	572
Nancy A Moran, Integrative Biology, UT Austin	573
Susi Sheridan	574
Saverio Sears, Sea ImpEx DK	575
Astro Space Education Co Intl	577
Katherine Hughes	578
Avi Dey	579
Bob Costa	580
Adam Wildavsky	581
E George Elias	582
Semmy Wu, Zozhi	583
Critical Situation	585
David G Fisher, Maharishi International University	586
Andrea Calihanna	595
Polinfo	596
Greg Undeen, The Climate Mobilization	597

To: Scientific Integrity Task Force
White House Office of Science and Technology Policy
From: Public Employees for Environmental Responsibility (PEER)
Subject: Scientific Integrity Policies Lack Key Components
Date: July 28, 2021

As a legal and advocacy organization working to protect public employees who protect the environment, PEER submits the following recommendations on strengthening scientific integrity policies within the federal government. Federal agencies currently have policies that do little to prevent or remedy scientific misconduct and often make scientists who file scientific integrity complaints the targets of retaliation.

In addition to our comments below, we urge the Scientific Integrity Task Force to publicly ask the administration to provide adequate funding and oversight of scientific integrity policies to ensure these policies are adequately implemented. In many agencies, there is not even dedicated staff devoted to a scientific integrity program on a full-time basis. Further, several of these collateral duty Scientific Integrity Officers have little or no dedicated budget or staff. This state of affairs renders agency scientific integrity policies into little more than rhetorical devices. This central deficiency is compounded by the fact that, despite a wide variety of scientific policies, many policies lack key components altogether, while others have some important provisions but lack others.¹

Below is a compendium of what current policies are lacking, what provisions need to be strengthened in existing policies, and the best practices that should be universalized in every federal policy.

I. Key Components Lacking in Their Entirety

The Scientific Integrity Task Force should recommend that each federal policy contain the following critical elements. Currently, none of the policies have these elements.

A. Protections for Scientists

In his 2009 memorandum directing the creation of scientific integrity policies, President Obama specified that agencies should provide additional protection for scientists:

¹ [Donald Trump's Postponed Science Test - PEER.org](#)

"Each agency should adopt such additional procedures, including any appropriate whistleblower protections, as are necessary to ensure the integrity of scientific and technological information and processes...."²

Unfortunately, no agency adopted such additional procedures. That lapse was, in our view, primarily due to the guidance from the White House Office of Science & Technology Policy (OSTP) that all an agency needed to do was to reference existing whistleblower law:

"Under these scientific integrity guidelines, [Agency or Department name] shall continue to comply with the requirements of the Whistleblower Protection Act of 1989...."³

Current law, however, only protects scientists who report violations. As PEER has repeatedly pointed out, scientists are often targeted for controversial research that exposes flaws in agency positions. Doing such work is not whistleblowing, yet it is important for, in President Obama's words, "the integrity of scientific...processes."

EPA's policy attempts to fill this gap but falls short of providing enforceable protections to scientists who report violations. EPA's policy purports to extend "whistleblower protections to all EPA employees who uncover or report allegations of scientific and research misconduct, or who express a differing scientific opinion, from retaliation or other punitive actions. . . ."⁴

This provision applies to scientists "who express a differing scientific opinion." However, this provision does not specify who enforces this protection and/or by what means. As such, it serves only as window-dressing rather than as a meaningful, enforceable safeguard.

To both be effective and meet the intent of President Obama's and Biden's directives, every scientific integrity policy should prohibit harassment of, or threats against, scientists due to the policy implications of their work. In an earlier submission, PEER recommended provisions agencies should adopt to protect scientists from reprisal for the content – as opposed to the quality – of their research and findings.⁵

B. Punishment for Violators

None of the policies specify penalties for violations by employees. As the Scientific Integrity Officer (SIO) at the Environmental Protection Agency (EPA) put it:

² [09_12_05_obama_science_integrity_memo.pdf \(peer.org\)](#)

³ Whistleblower Protections for Scientists Sidelined - PEER.org

⁴ See EPA Policy at IV A3c

⁵ [Scientific Misconduct Carries No Penalties - PEER.org](#)

“We’re not playing a blame game. The way our scientific integrity policy is written is that specific disciplinary accountability is not in our lane. So, our work is to figure out what happened and safeguard the science.”⁶

A scientific integrity policy that carries no penalty for those violating the policy provides no safeguards for the science and sends the signal that the policy can be ignored with impunity. In a prior submission, PEER detailed how to fill this fundamental gap.⁷

C. Sanctions for Political Appointees

Although the 2009 Obama memorandum targeted political manipulation or suppression of science, none of the policies provide any specified sanctions for political appointees who violate these policies. Indeed, political appointees may, by the very nature of their position, be the largest source of pressure for political manipulation of science. Yet, some policies, such as the Department of Interior's, do not address political appointees at all.⁸ Even policies that reference political appointees, such as EPA's, do not specify any steps for addressing validated allegations involving political appointees.

PEER urges that findings regarding policy violations by a political appointee be publicly reported to that official's appointing authority and/or the White House.

D. Review of Agency Decisions Not to Investigate

A principal purpose of these scientific integrity policies, in the words of President Biden's memorandum, is “Restoring Trust” by the public in the quality of government science. Yet, all of the policies allow the agencies to decline to investigate misconduct allegations without any outside review of that decision. This lapse enables agencies to cover up scientific fraud under the cover of their scientific integrity policies.⁹

Restoring public trust would require two measures: 1) An independent review of any decision not to investigate an allegation that specifies violations of the scientific integrity policy; and 2) That review be publicly posted so that the public can be assured the decision not to investigate was based on the merits (or the lack thereof) of the allegation.

E. Independence of Scientific Integrity Officers

In many agencies, these officials perform this function as a collateral duty to their main job. This situation puts Scientific Integrity Officers at risk of reprisal for performing this job well. In some cases, the SIO may be reporting to, either directly or indirectly, an official accused of scientific misconduct. In one case, PEER represented an SIO at the Bureau of Reclamation who was fired after he filed a scientific integrity complaint against the Secretary of Interior's press office for the slanted way it summarized the science on a complex and controversial issue.¹⁰

⁶ [The Fight to Clean Up the EPA \(theintercept.com\)](https://theintercept.com/2019/05/27/scientific-integrity-policy/)

⁷ [Scientific Misconduct Carries No Penalties - PEER.org](https://peer.org/publications/S170118)

⁸ [How Interior Sabotaged Its Scientific Integrity Policy - PEER.org](https://peer.org/publications/S170118)

⁹ See examples detailed in https://www.peer.org/wp-content/uploads/2021/05/5_27_21-Memo-to-Scientific-Integrity-Task-Force.pdf

¹⁰ [Purged Science Advisor Tests Interior's Integrity Policies - PEER.org](https://peer.org/publications/S170118)

PEER urges that SIOs be selected from retired annuitants or academics and given fixed terms to help secure some modicum of independence from the chain of command they are being asked to scrutinize and, in some circumstances, investigate.

II. Provisions That Must Be Strengthened

Some policies contain provisions that should be strengthened.

A. Investigative Protocols

Some agencies, such as the National Oceanic and Atmospheric Administration (NOAA), have policies that detail how non-frivolous allegations should be investigated. By contrast, EPA has no protocol at all. Nor is it even clear whether and how allegations at EPA are investigated at all, as that agency has filed no report of activities since 2018.

In addition, some agencies, such as the Interior Department, task “Bureau heads” with appointing “coordinating managers” to oversee inquiries.¹¹ This feature can undermine the independence of inquiries, as the Bureau Director may have a professional interest in ensuring that allegations are not upheld.

Every agency should have protocols for the investigation of serious complaints by experts who are independent of the agency chain of command. Moreover, these protocols should be somewhat uniform as there is no compelling rationale for the wide variation in how investigations are conducted from agency to agency. In addition, a more coordinated government-wide process would make it easier to assemble panels of independent experts from a wider variety of specialties.

B. Correction of Lapses and Violations

Most of the policies lack provisions requiring correction of the record when lapses in scientific integrity are found. While many policies reference the Information Quality Act (Public Law 106-554, Section 515), which has a process for correcting the record, none incorporate that record correction process into their scientific integrity policies. Nor do these latter policies require public notice of retraction when an error has been determined.

Some agencies, such as the U.S. Geological Survey, take the position that a scientific integrity violation requires an intentional act and will not recognize, let alone redress, losses of scientific integrity committed through negligence, no matter how gross.¹²

To restore public trust, all agency policies should require correction of scientific integrity lapses – whether intentional or negligent – followed by public notice of the same.

C. Transparency of Records

Today, federal agencies have greater discretion to withhold scientific research from public view than ever before. This state of affairs reflects the confluence of two trends: 1) During the Trump era, to reduce their legal vulnerability, federal agencies purged

¹¹ See USDOJ 305DM3 §3.6E

¹² See [Federal Lab Biosafety Whistleblower Targeted - PEER.org](#) and [PEERMail | Something Extraordinary – A Whistleblower Wins - PEER.org](#)

administrative records to remove evidence that did not support the agency decision or revealed internal dissent or controversy;¹³ and 2) A recent U.S. Supreme Court decision strengthened the ability of agencies to withhold scientific facts and findings by keeping them in draft form.¹⁴

These strictures run counter to the scientific integrity precepts put forth by both Presidents Obama and Biden. Moreover, there is no cogent reason why agency records transparency practices should vary from agency to agency. Further, as PEER has previously argued, the current agency-by-agency approach employed by this Task Force undercuts transparency. Instead, the White House should issue a single government-wide requirement that all records be included in official administrative records and that scientific research and findings should not be withheld from release under the pre-decisional exemption in the Freedom of Information Act.¹⁵

D. Conflict of Interest

Some agency policies have strong prohibitions against conflicts of interest. NOAA, for example, defines a conflict to be:

“Any financial, personal, professional, political, legal or other non-financial interest, which may influence an individual’s scientific activities or judgment by:

- a. Impairing the individual's objectivity;
- b. Creating an unfair competitive advantage for any person or organization; or
- c. Creating the appearance of either item listed above.”¹⁶

Some policies lack this prohibition altogether. One agency, Interior, had a similar prohibition but rewrote and substantially narrowed this provision in late 2014 without any public notice or explanation. Interior's current conflict of interest definition reads:

“Conflict of Interest. Any personal, professional, financial, or other interests of those covered by this policy and/or their immediate family members that is prohibited by an applicable law or policy....”¹⁷

Missing from this newer definition are specific references that encompass –

- The appearance of a conflict, no matter how blatant;
- Favoritism for someone who is not a family member, such as a romantic partner;
- An impairment of objectivity caused by a previous publicly stated position on a question that is about to be explored;
- Cronyism; and
- Creating an unfair advantage for a favored associate.

¹³ [Alternative Facts on the Rise in Federal Decision Records - PEER.org](#)

¹⁴ [BLOG | Supreme Court FOIA Decision and Official Candor - PEER.org](#)

¹⁵ [Scientific Transparency Policies Should Be Uniform - PEER.org](#)

¹⁶ NOAA Administrative Order 202-735D-2 §3.02

¹⁷ USDOJ 305DM3 § 3.5 E

Moreover, by limiting conflict to a violation of a pre-existing rule, this definition removes any new or more rigorous element, leaving issues of conflict to be hashed out under pre-existing ethics processes.

These types of definitions should not differ from agency to agency, and they should be explicit. PEER would urge that all agencies adopt the broad conflict provision NOAA has.

III. Best Practices That Should be Universalized

Some agency policies contain provisions that should be candidates for government-wide adoption, including the following:

A. Right to Publish

NOAA's scientific integrity policy explicitly encourages its scientists "to engage with their peers in academic, industry, governmental, and non-governmental organizations by ... publishing their work in appropriate outlets," NOAA's policy also provides that its scientists "are free to present viewpoints, for example about policy or management matters that extend beyond their scientific findings to incorporate their expert or personal opinions." In such instances, NOAA simply requires its scientists to state clearly that they are presenting their individual opinion, not those of the agency.¹⁸

Unfortunately, this admirable policy is constrained by a contradictory rule issued by NOAA's parent Department of Commerce. The Bush Commerce Department issued an administrative order governing "Public Communications" which repealed a more liberal "open science" policy adopted by NOAA in 2006. That order, which remains in effect, forbids scientists from disclosing information that has not been approved by the chain of command, even if they prepare it and deliver it on their own time as private citizens.¹⁹

PEER would urge that the Commerce "Public Communications" order be rescinded and that the unalloyed NOAA policy of encouraging publication by scientists be universally adopted by federal agencies.

B. Differing Professional Opinions

We also commend the Nuclear Regulatory Commission (NRC) procedures and timeline to resolve scientific disputes in its Differing Professional Opinions (DPO) Program Handbook.²⁰ The DPO receives review by an *ad hoc* panel, and the NRC policy provides confidentiality protections for submitters. A detailed and well-thought-out process such as this one would assist agencies in dealing with scientific disputes in a constructive manner that promotes scientific integrity.

C. Delay of Publication

¹⁸ NOAA Administrative Order 202-735D.2 §5

¹⁹ [Lift Gag Order Muzzling NOAA Scientists - PEER.org](#)

²⁰ [Management Directive 10.159, "NRC Differing Professional Opinion Program."](#)

In addition, we commend the EPA rule on the suppression of scientific findings, which "prohibits all EPA employees, including scientists, managers, and other Agency leadership, from suppressing, altering, or otherwise impeding the timely release of scientific findings or conclusions."²¹ (emphasis added). Especially in matters where regulatory decisions can be affected by the delay of scientific information, such delays can be the functional equivalent of outright suppression. For that reason, impeding the timely release of scientific data should be considered a form of suppression.

Concluding Comments

In closing, three overarching comments are in order:

1. *Truly Protecting Scientific Integrity Requires a Statute*

The very nature of scientific integrity policies is reliance upon the Executive Branch policing itself. History has demonstrated that to be a problematic proposition at best.

A basic challenge is that federal scientists and their work products presently have scant legal protection.²² To remedy this deficiency, the White House should ask Congress to statutorily protect scientists by classifying participation in the peer review process, whether as an author or reviewer, as a protected activity enforced in the same way and through the same legal processes employed by the federal Whistleblower Protection Act.²³

2. *Agency-by-Agency Variation Should Be Kept to a Minimum*

No purpose is served by having different definitions of key terms or variations in transparency or other basic rules undergirding scientific integrity principles. Different rules can function to lessen protections.²⁴ Ideally, the federal government should have one set of rules governing these issues.

3. *Task Force Hampered by Lack of Independence*

Many of the Task Force members have been acting as SIO's for their agencies. As such, the Task Force is being asked to evaluate the performance of its own members in finalizing its "Review," as mandated by Section 2 of President Biden's memorandum.

Just as most scientific integrity policies require that those who review allegations of misconduct not be involved with the matters they are reviewing, so too the Task Force should ask agency officials responsible for the administration of these policies not to participate in the assessment of that administration.

Finally, the Task Force should consult with scientists who have reported allegations, have been members of review panels, and former officials who have direct experience. Otherwise, the Task Force findings will be burdened by the fact that many of its members will benefit from a Review that glosses over past failures.

²¹ EPA Policy at IV A1d

²² <https://fisheries.org/2017/06/emerging-law-of-scientific-integrity-a-bumpy-birth/>

²³ See [Federal Scientists Face Official Barriers in Publishing - PEER.org](#)

²⁴ See [Scientific Transparency Policies Should Be Uniform - PEER.org](#)

From: [Richard Vance](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Sunday, June 27, 2021 9:04:54 PM

Greetings,

Want integrity?

Get rid of political appointees at science agencies!

When the FDA appointees approve junk not recommended by the science panels you've just ruined FDA integrity and increased vaccine skepticism. We already know the FDA is owned by big pharma so next in line is eliminating the revolving doors!!! Same for the EPA, FAA, FTC, DOT, DOD, DOS, ALL CABINETS AND AGENCIES JUST STOP OVERRULING SCIENCE!

Want integrity? Provide ongoing science education in tv and in social media. Kids need a Dr Wizard mentor. Cabinet agencies must continually communicate to the public about the science they use to make policy. Get back to the 50s when government taught science in public service announcements.

The public needs to be taught the basics of climate physics using kindergarten terms. Government can do that, why aren't you?

Richard Vance

From: [Eric Geimer's Best of Hawaii](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Re: "Request for Information To Improve Federal Scientific Integrity Policies"
Date: Monday, June 28, 2021 3:29:29 PM

Aloha,

In a recent twitter post <https://twitter.com/WHOSTP/status/1409580391434964993?s=20> you seemed to invite comments from US citizens on ways we feel the federal government may seek to restore public trust in science, is this correct? If so, thanks! Happy to help reinforce one of the ways you are already likely to be considering, and cheer on, saying, please, go for it!

Simply put, people tend to prefer what they are familiar with, in psychology this may be known as the mere-exposure effect, and in social psychology it may be referred to as the familiarity principle. If the federal government is able to utilize a portion of its funds, however small, to purchase advertising that is pro-science throughout the various mediums consumers may come across it, then over time, more Americans may become familiar, once again, with science and its benefits, and therefore prefer it. This effect may be expedited if advertisements may be targeted towards media mediums where those people presently tend to doubt science are most likely to come across the advertising.

Two personal anecdotal examples come from hearing about the benefits of a plant-based, fruit & vegetable-heavy diets in what I assume to have been federally funded advertising aired during conservative-AM-talk-radio shows in the 2006-2010 timeframe, in Florida. Though no longer a listener, and though it took some time, my own diet has moved in such a healthy direction. Another example comes not from an experience here in the USA, but while vacationing abroad, in Australia. It seemed surprising, and delightful, that throughout Sydney, where one may expect to find corporate advertisements, they may also encounter science-centric messages, one assumes that are funded by the government. These are targeted in a different way than above, and seemingly, very cleverly: in restrooms there may be (and was, in at least one case according to personal memory) a simple, easy to grasp poster relating to digestive health and common problems that may warrant a medical checkup. Similarly, evidence-based healthy-eating guidelines may be posted as advertisements near fast food locations, etcetera.

These two types of targeted, science-based advertising, and federally funded, pro-science advertising in general, even when deployed in a manner that is not targeted, may go at least some of the way to inducing in more Americans a preference for science, if saturation is high enough to unlock the positive benefits of the mere-exposure effect.

Thanks so much for taking the time to solicit and review suggestions like this! This was a lot of fun to write up for you. Best of luck in accomplishing your task,

Eric Geimer

From: [Marlo Barnett](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Monday, June 28, 2021 3:39:32 PM

Good afternoon,

My name is Dr. Marlo Barnett, to help improve the effectiveness of General scientific integrity policies to enhance public trust in science their must be equitable representation at the table, discussions and content must be viewed through the lens of diversity, equity, inclusion, and seek out educators and/or people that are invested and committed. Educators who not only talk the talk, but they are the change they want to see in the educational systems.

From: [jackie](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Response: Request for Information To Improve Federal Scientific Integrity Policies
Date: Tuesday, June 29, 2021 2:57:41 PM

Revise the way information is provided to patients regarding their health by ensuring that patients reasonably understand the medical issues at hand. Now clinicians will have patients sign documents without really ensuring that the patient understands the issue, recommendations and impact. Recommend that the conversation be recorded, to ensure integrity of process. The recording should start after the patient/power of attorney accepts or declines in writing whether to participate in the recording; benefits of participation should be shared with the patient. If the person declines, document and proceed to the fullest extent possible to ensure understanding....

Thx for all allowing me to share.....

From: [McNutt, Marcia K.](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Tuesday, June 29, 2021 6:15:47 PM

I'm submitting these comments in my personal capacity, based on my experience when Director of the USGS from 2009-2013. These should not be viewed as the opinions of the NAS.

As an agency head during the Obama administration, I noted the following.

1. I served in an administration that understood the importance of science and respected scientific input.
2. During that time, OSTP under John Holdren requested that all agencies update and improve their scientific integrity policies, subject to OSTP guidelines on what sort of result was desired.

Nevertheless, even a science-sympathetic administration was not immune to political interference in science. The problem that is universal to our federal government is that scientists rarely hold the top spot in departments with policy or management responsibilities, Cabinet secretaries and independent agency administrators are more likely to be lawyers or business executives (Steve Chu and Ernie Moniz heading up DOE were a refreshing exception.) For the very few that are regularly led by scientists - NIH and NSF - scientific integrity issues are few and usually handled effectively internally.

The problem with the non-scientist political appointees who typically hold the top policy spots is that they don't even realize when they are not being faithful to the science because they don't understand it at a deep level. They make slight alterations in emphasis or interpretation to support administration priorities without even realizing that what they are doing is messing with the science. They usually are appalled to learn that what they have done is not consistent with the science.

As an example, back when I was USGS director my agency wanted to put out a press release on the multiple documented threats to bats - important pollinators - from white-nose syndrome as well as unintended conflicts with windmills, both of which were additive impacts to threatened populations. When the press release for the study got to the DOI, the press people there altered it to emphasize the disease issue and downplay the impact of windmill strikes, with the explanation being that they didn't want to put too much emphasis on something that interfered with the administration's clean energy agenda. When I pointed out to the A/S that if the additional stressor had been oil and gas generation on public land, and the leadership in the prior administration had sought to downplay it, all sorts of accusations of political interference with science would have been lodged. The A/S immediately grasped the problem, and didn't allow the DOI press people ever again to alter a USGS press release.

What seems to me to be important in protecting the integrity of science is to have the top scientist in any department or agency (for example, the Chief Scientist at NASA as the head of the agency is rarely a scientist, to be someone whose first loyalty is to the integrity of the scientific results, and only secondly to the administration's agenda. The agenda for the administration will clearly influence what questions are being asked, but should never influence the answers to those questions. This scientist must also have both the interpersonal skills and the backbone to stand up to proposed interference, but in a way that doesn't turn the

political leadership against using science. He or she should also be respected enough not to need that job. There was at least one time when I had to threaten to quit rather than support a statement that a certain policy was based on science when it wasn't. But that is a much longer story.

The scientists in government service need to have the assurance that their leader has their back. Reputation is everything in science, and any political interference serves to undermine not only good policies, but also the scientists who do the work.

Feel free to contact me if I can answer any questions.

Sincerely,

Marcia McNutt
Former Director, USGS

From: [Auciello, Orlando](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Age Discrimination for Principal Investigatoyors
Date: Tuesday, June 29, 2021 9:50:04 PM

I have learned from talking to colleagues in one of the top Agencies providing funding to scientists at Universities and start-ups the program managers indicate to proposal reviewers to take into account the age of the principal investigators when reviewing proposals and submitting reviews for funding

This in my view is tantamount to Age Discrimination, since there are many scientist above 65 years who are as productive or even more than younger colleagues

My suggestion is to eliminate request information in the summary brief of the PI that can provide information on the age of the PI

Best Regards

"Live as if you were to die tomorrow.
Learn as if you were to live forever."
Mahatma Gandhi

Orlando Auciello
AAAS and MRS Fellow
President of MRS (2013)
Endowed Chair Professor
Materials Science & Eng Department
Bioengineering Department
University of Texas-Dallas

From: [George Smith](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI (Corrected text)
Date: Wednesday, June 30, 2021 8:21:14 AM

Brief comments to OSTP regarding forthcoming review of scientific integrity policies

Some years ago, I represented the British Royal Society on a National Academies Panel which looked into a range of issues regarding fraud and misrepresentation in science.

Since then, I have built up an file of case studies of actual breaches of scientific integrity that have been documented or otherwise reported in the public domain. I would be more than happy to share this information with your Task Force

I would strongly urge the Task Force to take a pragmatic approach to the investigation. It is very difficult to draw up general guidelines, based on first principles, that cover every possible area of bad behaviour. Instead, it will be more productive to look at a selection of real-world experiences of what has actually happened in the recent past, and to ask the question: "How could each of these incidents have best been prevented?" This will provide a robust template to address key aspects of observed behaviour patterns, including requirements for improvements in training, monitoring, record-keeping, regulation and legislation.

Yours sincerely,

George Smith,

FRS, FInstPhys, FRSocChem, FInstMaterials, FRoyalMicrosSoc, FMicrosSocAmerica, CEng, CPhys,

Emeritus Professor of Materials, Oxford University, Oxford, UK.

From: [Carrillo, Frank](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: Research Integrity
Date: Wednesday, June 30, 2021 11:52:07 AM

One simple protocol is the availability of the Literature Review page and contact information from other research sources. Thank you.

Frank W. Carrillo, MA - Casework Counselor
Alternate ADA Monitor
State Farm Correctional Complex

Request for information (RFI) on scientific integrity.

Comments from

S. Stanley Young, PhD, FASA, FAAAS

In effect there are no science cops. For that reason, the whole science community needs access to data sets used in papers that are used to set policy. Integrity is more likely to be displayed by researchers knowing that their work is open to scrutiny.

Any environmental epidemiology should follow these Young-Graham rules:

1. Use of Science Transparency Act

Any federal agency proposing rule-making or legislation shall specifically name each document used to support the proposed rule-making or legislation and provide all data used in said document for viewing by the public.

2. Federal Study Transparency Act

If federal funds are provided for a study, all data relating to the reporting of results of said study must be provided for scrutiny by the public at the time of publication.

Testimony of Committee on Science, Space and Technology Fostering Quality Science at EPA

S. Stanley Young, PhD, FASA, FAAAS

Openness and transparency are at the core of the scientific process. Science and technology have been the major drivers for social change, improvements in living standards and improved health for humans over the last 250 years.

To support openness, data sets used in papers supporting regulation by the EPA should be publicly available as quickly as possible. It is simply good science to have data used in papers public.

Some might think that peer review is enough to ensure the validity of claims made in scientific papers. Peer review is not enough. Peer review only says that the work meets the common standards of the discipline and on the face of it, the claims are plausible. Scientists doing peer review essentially never ask for data sets and subject the paper to the level of examination that is possible by making data electronically available. Also, the evidence is that many claims made in peer reviewed journals do not hold up. For medical observational studies over 80% of initial claims failed to replicate. Environmental epidemiology studies are likely no better. The scientific process is back and forth. This process would be faster and more efficient with data sets publicly available.

Three things make sense. Going back in time, key regulations and the papers used to support them should be identified. The EPA should secure copies of data used in those papers and make the data public. For example, several papers on air pollution and mortality use the ACS CPS II database. The EPA should secure a copy of this data set and make it public. Where data sets are not available, claims in those papers are essentially "trust me" science. The EPA should not be relying on trust me science. Using taxpayer dollars, the EPA supports current research. As papers are published on this research, authors should provide, at time of publication, three things: the study protocol, the statistical analysis code, and an electronic copy of the data set used in the publication. Basically, EPA funded authors should follow the guidelines for "reproducible research". Finally, going forward the EPA should fund data collection and analysis separately. Data collection and staging, the building of data sets, is a distinct area requiring different skill sets from data analysis. Each could be done more efficiently if done separately. If data building and analysis are together, there is a natural tendency authors not to share the data until the last ounce of information is extracted. It would be better to open the analysis to multiple teams of scientists.

The public, Congress, and the EPA should all want an efficient science process to support sound regulations. Making data available by implementing these three steps would be big steps toward improving the science process at the EPA.

02 Cecil and Griffin 1985

The Role of Legal Polices in Data Sharing

Joe Shelby Cecil and Eugene Griffin

Sharing Research Data

<http://www.nap.edu/catalog/2033.html>

Cecil and Griffin note that it is possible to share data for statistical purposes and protect personal identity.

“Statistical and administrative procedures have been developed that permit meaningful statistical analysis of data while preserving the anonymity of the respondents. For example, techniques of microaggregation permit statistical analysis of information on identified groups of individuals (Campbell et al., 1975). Release of such aggregated information would seem to be permitted under the act: since the information is not individually identifiable, disclosure is not restricted. A mutually insulated file linkage technique may even permit agencies to share large archives of aggregated data without violating the act (Campbell et al., 1975)”

Cecil and Griffin note a possible perverse policy strategy, italics added:

“The interpretation of the majority in *Forsham* suggests that the research records of a grantee cannot be obtained through the Freedom of Information Act. The fact that the research findings are controversial and that the findings are used in establishing public policy through various agency proceedings will not be considered in determining the right of access to research records through the FOIA. *This case suggests that an agency can insulate its actions from public scrutiny by funding a grant for controversial research and then basing its action on those findings. As long as the agency does not take possession or control of the records, the FOIA will not assist those who wish to challenge the findings that underlie the agency action.* Of course, if the data are filed with the agency, the FOIA will be a more effective means of obtaining disclosure.”

Campbell, D.T., Boruch, R.F., Schwartz, R.D., and Steinberg, S. 1975 Confidentiality-preserving modes of access to files and to interfile exchange for useful statistical analysis. Appendix A in A. Rivlin, ed., *Protecting Individual Privacy in Evaluation Research*. Report of the Committee on Federal Agency Evaluation Policy. Washington, D.C.: National Academy of Sciences.

From: [V Brooks](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Thursday, July 1, 2021 12:11:47 AM

Greetings,

A decision tree can filter out documents that are either “theory” or “proven”true or false.

To move ahead, we need to deal with real science, proven by other scientists or other method such as universities or research programs and confirmed. There should be a separate database of science that has been proven to be true.

Any “theory” should be stated at the top of public documents and kept in another separate database.

Best of luck,
Veronica Brooks

Sent from my iPad

From: [Livia D](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Response : OSTP Request for Information to Improve Federal Scientific Integrity Policies
Date: Friday, July 2, 2021 1:55:36 PM

Hello,

I am excited for the opportunity to provide information valuable to you from a professional perspective of engineering/business development/STEM area of expertise.

That is exactly the point to be made here in terms of intent, that starts with encompassing as large a perspective as possible, while reaching every level/field of study and attributed policy in the process and then narrowing it down in an elimination process of improvement at the end of the course/study.

I can be reached by email or phone for more information or questions.

Livia Dinu
Engineering Custom Solutions, Inc., a Subsidiary of Sly LLC

From: [SHERMAN W. BRAITHWAITE](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Proposal Acceptance Investigations
Date: Saturday, July 3, 2021 5:26:26 AM

I have submitted several proposals probably to all government grant-awarding entities in the United States. I keep being rejected. I get rejections like; 'Out of funding'; 'You were not responsive to the topic'; 'Your proposal has no merit'; 'Your proposal has merit and, we are out of funding'; 'At this stage, your proposal aligns with none of our projects'. Except for the truth concerning "out of funding", all of the excuses are lies. If you do some research into especially NASA's database of failed funded projects you will see that merit truly has no meaning. And NASA is busy funding projects to gain profit, in which they act like they will get more technology like Solar Panels and such. By the way, NASA unwittingly used Solar Panels and Nuclear Reactor Technologies to ruin the Space Industry. I learned that from the project I keep proposing to them in many different forms. So here is the thing, the same project in different forms gets different rejection letters ignoring stuff like merit and it is that they are "out of funding".

After all of the lies; Then, time and more money are wasted in educating the public on how proposals are supposed to be written to them. Seriously, NASA is the only entity that wants a bizarre act submitted to them? And basically, if the so-called imagined rules they claim have to be followed are not followed, a less important proposal that somehow followed the rules will get funding? It sounds even more stupids as I read it again and again. Then NASA isn't interested in innovations to get humans to space safer and more efficiently? NASA is running a writing class. It's not about the research being solicited for NASA funding. It all sounds stupid just as well when I read it again and again. Yes, it is all a likely story made up by NASA as an excuse for databases full of failures. After they reject an idea like mine, however, I truly feel that NASA is ill.

Let me just mention, there is no specific way to write a proposal. Most likely it will follow the format of a research paper. It is the usual format used in which everything in English is written. From it being, a simple sentence to it being, a paragraph. A proposal is written in paragraph format; A Subject (A General Statment or Thesis Statement), and a Predicate (Specific Statements or Examples of the Subject). It is the same format for an essay. The proposal simply has a few extra parts with specific names that are asked for. When all of those parts are submitted with a proposal, what is the problem? A few of my proposals submitted to NASA disappeared from one of their online submissions portals and, the rejection letter to me at that time was that *parts were missing from my proposal*. I simply felt it meant something else than that. Then NASA went out of their way to start and educate the public on what's asked for in proposal submissions. They have been doing that for the past few years joined by 3rd parties promoting that sort of necessity for NASA's Proposal Submissions Systems.

The people rejecting proposals cannot argue with the basic rules of how English writing is supported to be submitted. They can argue that parts are missing if you submit a proposal with missing sections they asked for. Then they probably need to tell you which parts are missing because their suggestion makes no sense if you find that your proposal files are missing from their online portal. The teachings that follow concerning education in how to submit proposals are even weirder when the program manager is educating you and proud of what he is saying when what he says means they were swindled. You must understand that one thing doesn't mean another. Anyhow, NASA now educates the public in how a proposal is supposed to be

written when in truth, you have to hire a firm that writes proposals to get your point across. I was very tempted to get that done and kept ignoring it because every time a great decision should be made in how I can get accepted for funding, I run out of money. In this instance, I get to wonder why anyone with money would want to get a research grant from the government? I also get to wonder what happens when the proposal writing firm fails at doing the job they were paid to do? Even more, how many people are supposed to read about the research being solicited to the government again? Thousands? Let me just mention, these people make me feel so low, I wish I never submitted any of my Intellectual Properties to be patented. I suppose after that, more than a thousand people saw everything. It's scare tactics these people are practicing? Your stuff is public. It's now trash?

NASA and space flight and Aviation and the US Air force and space flight and Aviation. Both entities sent me rejections like 'At this stage, your proposal aligns with none of our projects'. My proposals to those entities are always about flight. It's so weird how these entities that are great at always creating solicitations that seem to directly target my projects keep forgetting one thing; The proposal or Research Paper writing format. It is as simple as writing a paragraph. You simply ask for as well, some sections with specific names. What they also seem to forget is their business if they are surrounded by flight or not.

"NASA unwittingly used Solar Panels and Nuclear Reactor Technologies to ruin the Space Industry." All of my proposals to NASA and the DOE were rejected because somehow everyone has been forced to accept that space flight present and future cannot be accomplished without using Solar Panels and/or Nuclear Reactors. I also found out that NASA has something against people like me and they have been sitting on it like it is an egg about to be hatched. [NASA had a contest where people would demonstrate Mechanical Antigravity](#). Again, NASA uses a trick wording the solution as a *mechanical* feat. And in that other sense, none mechanical or using energy; The world of science and technology actually believes the problems can be solved by using power from the wall socket or Solar Panels and/or Nuclear Reactors. It's basically the people of planet Earth bragging that they know all. And yet, NASA still solicits help through Requests for Proposals. They definitely ask for help because they have nothing other than chemical rockets that are used for traveling from Earth to space and old Intellectual Properties used as references in stealing or corrupting new Intellectual Properties. It then turns out that if you want to actually show people an idea doesn't belong to them, you have to fund your projects yourself and let them keep dreaming of how they can make old failed technically Intellectual Properties, still never work. That is all these people do. They use old dead scientists like Einstein to Tesla, to steal ideas regardless of if it is some new idea invented. They dive into everything that becomes popular. From Alcubierre Drives to EM Drives. They enjoy playing around with garbage ideas and they keep rejecting mines. Here is a simple reference, [Electrogravitas](#). If it's related to flight and electricity is involved, depending on the depth at which the concept goes into being classical physics, as it moves closer to being gravity or in some sense, Black Hole Gravity, it's rejected and reference to be stolen. Like for instance. Look out for how often you hear about [Electrogravitas](#) from now on. They are on a roll.

The truth is, I do not believe you can "Improve Federal Scientific Integrity Policies". There never was any such thing. It's always been about money and a need to create the best lie in science. The truth about all proposals I have ever written for a research grant award from the US government is that neither you nor I know who is truly pulling the ropes, and I will let you know that the person is a selfish and crazy person. Imagine that; People that dealt with all sorts of mockeries, of flight technologies, and such reject by mentioning that; "At this stage, your

proposal aligns with none of our projects". There it is again. Is that a sign of people asking for help or one that means your research cannot be independent of all the scientific garbage all of the people on Earth practice in which they are forced to believe electrical power comes from a wall socket, Solar Panels, and/or Nuclear Reactors and lately what's been becoming popular, batteries?

Yes, you cannot "Improve Federal Scientific Integrity Policies". Science died years ago or it is at a standstill and no one cares to believe in such things just because their solutions and others' before them failed. Most people want to be like Einstein. Hey, if all you have left on Earth are these phony geniuses and thieves it will look just like what you speak of, Scientific Integrity is as dead as science.

I couldn't propose my ideas without interference? Weird. What sort of scientific community is it that is draining me silly? Just imagine that. Potential Aviation and Space Travel Technology I proposed is being called names while a lot of other ideas get praised as my ideas are sucked dry by more and more fantasies being flooded in your scientific systems. [Here is MIT's idea of the sort.](#) I bet one day NASA will fund it and they ignored me since around 2017. The truth is, I probably can't handle fame. In the case of NASA handling my proposals better, that would not have brought me fame. Fame is what I will one day steal from them and all the other phonies that don't know what they are doing. The only thing NASA would have brought me is the one thing that nut they are involved with would have brought me if they weren't so nosey, selfish, and a thief. Peace of mind.

In conclusion, if you are serious, your solutions lay in doing some good **"Proposal Acceptance Investigations"** with a twist of looking at who and what was rejected in the past. Let me just mention that the Alcubierre Drive and EM Drive could not have become famous, and later someone else comes up with a new idea like those ideas and he gets famous too, None of the popularity makes any sense. I probably shouldn't mention that. The 3rd up is actually that. 3rg up. He just isn't that famous. The ideas disrespect everything I have been inventing. They may seem like sane concepts, however, none of those 3 ideas can be fabricated to function and only a 4th idea is novel and can be fabricated to function because it was invented to do that. With the 3 ideas that people desire to float around, it's like as I have been working on perfecting my ideas all these years, somebody was picking at them. My ideas are novel; Or else, they would be just like those 3 ideas that don't have a power source. The power source, a notion that was a part of my inventions from the first day of conception since the 1990s to the present in which I have absolute proof that electrical power coming from a wall socket, Solar Panels, and/or Nuclear Reactors cannot power any of those 3 things (Alcubierre Drive and EM Drive and else). More so, the Alcubierre Drive is a mind game concerning a body standing still in space as a galaxy it was in leaves it behind. The EM Drive is a waste of energy even if there was enough energy to make it function. That 3rd person. I don't even want to speak of him. He talks trash about how the Chinese were trying to patent what he went ahead and patented before them, but all of his ideas are copies of what I have submitted for patenting. Hence I am Chinese? He literally patented physics concepts of how things would work in general. and again, there is no power source to go with his physics concepts. And that one thing, the power source is important because hypothetically, ***electrical power coming from a wall socket, Solar Panels, and/or Nuclear Reactors cannot power any of those things.*** I am almost starting to believe the 3rd person did it how he did it because ***Scientific Integrity*** is dead as people are forced to believe the absolute useful sources of electrical energy are what's on Earth already. Therefore, invent physics concepts and ignore that the useable power source to make it all function does not exist. I suppose except when it

comes to doing with Fusion Generators. It would seem that a lot of people believe that once Fusion Generators are a functional technology, they will be the ultimate source of energy. Anyhow, in the realm of science, I am used to, that's where *Scientific Integrity* went. It never existed.

In. Sherman W. Braithwaite.

From: [Ken Snider](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Tuesday, July 6, 2021 10:59:56 PM

To restore trust, all the scientific data of research used to make public policy decisions must be made public.

Hidden data, for whatever reason, creates distrust in the public.

For the American people to trust government decisions, all the data must be available electronically for anyone to check and verify.

When the government withholds data, the public will be skeptical of the reasons government scientists and officials proclaim as their justification for the secrecy.

Too often the government has withheld data and science that would cause a reasonable person to disagree with government agencies' decisions.

Too often the stated reasons for withholding the data turn out to be false. They were created to keep inconvenient science and data out of view so support for the agenda of the people in charge of the agencies would not be undermined.

If the data and science cannot be made public, for any reason, then the conclusions of that science must not be included or used to support any agency's decisions.

From: [dmr0313](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] RESPONSE TO ACTION ITEM
Date: Sunday, July 11, 2021 7:08:54 PM

On June 29, 2021 I received, from the AAAS of which I have been a member for a number of years, q POLICY ALERT the response of which follows:

I AM DAVID M. RICHMAN I WAS A FEDERALEMPLOYEE FROM 1958 TO RETIREMENT IN 1992

I HAVE AN MS DEGREE IN CHEMICAL-NUCLAR ENGINEERING.MY POSITION WHEN I RETIRED WAS PRINCIPAL STAFF ASSISTANT TO DEPARTMENT OF ENERGY'S DIRECTOR OF THE OFFICE OF ENERGY REASEARCH, NOW THE OFFICE OF SCIENCE.

RESPONSE TO ACTION ITEM JULY 12,2021

It's a request for information that could help improve federal agency scientific integrity policies. This was the first time I was exposed to this topic, "federal agency scientific integrity policies."

My first step was to seek a definition of this topic. I found a definition, apparently one defined by the USDA, that I liked and will use:

"Scientific integrity is the condition resulting from adherence to professional values and practices when conducting, reporting and applying the results of **scientific** activities that ensure objectivity, clarity, and reproducibility, and that provides insulation from bias, fabrication, falsification, plagiarism, inappropriate influence, political interference, censorship, and inadequate procedural and information security."

My next question was "where did I fit into this end result of scientific activities?" My answer is ensuring objectivity, clarity and reproducibility. The other stuff is up to the organization's leadership and staff that are responsible for dealing with those

responsible for reporting and applying the results of the **Scientific** activities. I have a hard time figuring out what conducting the results means unless it refers to the office responsible for conducting the **scientific** activity.

And my final question now is: "How did I help bring about the **scientific** activities that meet the scientific integrity definition?"

I was trained as a chemical-nuclear engineer, MS degree, worked for three years as a nuclear engineer at Brookhaven National Laboratory and was invited to join the Atomic Energy Commission (AEC) in 1958 with a focus on peaceful uses of atomic energy. I did so and in 1960 I was invited into the basic research arm of the AEC, the chemistry aspect. For 10 years I was involved in university research funding, proposal research review and interaction with the more applied aspects of the AEC as well. My funding and review aspects involved research and applied activities in AEC's national laboratories as well. I recognized the serious distinction between scientists involved in basic research and engineers focused on meeting societal need.

I determined that a federal agency needs a leader who determines the true goal(s) his or her agency are aiming to attain and appoints a manager for each goal, someone who truly understands the goal and the broad capabilities available and not available to achieve it. Right here there is a requirement that (from my point of view as an engineer) a manager, and staff as well, need to grasp: both the pros and cons of potential solutions to the problem(s), and what the problem(s) are that need to be solved to attain the goal. This may, or may not, involve basic scientific research and the manager being able to meet the requirement of scientific integrity.

When I worked for the AEC my role in reviewing and budgeting basic research was not difficult because the basic research

activities supported at our national labs and universities were Relevant to our mission. They were basic and met the requirements of the scientists doing them. My role once such research was underway was to do everything I could to support their activities, providing the resources needed by them and grasping their particular aims. In no way was I a manager of their activities; I was a supporter of them.

Having come from the applied side of AEC to the basic research side, I continued to interact with that side but observed that there was an almost formal separation and thus limited interaction between the applied and basic staffs. Later I realized that the different organizational units, typically under political appointees in an agency, almost encourage that lack of interaction and communication because they are competing with each other for budgets and staffing – and for recognition of their wonderful leadership. I later, in the Department of Energy, found it a much worse situation than decades before in AEC.

In 1971 I was offered an opportunity to participate in the International Atomic Energy Agency and served there for 2 years as head of a unit responsible for chemistry and pharmaceutical application activities.

When I returned to the AEC it was disbanded, split into the nuclear organization responsible for power reactors, etc., and the Energy Research and Development Administration (ERDA) which

Later (1978?) became the Department of Energy (DOE). I was quite active in ERDA in the development of the energy projects that were later taken up by DOE when it was formed. I was involved (I don't remember if in ERDA or DOE) in the establishment of a Solar Energy Laboratory and mention it here because in developing its budget goal, I had a hard time with the new appointee to head it wanting to state what it will accomplish which did not recognize that it would definitely

require a lot of basic and applied research at the lab as well as universities and by new industry as well. It would have definitely violated "Scientific Integrity" had that happened. I think I won that one.

When DOE was established in the late 70s I became a member there initially staff to an appointee of President Carter. My recollection is that I left that position a few months before she was fired. The appointment of this person as well as more recently the former governor of Texas who, when appointed did not know DOE had some responsibility for nuclear weapons, are reasons why there's a Scientific Integrity Task Force. But there are worse problems. When DOE was formed it included 75 schedule C employees. I met some of them and found most had one specific issue each wanted to solve. People like this are dangerous. When their president loses his term, they manage to stay on. Some do become capable but they are a negative impact to people like me who fought to ensure what you call Scientific Integrity really exists. The political appointees are competing for their concepts of what the Agency they're in should be doing, competing for that and budgets. I actually found some divisions doing similar programs instead of sharing them, a waste of time and money, and a serious failure of organizational management. This results in a major lack of communication in a billion dollar organization. I am reporting here on my observations during the period from 1978 when DOE was formed to the year of my retirement, 1992. While I bounced around in several different organizations in DOE's early years, I was invited, because of my many years of experience in AEC and ERDA, to a new position, to serve as principal assistant to the director of the Office of Energy Research. This included keeping the Director informed on national energy research issues as well as DOE activities cross cutting organizational elements within the office of Energy Research (now the Office of Science).

I also observed that an activity I thought failing the reason for DOE existing, was that for more time was being put into developing budgets than in reviewing what last year's budget accomplished. I viewed that as a serious internal issue affecting what the input ought to be to **scientific integrity**.

During my early period in AEC I found two basic research activities funded at universities by AEC that had been of major benefit to society that would have fit very nicely into **Scientific integrity**. One was a basic research program in the 50s, before my time, that was involved in exploring the presence of lead isotopes aimed at estimating the age of the Earth. That basic research program was supported by AEC and I suspect NSF as well. I don't know the details of its specific history, but it led to the removal for society of perilous lead from gasoline used in automobiles and lead from tin cans as well!

The other one was research done during my early period in the AEC. It was research of the chemistry of chlorine and fluorine released to the environment. It led to the awareness that these chemicals, used for refrigeration, were seriously dangerous in their release to the environment because they destroyed an oxide layer about 30 miles above the Earth. One of my non-scientific colleagues who had authority for what you are concerned with, scientific integrity, refused to report the impact found by the research because doing so was not part of the core of the research funding. I viewed this as a serious failure.

Prof. Sherwood pressed his case, publicizing his findings with press conferences and by testifying to state and federal legislatures. Opposition from affected industries arose and he was criticized, ridiculed and discounted. One industry group producing and using refrigerants called him an agent of the KGB. An international agreement, the Montreal Protocol, was enacted in 1987 to limit the production and release of CFCs. The unexpected discovery in 1985 of the Antarctic ozone hole by the British Antarctic Survey, confirmed within months by

NASA, had added some drama behind-the-scenes, while Antarctic fieldwork by teams of scientists confirmed the destruction of ozone in that layer. Prof. Rowland and his student Mario Molina as well as Paul Crutzen, a Dutch scientist concerned with the formation and decomposition of the ozone had all made pioneering contributions to explaining how ozone is formed and decomposes through chemical processes in the atmosphere. Most importantly, they have in this way showed how sensitive the ozone layer is to the influence of anthropogenic emissions of certain compounds. All three were awarded the Nobel prize in 1995.

What I view of concern is that the results of many basic and applied research activities funded by the AEC and now DOE never receive the recognition they deserve from the private sector that makes use of them and the economic benefits received by society as a direct result of federally reported basic and applied research.

July 12, 2021

To: The Scientific Integrity Committee,

There has been a long battle for standardization and oversight in the forensic science disciplines that is being poorly addressed [emphasis added]. In 2009, the *National Academy of Sciences* (NAS) report, “Strengthening Forensic Science in the United States: A Path Forward” brought these issues into the spotlight. In 2013, NIST was given federal funds to oversee a group called the *Organization of Scientific Area Committees* (OSAC) [emphasis added], which was tasked with creating best practices and standards for most forensic disciplines. A second group was formed called the *Academy Standardization Board* (ASB) as an official Standardization Development Organization (SDO) to review and approve the best practices and standards developed by the OSAC. The word *Academy* in ASB stands for the *American Academy of Forensic Science* [emphasis added]. Many other committees were formed as well, yet little progress has been made and the direction being taken is far from scientific. The need for scientific standards is vital to ensure that innocent people are not falsely convicted of crimes, and to ensure trust in government. NIST is not ensuring scientific principles are utilized.

Forensic sciences that are based on pattern recognition (fingerprints, footwear, handwriting, fracture matching, hair and fiber analysis, tire tracks, ballistics, etc.) have been used worldwide for over a hundred years. Writing standards for these disciplines should be simple, yet after eight (8) years of OSAC efforts, not one document has been approved for fingerprint comparisons. This is amazing considering that a vaccine for covid was developed and distributed throughout the world in less than one year. The draft documents that are being proposed have a multitude of issues, a small subset of these issues is listed below to show the lack of science.

- 1) Those on the OSAC and ASB are *stakeholders*; there is no assurance that OSAC committee members are knowledgeable in sound scientific practices. Well intentioned reformers are unaware and/or unwilling to recognize their own deficiencies. You cannot solve a problem at the level of which it was created.
- 2) The new proposals have not been validated, some concepts have even been shown to be invalid yet the OSAC and the ASB members approve concepts based on a vote, not data, stating the documents are *consensus* documents. General consensus IS a scientific concept however, it does not mean to simply take a vote. General consensus in science is saying that current doubts have been resolved. Relying on a majority vote downplays the value of science and is nothing more than replacing old dogma for new dogma.

One scientific concept that is being misused is the concept that no scientific conclusion is ever absolute. This statement is somewhat correct but does not apply to concepts that have been falsified, e.g., science whispers yes and screams no. Conclusion arrived at by induction are not absolute, however, concepts that have been falsified should be solid (once a black swan is found the premise that all swans are not all white should be absolute). Those developing standards are unaware of this basic scientific concept.

Another scientific concept that is being misused is the idea that repeatability/reproducibility is a cornerstone of science. Reproducibility IS required for experiments; yeast should make bread rise regardless of who is performing the task. However, reproducibility is not how analytical

conclusions should be tested for correctness. A second person independently performing a pattern recognition problem and arriving at the same conclusion does not add weight to the conclusion, it is merely says, ‘...and Bob thinks so too’. Much like a long division problem, analytical conclusions should be checked by having others peer review the validity of the conclusion, i.e., that it was arrived at in a valid manner.

Committee members are not given any directive that documents need to follow scientific protocols. However, being an *advocate* of OSAC documents is highly valued and rewarded by receiving OSAC awards (OSAC Bulletin, July 2021). Awards for *promoting* a view goes against science. Science highly values skepticism (over confirmation) as the best method of evaluating information for correctness. Science recognizes the value of critical thinkers in the quest for truth, justice and transparency.

- 3) In 2016, the OSAC recommended changing the term ‘identification’ (as in ‘this fingerprint was identified as being from person A) to ‘source identification’ so that an identification is not taken as being a fact. Changing the term to *source identification* does not change how the conclusion is perceived by the courts or jurors.
- 4) In 2020, the OSAC recommended not to use the word ‘conclusion’ because they said it was confusing. *Drafting conclusions* IS the task of those performing scientific endeavors! Voting not to use the word is absurd at best and shows a lack of scientific knowledge by those tasked with reform.
- 5) Documents encourage forensic practitioners to give their opinions and beliefs in court. Sound science recognizes that conclusions should be data driven and every effort should be made to minimize opinions and beliefs of the practitioner in order to reduce subjectivity.
- 6) Statistical terms are encouraged, even though there is no means to measure the correlation between two items. The information being given to the courts is nothing more than guesswork being falsely represented as scientific.
- 7) The lack of references in the documents indicates the lack of validation behind concepts. Documents that have references are selectively citing research and ignoring contradictory research.
- 8) Many recommendations simply say, ‘the forensic service provider shall have a policy on....’. This does nothing to ensure sound practices or promote consistency within the discipline. The ASB defines a Best Practice as ‘the optimal way to carry out an action”. Recommending that agencies make up their own policy is not stating the optimal method for carrying out an action. There is irony that the groups developing requirements for others are not follow their own requirements.
- 9) Proposed documents, i.e. *draft* documents, have had the draft stamp (watermark) removed in an effort to encourage agencies to implement the OSAC recommendations prior to any validation.
- 10) Those on the ASB, reviewing the work of the OSAC, are the same individuals that are on the OSAC. Reviewing and approving your own work IS NOT rigorous scientific scrutiny; it is rubber stamping disguised as an impartial review.
- 11) In addition to NIST overseeing the OSAC, and the ASB reviewing the work of the OSAC, there is another oversight board over the ASB. ANAB (ANSI National Accreditation Board) has

accredited the ASB as an official Standards Development Organization. Even with four levels of oversight, and multiple levels of oversight within each group, basic scientific protocols are not being promoted or followed. All of these groups have been made aware of these issues and continue to ignore the problems (again, giving awards to those that advocate for these documents). This is nothing less than negligence.

- 12) A proposal for a means of measuring information was proposed to the ASB fingerprint committee from a person outside of OSAC, however the ASB members voted against considering the proposal (they voted not to read it) because they wanted to wait for an OSAC proposal on the topic. This culture, selectively acknowledging information, leads to the suppression of valuable information. Science through bureaucracy is not science, it's pseudo-science and politics.

Although there are dozens of other issues and examples, I have limited my concerns to those that are extremely basic and obviously unscientific. If the Scientific Integrity Commission wants to recognize the issue and address these concerns, then I would be more than willing to provide more examples and concerns. The ASB meetings are open for the public to attend, with approval by the Chair. I encourage you to sit in on one meeting to see the problems for yourself.

The current system is not effective and there is no excuse for the lack of progress. Quality does not take time or money; it takes knowledge, effort, and clear goals (developing standards that adhere to science); constantly assessing if end products meet the goal. The current system is not improving consistency between agencies, it is not improving forensic conclusions by ensuring sound data driven conclusions are arrived at or given in court, and it is not ensuring scientific integrity, trust in the process, or justice. NIST is not following or enforcing sound scientific protocols. NIST is spending more time and effort on marketing OSAC recommendations than in reviewing them for scientific validity. This is much like the quote from Andrew Gelman, "It's not just that the emperor has no clothes, it's more like the emperor has been standing in the public square for fifteen years screaming, I'm naked! I'm naked! Look at me! And the scientific establishment is like, Wow, what a beautiful outfit."

Solutions:

The solution is to require that forensic conclusions be based on demonstrable data, validated methods and validated criterion for conclusions, not based on concepts voted in as being favorable by likeminded individuals, and/or based on the opinions/beliefs of practitioners. Conclusions need to be reviewed for validity, not simply reproduced by another analyst. The lives and liberties of the public are at stake, as well as the integrity of government and science. This is not merely a potential problem, it is a problem that has affected hundreds of innocent people, as shown by the NAS Report on forensics and by cases found by the innocence project. I am hopeful that the Scientific Integrity Commission will acknowledge these issues and be part of the solution.

Sincerely,

Michele Triplett,

Examples and References (not comprehensive):

Nist/OSAC home page:

<https://www.nist.gov/osac>

NIST/OSAC Mission Statement:

https://www.nist.gov/system/files/documents/2020/04/23/OSAC%20Organizational%20Priorities_March%202020_CURRENT.pdf

Source Identification is reached when the friction ridge impressions have corresponding ridge detail and the examiner would not expect to see the same arrangement of details repeated in an impression that came from a different source.

A conclusion shall not be communicated as a fact. It is an interpretation of observations made by the examiner and shall be expressed as an expert opinion.

https://www.nist.gov/system/files/documents/2020/03/23/OSAC%20FRS%20CONCLUSIONS%20Document%20Template%202020_Final.pdf

Strength of the evidence: A means of describing the weight of support the evidence lends to one source proposition over the other. The strength of the evidence is often represented as a Bayes Factor (also known as a likelihood ratio), and may be described verbally or numerically.

https://www.nist.gov/system/files/documents/2020/03/23/OSAC%20FRS%20ARTICULATION%20Document%20Template%202020_Final.pdf

Vacuous standards - Subversion of the OSAC standards-development process

<https://pubmed.ncbi.nlm.nih.gov/32671333/>

Email to OSAC members:

“The term “conclusion” is not included in the list above nor is it used in the OSAC Organizational Priorities & Minimum Requirements for Standards Development document. The term, “conclusion” is used in different ways and can mean different things. Because the meaning of the word can be ambiguous and not clear to the reader, the FSSB does not support the use of the term “conclusion” in future standards and OSAC work products.”

“OSAC is seeking nominees to receive the 2021 Sharon B. Nakich Award. This OSAC peer-to-peer award is in honor of our colleague, Sharon Nakich, and acknowledges a helpful attitude, kindness, teamwork, or behind-the-scenes contributions to support the goals of OSAC. It recognizes an individual who has made significant contributions to promote OSAC’s mission through his or her support of OSAC.

This nominee works diligently and tirelessly as a champion for OSAC, at times without recognition.”

OSAC Standards Bulletin July 2021

Response to [RFI 86 FR 34064](#)

Dr. Mallory Suzanne Graydon

Abstract. *Building trust in evidence-based governance requires first building trust in the scientific literature and in academia. Such trust depends on many factors, but at the least should not exist without both (a) massively improved standards of rigor in some scientific domains and (b) equitable representation of society within both government and academia.*

Rigor in the sciences (especially critical software assurance)

As a research computer scientist working for NASA, I specialize in assurance that software-intensive systems are fit for use in safety-critical contexts, especially aviation. I have met many professional developers who express disdain for the academic literature in my subject. There are good reasons for this disdain: the way we fund research in this field rewards publishing large volumes of papers, regardless of scientific merit, and rewards researchers for overpromising short-term results rather than for the steady production of high-integrity, basic-science studies and experiments on which a trustworthy body of knowledge must be built. Addressing this will require substantive changes in both what scientific grants are offered and on how potential and realized performance are judged.

The output of my scientific field guides the policy of safety regulatory bodies such as the FDA (regulating medical devices that contain software), the FAA (regulating avionics, air traffic management, and the like), and other government agencies. It also informs voluntary practice in fields where safety-related software assurance measures are largely voluntary undertakings meant to reduce product-liability-related legal risks (e.g., in automotive applications). It is thus vital that the scientific investigation of software assurance practices provide a solid foundation for decision-making about practices.

Despite the importance of a good understanding of the material at hand, vanishingly few controlled experiments—the gold standard for research in medicine—are performed. While examples do exist¹, I generally do not expect to see any such studies published in a given year, let alone high-quality ones with detailed methodology sections, well-thought-out means of addressing threats to validity, etc. Instead, we see evaluations described as ‘case studies’ that are nothing more than smoke-test applications of a proposed technique to a toy example,

¹ E.g., J. C. Knight and N. G. Leveson. An experimental evaluation of the assumption of independence in multi-version programming. *IEEE Transactions on Software Engineering (TSE)*, 12(1):96–109, January 1986. <http://dx.doi.org/10.1109/TSE.1986.6312924>.

without even the basic trappings of what would comprise a proper case study². Many papers merely make proposals for “frameworks” or “approaches” or other ill-defined intellectual content. Other papers repeating proposals made elsewhere with no more than a hand-waving explanation of any difference that would justify publishing yet another mere proposal, let alone a substantial scientific assessment of the merits of the proposal³. It is unsurprising that a literature full of toy examples that betray little understanding of the realities and complexities practitioners face does not inspire confidence amongst industrial practitioners.

In some ways the dearth of empirical results is a byproduct of the nature of this scientific field of study. Safety, in the sense of the absence of major accidents, is notoriously difficult to measure: major accidents (thankfully) do not occur in industries such as aviation at rates that would make them subject to well-run correlation studies. The ethics of studies where the uncontrolled variable is risk to the public pose ethical concerns. And when the intervention to be studied is the way in which a years-long engineering effort involving many professionals is performed, the cost of obtaining a large number of samples in a study is prohibitive.

But it is possible to conduct meaningful scientific studies if that is one’s goal. One can, for example, study the principles thought to be at work in proposed techniques and frameworks, starting with pilots and working up to larger scale experiments using suitable volunteer subjects. But getting academia as a whole to do such work would require changes in the way research is funded and monitored.

The vast majority of the funding calls I have seen in my discipline over my career ask for vaguely-defined solutions to problems that are seen as either pressing the relevant industries now, or problems that are anticipated to plague them soon. For example, DARPA’s Automated Rapid Certification of Software (ARCOS) project, on which I serve as a government review panel member, seeks to dramatically reduce both the time and expense of certifying safety- and security-critical software for use in military applications.

This is a worthwhile aim. However, the research bids such lofty calls attract are often long on promises to solve the grand problem and short on the kind of basic research that would actually underpin a trustworthy scientific literature on the subject. For example, ARCOS attracted participants who promise automatic software test case generation, evidence artifact collation, automated safety argument construction, and argument confidence quantification. Automatic

² For case study research generally, see the prescriptions in R. K. Yin. *Case Study Research: Design and Methods*, volume 5 of Applied Social Research Methods Series. Sage Publications, Thousand Oaks, CA, USA, 3rd edition, 2002. For case study research in computer science generally, see P. Runeson and M. Höst. Guidelines for conducting and reporting case study research in software engineering. *Empirical Software Engineering*, 14:131–164, 2008. <http://dx.doi.org/10.1007/s10664-008-9102-8>.

³ I have criticized papers in my field for exactly this, e.g., P. J. Graydon and C. M. Holloway. An investigation of proposed techniques for quantifying confidence in assurance arguments. *Safety Science*, 92:53– 65, February 2017. <http://dx.doi.org/10.1016/j.ssci.2016.09.014>.

test case generation is an important, established field; contributions to it would be welcome. But when research funding is spent based on proposals framed in terms of the impact the whole field will bring (e.g., faster, cheaper certification), rather than focusing on specific studies or experiments that will be done, it is not clear the result of each additional research effort will contribute to the whole.

Moreover, focusing on a complete solution, rather than the efficacy of pieces that can only be evaluated properly in isolation, might result in the premature promotion of immature technologies. For example, chasing ARCOS's lofty goals has caused participants to pursue both automated argument generation and argument confidence quantification alongside more mature technologies. Automated argument generation largely misses the point of safety arguments⁴, is not known to have practical value, and will not receive substantial empirical evaluation as part of ARCOS. And argument confidence quantification has a poor track record, plagued by repeated failures to produce trustworthy analyses and a total lack of empirical evaluation that ARCOS will not contribute to⁵. Describing those among more mature technologies in the same project may give potential users a false sense of their maturity.

While the problem ARCOS is meant to address is pressing, the structure of such a project precludes giving each incorporated technology the kind of rigorous evaluation it deserves, for the reasons described earlier: one can kick the tire on an assembly of individually well-evidenced component technologies as means of solving a bigger problem, but that does not obviate the need for more in-depth studies and experiments showing the effectiveness of each component. Actually achieving trustworthy results would also require instead a years-long program of related basic research: basic research on automatic test case generation, with empirical evaluations of efficacy at increasing scales. Basic survey and interview research to understand how safety and security auditors perform their work. Correlational studies to identify which of their habits is effective and which could stand improvement. Human subjects experiments to assess the performance of human beings performing those tasks. Efficacy studies to complement the knowledge from basic human-performance studies by show the effectiveness of entire techniques in a way that is more comprehensive even as it is more subject to noise from low sample counts and other threats to validity.

Putting off such basic research in favor of work that promises solutions to big problems but cannot deliver solid empirical evaluations of the matter at hand incurs the epistemological

⁴ Practitioners and researchers seem to differ on the aim of safety arguments. See, e.g., P. J. Graydon. The safety argumentation schools of thought. In *Proceedings of the Workshop on Argumentation for Agreement and Assurance (AAA)*, Tokyo, Japan, November 2017. <https://shemesh.larc.nasa.gov/people/msg/graydon2017thesasots.pdf>. My colleagues C. M. Holloway (NASA) and K. S. Wasson (Joby Aviation) have excellent thoughts about this, some of which came out of the FAA-sponsored Overarching Properties Working Group and will be published in a forthcoming white paper entitled *An Introduction to Constructing and Assessing Overarching Properties Related Arguments (OPRAs)*.

⁵ See Graydon 2017, *IBID*.

equivalent of technical debt in the field: we are proposing to build practice on a web of poorly-evaluated notions and unchallenged assumptions and failing utterly to produce the basic results upon which future progress might be made.

At the same time as researchers are incentivized to promise solutions to current problems, rather than promise to conduct the high-integrity studies it would take to have a trustworthy body of literature in my field, they are incentivized to publish a great many papers. Promotion and tenure criteria are often tied to paper count, and research grants often require “dissemination.” This incentivizes the writing of low-quality papers. Rather than dense, high quality papers as the material to report them is available, researchers often write multiple papers per year regardless of whether there is anything substantial for them to say. The result has been a proliferation of low-quality conferences and workshops where such papers survive peer reviews performed by volunteers who often lack the deep knowledge to effectively criticize each submission. I have participated in several workshops that essentially sprang up to publish the low-quality work demanded by large research contracts. These venues produce such low signal to noise ratios that the quality of the academic literature would noticeably improve if all of the papers published to them were instead consigned to a wastepaper basket.

These problems are not solely the result of government policy. But policy does contribute: a large amount of research in my field is funded by the US Government, through agencies like DARPA, NSF, and NASA. These organizations could:

1. Substantially increase the proportion of their research funding that goes to basic research with high-quality study and experiments rather than the more synthesis-oriented, poorly evaluated research that aims to address pressing problems. The latter has its place, but can no longer be allowed to eclipse the former.
2. Evaluate grant applications and research outcomes much more heavily on the scientific rigor of the research. Proposals must sketch methods, list key threats to validity, and sketch an approach to mitigating them.
3. Assess applicants more in terms of good scientific conduct rather than prominence in the field or past grants completed without major incident. Researchers should be assessed in terms of their willingness to question their own positions and history of performing high-quality studies and experiments with high probative value rather than, e.g., publication and citation count and related metrics.
4. Sponsor workshops and mentoring arrangements to help entire research communities learning to do the scientific work they should have been doing all along but have little experience or preparation for.
5. Explicit funding for experts to perform peer reviews, and to conduct research and training to improve the efficacy of such reviews.

Policy might also help in generating the engagement of industry in producing a robust data set to use for correlational research. The actual practice of software assurance is often hidden from researchers into the field by engineering organizations eager to preserve trade secrets. Yet a little data collection from these activities, coupled with well-conceived data aggregation

and anonymization, might help to produce data sets that could provide vital information about what is working, and not working, in practice. Consider establishing working groups at, e.g., FAA to determine what kind of data collection might be possible and what kind of incentives and privacy preservation measures would be needed to encourage the required corporate participation in data collection.

Equitable participation in government and academia

It is important that government researchers, funding bodies, and academics performing sponsored research represent an equitable cross-section of the population. If we do not, perspectives will be missed with the result that entire communities will see the resulting work as not representing their interests (or worse).

But there are barriers to equitable participation. As a white, transgender woman, I'll constrain brief comments here to matters that directly affect me and people I know well.

The federal government does little outreach to the LGBTQ+ community. Our agency's HR staff does not routinely attend LGBTQ+-focused hiring events. Our LGBTQ+-focused employee resource group is willing to step up, but lacks funding to attend. Not only is no special effort made to reach potential LGBTQ+ interns, but the obscurity and short-application-timeline-nature of our process effectively favors applicants who are told about opportunities by advisors, which may or may not be LGBTQ+ friendly or working with an equitably balanced student body.

What little outreach to potential LGBTQ+ employees the government does do might be targeted too late in the hiring process to produce the needed equity. Many LGBTQ+ people face barriers to achieving the necessary qualifications due to discrimination in employment, housing, and medical care. Consider outreach directly to local LGBTQ+ support centers and funding of scholarships with associated school-to-work recruitment pipelines.

Moreover the federal government continues to impose disincentives to LGBTQ+ folks choosing to work as government research scientists rather than in industry or the academic sector. Health insurance available to me, for example, does not cover some kinds of care needed by transgender employees that is often standard in corporate- or university-sponsored insurance plans. As a result, I have spent several tens of thousands out-of-pocket for needed medical care; a cost that job seekers considering government service must weigh carefully.

Interns and employees face workplace facilities that lack gender neutral toilets as options for employees who want them. When my own building was remodeled, I proposed an approach I had seen in Sweden: clusters of gender-neutral single-occupancy restrooms shared by all. This was dismissed without serious investigation, but should be put into practice as a safe and convenient solution for all.

Recently, I was contacted about chosen names by a summer intern. Our IT department insisted that her email address follow the pattern of her legal name. This is problematic in a country where short-term employees like interns may not be safe coming out in the environments they will return to, or face challenges and expense in changing their legal names. Employees at all federal agencies should be able to use a chosen name for email and nearly all workplaces purposes, as employees at some agencies already can.

As a federal employee, I might also be asked to travel to other states, or even to relocate as employees in some federal agencies have been asked to do in recent years. I live in a state with some LGBTQ+ protections, including non-discrimination in housing, medicine, and public accommodation. I would not relocate to a state that does not offer such protections. Consider allowing remote work for the many categories of employees whose duties can be largely or entirely performed remotely, to allow employees to work from less oppressive climes.

If I travel to states that outlaw the medical care I need or allow doctors to refuse to treat me on religious grounds, I take a grave personal risk that I will be allowed to suffer and possibly die should an accident create an unexpected need for medicate care. Consider banning non-essential federal travel to states that pass anti-trans-healthcare measures, as states such as California have already done.

The industrial and academic environments in related disciplines have long been dominated by particular demographics, often white, cis, heterosexual men. Recent news from companies like Google and Microsoft and climate surveys in federal workforces shows both a lack of appreciation for the equity needs of others an intense pushback against the folks who point this out. At the same time, diversity trainings seem not to have been particularly effective. The obvious suggests itself: protect the minorities we do have, compensate them for their efforts to build equity, delegate authority to them to achieve that end, and protect them from the inevitable backlash when and where it occurs. While I am less knowledgeable about the

From: [honu20061](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Tuesday, July 13, 2021 3:23:34 PM

Endangered Specie Act listing decisions are supposed to be ONLY based on best available science. By law and reg. No economics, no politics. Yet listing decisions are routinely interfered with and delayed (itself an integrity violation) by both political and and career leadership at office director, regional, and HQ levels. This happens in both Democratic and Republican administrations. If you can get that to stop this effort will be success. If not, it's all more lip service. The interference ranges from delays for political timing to interference with scientific and risk determinations (endangered vs threatened) etc. All of which is a violation of the ESA and any reasonable scientific integrity concept.

From: [Muniappan, Rangaswamy](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Information to Improve Federal Scientific Integrity Policies
Date: Wednesday, July 14, 2021 12:28:03 PM

The Bureau of Resilience and Food Security (RFS) at USAID manages Innovation Labs that conduct research and development on various aspects of agriculture in developing countries. The Integrated Pest Management (IPM) Innovation Lab is one of the programs supported by RFS. This program began operation based on a study and recommendation by the National Research Council.

To be awarded the IPM Innovation Lab, USAID released Request for Applications in 1993, 2004, and 2014 for U.S. universities to respond to. Virginia Tech competed and secured the program in all three releases. Typically, USAID issues a Cooperative Agreement to the successful university for a five-year period and renews for an additional five-year period if the external evaluation conducted at the fifth year of the first five-year term receives a satisfactory report.

USAID followed this practice for the first two RFAs (1993 and 2004) of the IPM Innovation Lab. However, at the fifth year (2019) of the third RFA released in 2014, the RFS, USAID administration informed Virginia Tech that it is not going to renew the IPM Innovation Lab for the next five years even though it received a satisfactory evaluation by the external evaluation team, which was authorized by USAID and conducted in 2019. Upon inquiry, the Chief Scientist informed the IPM Innovation Lab at Virginia Tech that USAID administration has decided to solicit more competition for issue of Innovation Labs and hence it is not renewing the IPM Innovation Lab for a second five years. However, the same procedure was not followed by the RFS for the Collaborative Research on Sorghum and Millets Innovation Lab and Collaborative Research on Sustainable Intensification Innovation Lab at Kansas State University and Livestock Systems Innovation Lab at the University of Florida. These Innovation Labs were renewed for a second five-year term after the end of the first five-year term in 2019 and 2020.

The reason given by the RFS USAID for not renewing the IPM Innovation Lab at Virginia Tech for the second term was misleading as it did not follow the same reasoning for the Innovation Lab managed at Kansas State University and the University of Florida. Additionally, USAID eliminated the IPM Innovation Lab altogether, a program that generated billions of dollars in benefits to developing countries, generated over \$15 million in leveraged funds, trained over 600 graduate students in the U.S. and abroad, collaborated with over 100 institutions, and introduced dozens of sustainable farming solutions to the developing world. Based on these discrepancies, more clarity and/consistency is needed for how and why certain Innovation Labs are renewed or not, given a successful research history and review.

Sincerely,

R. Muniappan
Director, IPM Innovation Lab
Virginia Tech

From: [Avi Ornstein](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] "SI-FTAC RFI"
Date: Thursday, July 15, 2021 11:04:55 AM

In over four decades of teaching science and math to pre-college students, I learned that the most valuable thing I was able to do was teaching my students how to learn. I could not foresee what future path they would follow, but it was critical that they could take valid information and use it to reach rational decisions.

Students need to be able to turn to governmental sources to get factual information. They also need to see good role models in the government regarding scientific research and advice. I learned this first-hand. My father, Leonard Ornstein, was one of the leading research scientists in the 1960s. I was directly influenced by him and by the diverse scientific community with which he interacted. I wound up going to MIT, where I earned a bachelor of science degree in biology.

I wound up taking a different path from most MIT graduates. I selected to teach younger students, but I drew upon my personal experiences. I taught them to use primary sources and to do actual research. The various awards I received over my professional career reflected the value of how I taught my students. Many went on to follow careers in science, but—more importantly—my students learned how to use factual information to make rational decisions.

It is fundamentally important that the government supports scientific research and selects a diverse community to serve as role models for our diverse student population. These decisions will directly affect their future and will therefore similarly affect the future of our nation.

Dr. Avi Ornstein
Retired science teacher

From: [Patricia Pinto da Silva](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Thursday, July 15, 2021 12:05:53 PM

To whom it may concern.

Thank you for the opportunity to comment - a strong SI policy and implementation plan is critical to ensuring the best available science is produced, shared and used to support decision-making. It is also essential in order to attract and retain the best available scientific staff.

Currently, at NOAA, if I have a scientific integrity issue I would like to raise, I am supposed to go to the SI point person in my Agency. That person is part of the organization that is involved in the alleged scientific misconduct. Given this process design, I would not feel comfortable raising issues that relate to any high level management members given their collegial and social interactions with SI officers. While I understand that discussions with SI officers are considered confidential I would argue that establishing an autonomous group outside of the agency to review and investigate SI allegations would increase the perception of commitment and cleaner boundaries between the agency and individual bringing an issue for review. In my mind, this would improve the likelihood of confidentiality being honored and limit the ability of pressure or interference by high level actors in the agency in response to an allegation.

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From: [David Duncan Dow](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Cc: [David Dow](#)
Subject: [EXTERNAL] SI-FTAC RFI Thursday,
Date: July 15, 2021 3:40:21 PM

I am a retired biological oceanographer from the Northeast Fisheries Science Center in Woods Hole, Ma. and former employee at NASA's Earth Resources Laboratory at the Stennis Space Center in Mississippi where I did remote sensing research. I am a grassroots environmental activist living on Cape Cod where I have been engaged in the Safe Drinking Water Act/Superfund cleanup at Joint Base Cape Cod, since the late 1980's. In more recent times I have been engaged in the dialog on including climate change in managing commercial/recreational fisheries in a more sustainable fashion and North Atlantic right whale deaths from entanglements in lobster pot gear and ship strikes. I served on the Habitat Plan Development Team for the New England Fishery Management Council which helped develop Omnibus Habitat Amendment 2 which was released in 2018 by the NOAA Fisheries Greater Atlantic Regional Fisheries Office. I also served as the Recreational Fisheries coordinator in the Northeast for a number of years and participated in the re-audit of the Marine Mammal Protection Act in the mid-1990's.

I was a mid-level bureaucrat/scientist and not a policy maker. Thus the items that I list below on scientific integrity and use of the best available science in making policy decisions & developing regulations may not reflect policy decisions that include socioeconomic considerations; political priorities; Environmental Justice concerns; and agency policies (i.e. speaking with one voice). During my work career, I worked in academia (College of William & Mary; University of Michigan's Great Lakes Reach Division and Louisiana State University's Center for Wetland Resources). I worked in private industry for an environmental consulting firm (Hittman Associates in Columbia, Md.). Thus I was a jack of all trades and master of some.

1. Failure to include climate change effects in OHA 2 which was released in 2018, even though NOAA Fisheries scientists released a report in 2017 on how to include this environmental stressor in the management of fisheries under the Magnuson-Stevens Sustainable Fisheries Act. The 2020 NOAA Fisheries State of the Ecosystems report for the Mid-Atlantic and New England regions pointed out that climate change effected the marine food chain (Microbial food web added to the grazing food chain) and top down changes in predation/competition as fish species and their prey change their locations in space and time.

The Northeast Fisheries Science Center's Population Dynamics models still assume the "Natural Mortality" is constant (excludes changes in recruitment of managed fish stocks and altered predation/competition from Apex predators at the top of the food chain). This approach ignores much of the academic research supporting an adaptive, ecosystems-based management approach for finfish (see Univ. California- Santa Barbara and Lenfest Ocean Program research endeavors on A, EbM). Thus from my perspective they are not using the best available science in the fisheries management process both inshore (0-3 miles: Atlantic States Marine Fisheries Commission & Massa.

Division of Marine Fisheries) and offshore (3-200 miles; Mid-Atlantic and New England. Fishery Management Councils; NOAA Fisheries GARFO). These Populations Dynamics models are the basis for quota management in recreational and commercial fisheries and deciding whether a stock is being overfished (female standing stock biomass) or subject to overfishing mortalities. Striped bass and sea herring stocks offer good case studies.

As a retiree and grassroots environmental activist, I don't know who made these policy changes
To exclude climate change from the fisheries management dialog.

2. Reducing NARW mortalities from lobster pot gear entanglements, ship strikes, increasing ocean noise and climate change effects.

This problem involves NOAA Fisheries interactions between the Marine Mammal Protection Act; Endangered Species Act; M-S Sustainable Fisheries Act and Department of Interior location of oil/gas drilling /seismic surveys/location of ocean wind farms. Marine ENGOs sued NOAA Fisheries because its NARW population recovery plan was inadequate under the MMPA and its plan to reduce pot fisheries under the ESA was focused on restoring the NARW population until 2030. The Bureau of Ocean Energy Management Updated EIS for the Vineyard Wind 1 project off of Cape Cod included a cumulative environmental impact statement for 20 wind farms to be built between North Carolina and New England between now and 2030. This analysis indicated possible impacts on fisheries management and NARW populations. When I participated in a public meeting on Cape Cod on the MMPA Large Whale Take Reduction Team proposal to restore NARW populations (where death rates greatly exceeded birth rates) the NOAA Fisheries GARFO staff indicated that they didn't have authorization to conduct a cumulative environmental impact analysis or utilized a A, EbM management approach like BOEM. The Massa. DMF was sued by Marine ENGOs for not having an Incidental Take Permit under the MMPA from NOAA Fisheries for NARWs killed in state jurisdictional water from interactions with pot gear for crabs and lobsters. Thus both NOAA Fisheries and the Ma. DMF were forced to take action due to litigation from concerned constituents.

As a retiree and grassroots environmental activists, I have no idea who in NOAA Fisheries decided to place lobster/crab pot fishing above protecting the critically endangered NARW which is the focus of the whale watching industry on Cape Cod. Since climate change is forcing both right whales and lobster pot fishing either further offshore into the deeper ocean or Northeastwards into the Gulf of Maine/St. Lawrence, NOAA fisheries Policy Makers should have foreseen the "Unusual Mortality Event" in large whale populations along the Atlantic seaboard and made appropriate policy/regulatory changes. I gather Congress is considering changes in the MMPA or ESA legislation to reduce NARW mortalities.

* SDWA/CERCLA Cleanup at Joint Base Cape Cod has exhibited many situations where the best available science was ignored in the mitigation of toxic contamination of groundwater and removal of source areas of pollution.

I will mention just one incident of the toxic contamination of public and private drinking water wells in Falmouth and Mashpee from Ashumet Valley Plume at JBCC. The AVP underlies the Yearling Meadows development where I live in East Falmouth.

In the mid-1980's, the Falmouth Ashumet Valley Public Drinking Water Well was closed because of toxic contamination from this off-base plume and replaced by a groundwater well on Upper Cape Water Supply Reserve (which is now threatened by the Army

National Guard's Multipurpose Machine Gun Range 5000 acre buffer zone for machine gun bullets). Unexploded ordnance

(howitzer and mortar shells) from the Central Impact Area Plume source area is mechanically extracted from the soil in Pitch Pine/

Scrub Oak Habitat which allows toxic contaminants (lead, perchlorate; PFAS; RDX; etc.) to move from the soil or pore water into

the underlying groundwater. It was only recently that the Ma. Department of Environmental Protection's PFAS mcl of 20 parts per

trillion was incorporated as the water safety limit for PFAS chemicals. Previously they utilized the EPA Hazard Level of 70 ppt for

PFOS and PFOA as the safety level for providing Granular Activated Carbon filters to contaminated public and private drinking

In Falmouth and Mashpee (disposing of these PFOS/PFOA GAC filters is a major challenge).

Yesterday I participated in an Environmental Working group PFAS ZOOM Conference where a Harvard scientist mentioned that

state/Federal legislation and litigation by ENGOs forced the Department of Defense to take limited action on dealing with PFAS

contaminant of our drinking water; food; household products; cosmetics; aerial transport effects on seabirds on Georges Bank; etc.

We need to implement the Precautionary Approach and Essential Use Doctrine for existing products with PFAS in them, plus renew

the Polluter Pays requirement under CERCLA to reduce our PFAS challenges. The European Union has much more effective policies

and regulations for addressing PFAS contamination than does EPA or FDA.

Thanks for your consideration of these comments.

Dr. David D. Dow
East Falmouth, Ma.

From: [David Duncan Dow](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Cc: [David Dow](#)
Subject: [EXTERNAL] David Dow's Addendum Public Comment for SI-FTAC RFI
Date: Friday, July 23, 2021 8:57:35 AM

Since I plan to comment at the "Communications" session next week, I decided to briefly outline the basis for my concerns about scientific integrity in developing government policies and regulations. I was asked by the **Social & Environmental Action Committee** at the **Unitarian Universalist Fellowship of Falmouth (UUFF SEAC)** to develop a series of pieces on the: "**Challenges Facing the Cape Cod Aquifer**". This exercise in "**Science Translation**" has posed certain challenges in communicating PFAS monitoring and science in the Waquoit Bay Watershed (where the UUFF is located) into addressing exposure pathways and potential health effects on sensitive human populations (women of child bearing age and kids; recreational fishermen/women who eat what they catch; seniors with pre-existing health conditions & members of the Mashpee Wampanoag Tribe who hunt and fish in this area). The UUFF SEAC and other community of faith entities are concerned about **Environmental Justice aspects of PFAS contamination on humans and wildlife**.

I have developed drafts of 5 installments which include a section on additional resources for those desiring more information on the effects of water quantity; nutrients (Nitrogen and Phosphorus); toxic chemicals and climate change in Cape Cod Aquifers using the Waquoit Bay watershed as a case study. When I worked at the Northeast Fisheries Science Center in Woods Hole, Ma., I participated in an EPA study on the **Waquoit Bay Watershed Ecological Risk Assessment** which identified nutrients ("Nitrogen" in Waquoit Bay and "Phosphorus" in Ashumet Pond) as the major human stressors in the watershed. I wrote the section of the report on the effects of "P" contamination on Ashumet Pond and the pollution emanating from **Joint Base Cape Cod (JBCC)**. I have been engaged as a grassroots environmental activist in the Safe Drinking Water Act/Superfund cleanup at JBCC since the late 1980's. The **Ashumet Valley Plume (AVP)** from JBCC runs underneath the Yearling Meadows development where I live in East Falmouth, Ma. This plume forced closure of the **Falmouth Ashumet Valley Public Drinking Water Well** in the mid-1980's because of toxic contamination from JBCC. In more recent times PFOS and PFOA above EPA's Hazard level (70 parts per trillion) were detected in public and private drinking water wells in Falmouth and Mashpee requiring **Granular Activated Carbon (GAC)** treatment. Recently the **Department of Defense** agreed to adopt the Massachusetts DEP maximum contaminant level of 20 parts per trillion for the sum of 6 PFAS chemicals as the water safety monitoring level for the plumes at JBCC.

Since the water and sediments of Ashumet Pond are contaminated with PFAS chemicals, I have been pushing for monitoring of the 6 PFAS chemicals in the mcl in finfish and shellfish that pose threats to Sensitive human populations and wildlife. This request has not been supported by the AFCEC (Air Force Civil Engineering Center); EPA Region 1; Massa. Department of Environmental Protection; Cape Cod Commission; etc., since there are no health or food consumption standards for PFAS chemicals in food. The Food and Drug Administration (FDA) doesn't feel that PFAS contamination of food items is a major exposure pathway for the US population. This decision was questioned by scientists at the recent Environmental Working Group PFAS conference.

As the former Recreational Fisheries Coordinator in the Northeast where I had to explain PCB contamination of finfish and shellfish to saltwater anglers, I find this FDA conclusion dubious. Finfish in Ashumet Pond are subject to food consumption alerts from methyl mercury in finfish and cyanobacterial toxins in shellfish. We have periodic red tides in marine waters that lead to mussel consumption alerts. Scientists from the **University of Rhode Island's STEEP (Sources, Transport, Exposure and Effects of PFAS)** grant are studying PFAS bioaccumulation pathways in seafood (which differs from PCBs and methyl mercury because PFAS chemicals are soluble in both fats and water). The **Silent Sprint Institute REACH (Research, Education, and Action for Community Health)** grant established the **PFAS Exchange** an online resource for the public and medical professionals.

Thus unlike many other parts of the country with PFAS contamination issues in food and drinking water,

we have a lot of research on this issue (including the US Geological Survey of potential fish contamination) and translation off this into information products accessible to the public. Thus it is a mystery to me why neither JBCC regulators (Ma. DEP and EPA Region 1) or AFCEC/Army National Guard (ANG) are willing to address PFAS chemicals finfinfish and shellfish. Mechanical removal of unexploded ordnance (mortar and howitzer shells) from the Central Impact Area plume source area threatens toxic contamination. (RDX, perchlorate; heavy metals; PFAS; etc.) of the Upper Cape Water Supply Reserve groundwater which provides drinking water to Falmouth as a replacement for the closed Falmouth Ashumet Valley Public Drinking Water Well.

I found it hard in my **Toxic Chemical Installment on the Challenges Facing the Cape Cod Aquifer** to explain why it has taken so long to develop PFAS regulations and advise the public on ways to avoid exposures in life styles if they are concerned about health effects on sensitive populations. The EWG PFAS conference described legislation and litigation strategies to address this shortfall in polluter pays responses to PFAS contamination. AFCEC provided GAC filters to public and private drinking well owners in Falmouth and Mashpee to remove PFOA and PFOA above 70 ppt. How will these filters be reused or disposed of ?

Thanks for considering these comments.

Dr. David D. Dow
East Falmouth, Ma.

From: [David Duncan Dow](#)
To: [MBX OSTP Scientific Integrity RFI](#); [David Dow](#)
Cc: [David Dow](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Wednesday, July 28, 2021 3:02:57 PM

My verbal comments for the “Communications” Session on July 28:

I am Dr. David Dow, a retired marine scientist and grassroots environmental activist living in East Falmouth, Ma. on Upper Cape Cod. I was asked by the Social and Environmental Action Committee at a local church to write a series of pieces in the: “Challenges facing the Cape Cod Aquifer”. I choose the Waquoit Bay Watershed where I live as a case study for water quantity; nutrient, toxic chemical and climate change challenges.

I recently submitted written comments to the OSTP Scientific Integrity public comment website on the challenges in science translation of PFAS research and monitoring to action by regulators and policy makers at the county/state/Federal levels. We have numerous reports in local print and broadcast media on the results of investigations by the US Geological Survey; University of Rhode Island STEEP grant; Silent Spring Institute PFAS Exchange website; etc. on summaries of PFAS science. Other than the Ma. DEP maximum contaminant level of 20 parts per trillion for the sum of 6 PFAS chemicals, we have limited response by our local elected officials and the Cape Cod Commission. Recently the Department of Defense decided to use the state PFAS MCL as the target for monitoring the cleanup at the SDWA/CERCLA cleanup at Joint Base Cape Cod.

As the recent Environmental Working Group PFAS conference pointed out, EPA and other Federal agencies have:

- * Ignored cutting edge research on PFAS chemical exposure pathways and health effects on humans & wildlife which has led to legislation and litigation at the state/Federal levels
- * Localities lack the resources (\$ and people) to address PFAS source removals and treatment of contaminated drinking/groundwater, so that the polluter pays concept needs to be re-instated
- * We need to adopt the European Union concept of removing non-essential uses of PFAS chemicals in products and items already containing PFAS chemicals in order to reduce public exposure.
- * Food and airborne exposure routes need to be the focus of additional research and monitoring followed by the development of appropriate policies and regulations
- * As the former Recreational Fisheries Coordinator in the Northeast at the Fisheries Lab in Woods Hole. PFAS bioaccumulation in the aquatic food chain in finfish and shellfish needs to be explored, since it differs from PCBs and methyl mercury
- * OSTP and other federal agencies need to develop PFAS information products more accessible to the concerned public and diverse constituent groups.

Thanks for the opportunity to offer this public comment.

Dr. David D. Dow

From: [John Richard Schrock](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI Total Loss of Research "Published" in Online-Only Journals or Discarded in Print
Date: Thursday, July 15, 2021 4:54:26 PM

To: Scientific Integrity Fast-Track Action Committee (SI-FTAC), OSTP
From: John Richard Schrock, PhD [academic journal editor]
Re: Loss of Research "Published" in Online-Only "Journals" and the Need for Multiple Paper Archives.

When much scientist effort is dedicated to securing grants, conducting research and then publishing results, it is a serious problem when research is then lost by the storage of that publication only online and the sponsoring organization or publisher no longer exists.

In addition, older journals that were printed and bound in libraries are being discarded by librarians who incorrectly assume that everything is now available online, when it is not.

A small number of missing "journals" may be fly-by-night predatory publishers. But many are bonafide journals where a critical mass of supporting scientists is lacking and the journal goes out-of-print. Indeed, a survey of science journals at a cut-off date such as 1900 or 1950 will find the majority of science journals printed before that date are no longer published, but we know the results of the science since they were archived in libraries. Many of today's journals are online-only, promoted under the argument that open access is available to researchers in poor countries. But unfortunately, many are not archived.

Despite claims that everything is available online, it isn't. This has been documented for two decades. In "Going, Going, Gone: Lost Internet References," Dellavale et al. in 2003 found that internet links eroded (linkrot) at a rate of ten percent every 15 months. Today, in "Dozens of scientific journals have vanished from the internet, and no one preserved them," Jeffrey Brainard (2020) notes that 84 online-only science journals and nearly a hundred more social science/humanities journals have disappeared, and an additional 900 journals only published online are likely to disappear as well.

While many librarians are under the impression that only recent science research is of value, and they are discarding old bound journals without checking with the state of holdings at sister institutions, there are many fields of research that must refer back to older literature. Systematic zoology is one such field, where zoologists must, for good reason (and to comply with their code of nomenclature), check with other previously-described species going back to the 10th edition of *Systema Naturae* by Carl Linnaeus published in two volumes in 1758 and 1759, and all related descriptions published elsewhere since then.

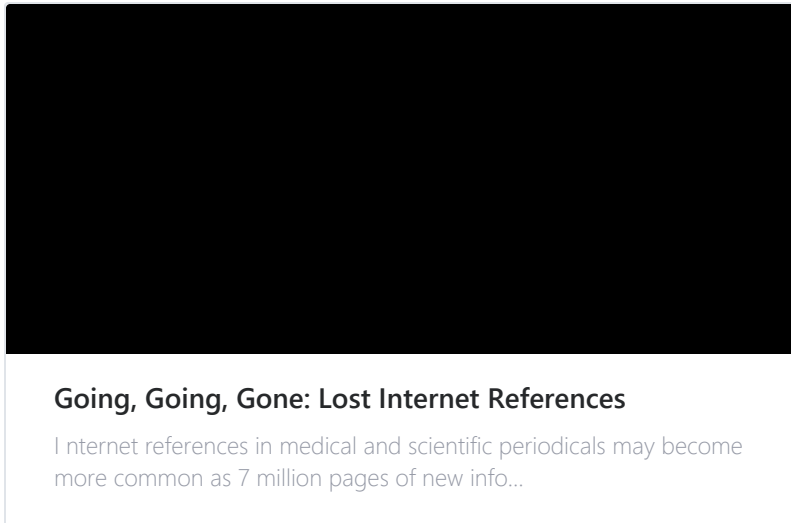
Ten years ago, I could file an inter-library loan request for seven journals including some from early 1900s Europe for such research, and would receive seven results. This year, a similar request for seven yielded two! Libraries had discarded journals assuming some other library would keep them. None did.

There are other fields of science that likewise still rely on earlier published science that is now being lost as well. The cost of maintaining a journal printed on acid-free paper (lasts 500 years and you then copy it again on acid-free paper) is insignificant compared to the continual

purchase and maintenance of digital equipment and the ongoing migration to newer hardware and software. Indeed, if you did not migrate your files from MS-DOS a decade ago, they are probably lost. This continual cost of migration is why there is no foreseeable way to underwrite the storage and maintenance of online journals when there is no longer a sponsoring/paying professional association of publisher supporting it.

I provide two links to the cited research below.

[Going, Going, Gone: Lost Internet References](#)



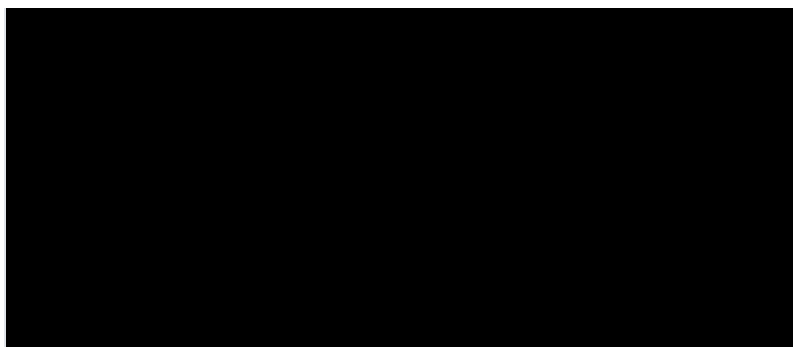
Going, Going, Gone: Lost Internet References

1. Robert P. Dellavalle^{[1](#), [2](#), [3](#), *},
2. Eric J. Hester^{[2](#)},
3. Lauren F. Heilig^{[2](#)},
4. Amanda L. Drake^{[2](#)},
5. Jeff W. Kuntzman^{[4](#)},
6. Marla Graber^{[4](#)},
7. Lisa M. Schilling^{[*](#)}

See all authors and affiliations

Science 31 Oct 2003:
Vol. 302, Issue 5646, pp. 787-788
DOI: 10.1126/science.1088234

[Dozens of scientific journals have vanished from the internet, and no one preserved them](#)



Dozens of scientific journals have vanished from the internet, and no one...

Specialists worry about a potential loss to scholarship

<https://www.sciencemag.org/news/2020/09/dozens-scientific-journals-have-vanished-internet-and-no-one-preserved-them>

Dozens of scientific journals have vanished from the internet, and no one preserved them

By [Jeffrey Brainard](#) Sep. 8, 2020

From: [Melinda Gormley](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Thursday, July 15, 2021 7:20:24 PM

Request for Information to Improve Federal Scientific Integrity Policies

Submitted by: Melinda Gormley, Research Development Officer, School of Biological Sciences, University of California, Irvine and 2015-2016 AAAS Science and Technology and Policy Fellow, Scientific Integrity Program, Environmental Protection Agency, Supervisor: Francesca Grifo

Please consider seeking greater alignment between the principles within responsible conduct of research (RCR) guidance released from federal agencies, such as NIH and NSF, and OSTP's scientific integrity guidance. While scientific integrity and research integrity have unique facets, there are many similarities in the principles; however, the two sectors use different language and scientific integrity has a broader focus than RCR.

RCR training is required for graduate students working on a project funded by NIH and NSF. Academia has embraced that STEM graduates will go into careers across various sectors. Undergoing a process of aligning features of the two sets of guidance would provide a common language and set of principles that graduates will see in their workplaces, whether they accept jobs in academia or government.

Also, RCR guidance at NIH and NSF would benefit from an update to reflect changes over time in STEM education and among STEM students. Increasingly, STEM students who are pursuing graduate degrees seek training to improve their ability to engage with the community and policymakers because they want science to be trusted and they value evidence-based policy making. Such students seek training in communication and policymaking. RCR training tends to focus on fabrication, falsification, and plagiarism (FFP) and questionable research practices (QRP) and other features that are about the conduct of research. They are not as broadly focused as scientific integrity with its attention to professional development and communication. We know that the advisor of a graduate student or postdoctoral fellow can stop them from participating in professional development opportunities. Communication training given at institutions of higher education rarely seems to address responsible communication practices, while having a disclaimer at the beginning of a presentation is common practice among governmental employees.

While these suggestions may appear outside the scope of the RFI, it could be instructive to look to research integrity and RCR policies and consult with the federal offices that oversee them. Another group of people to consult are the academic scholars and educators who perform research on RCR and give RCR training.

Thank you for undertaking this process to reassess scientific integrity in the federal government. It's an incredibly important endeavor that is implemented inconsistently across agencies.

Sincerely, Melinda

*** **

Melinda Gormley, PhD
Research Development Officer • UCI School of Biological Sciences
University of California, Irvine •

Secretary of AAAS Section L – History and Philosophy of Science
Workgroup Member – AAAS Governance Modernization Project

From: [CHERYL GROSS](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Thursday, July 15, 2021 8:54:40 PM

As a semi-retired environmental scientist, activist, and member of the Union of Concerned Scientists, I am commenting in response to the OSTP request for advice on strengthening scientific integrity policies across federal agencies.

I've worked on a wide range of environmental issues since the '70's, as a NJDEP senior scientist, with consulting firms, as a private consultant, and as an activist. My interactions with the federal government include having sued it in 2000 regarding the Malathion spraying issue.

The problems encountered over forty years involved political and administrative level interference that ignored scientific fact, thanks to lobbying, campaign funding, revolving door hiring and a lack of scientific knowledge regarding their own agency's issues on the part of administrators. The level of interference in staff decisions that had been based on science reached to that of the Vice President in the Malathion negotiations, where Gore directed EPA Director Browner to physically remove a rejected pesticide exemption from a Division head's desk and approve it. It had taken two years to achieve the rejection based on scientifically-valid evidence of serious health impacts; it was removed in two minutes following his order.

Also, the manipulation of Risk Assessments and use of corporate-provided research and impact statements as the basis of decision making allows approval of materials and projects with proven likelihood of neurological, carcinogenic, and environmental impacts. There is no agency follow-up to determine the results of their approvals.

I urge the following:

Prioritize the Precautionary Principle in all science-based decision making. Agencies must err on the side of health and environmental protection when evaluating projects and product approval or registration. Risk Assessments attempt to compare human and environmental health damage to the growth of financial wealth from a project or product. Aside from the horrifying values and lack of ethics that implies, it is not science.

Include environmental justice factors in the science. Zoning isolates specific areas in communities as central sites of pollution generation from industrial or agricultural operations. Another plastics factory in Louisiana's industrial area means more and synergistic impacts on already suffering minority populations; another pesticide registration means increased or synergistic impacts on farm workers and their families. .

Help ensure scientific validity of applicant claims and research by holding applicants financially liable for impacts. For too long the public has had to prove, after the fact, that projects and products resulted in devastating health and/or environmental impacts and often bear the health and remediation costs. If a pplicants claim a project or product is safe, agency approval or registration must require they cover all health and remediation costs if there are negative impacts; evidence of sufficient insurance or funding must be provided.

Be transparent in decision making. Agencies must provide the scientific basis for their decisions to stakeholders.

Appoint Administrators with a firm basis in the science-related aspects of their

agencies and no connection to corporations or funding/lobbying groups related to the corporations they will be regulating. For example, Tom Vlisack recently went from lobbying for industrial ag to heading the Department of Agriculture. The chances of unbiased, scientifically-valid decision making on his part are slim.

Create a panel of scientists with no ties to corporate entities to review all staff claims of inappropriate administrative changes to reports, suppression of data or reports, or failure to act.

Provide an ombudsman to protect employees who protest Administrators' changes to or suppression of science-based findings or failure to take appropriate action on findings. Require the ombudsman to investigate any claims of intimidation.

Enact a policy requiring Administrators to publicly reveal the basis for any changes, suppression, or failure to act. For example, Ms. Browner would have had to explain to staff and stakeholders why she approved a use exemption for Malation that was denied by staff on the basis of health impacts and availability of a safer alternative. Identify connections between agency personnel and the entities they regulate. The tight relationships between industrial agriculture and the Department of Agriculture and between the chemical industry and the EPA prevent pure science-based decision making, as financial and future career opportunities can take precedence.

Science-based decisions by agencies need funding to carry out implementation.

Legislators are more likely to provide it if they have accurate information. Ensure that agencies inform legislators concerned with specific issues of scientific findings that are affecting agency decisions on those issues. Legislative staff also need facts to interact with agencies and adequately advise legislators. Our environmental group provided a Senator's staff, at their request, with scientific data pertaining to an issue before they met with Department of Ag staff. The Senator's staff said it was the first time they'd ever gone into a meeting with the accurate, referenced scientific data they needed to refute false safety claims of an Ag program. The results were millions appropriated for a safer program not only still in operation but recently expanded. The Union of Concerned Scientists will provide a far more comprehensive list of suggestions. I wished to emphasize these few based on my personal experience.

Cheryl Gross

From: [Anne Millbrooke](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [WARNING: UNSCANNABLE EXTRACTION FAILED][EXTERNAL] SI-FTAC RFI
Date: Thursday, July 15, 2021 9:59:36 PM

Dear Decision Influencers and Decision Makers:

I would like to add to my previous comment that I fully support the recommendations of the Union of Concerned Scientists:

- The newly established scientific integrity officials at all federal agencies should be empowered to effectively implement their agency's policy.
- Agencies should adopt a public communications policy that ensures federal science can reach decisionmakers and the public accurately and promptly.
- Agencies should create well-defined, consistent, and transparent clearance procedures for scientific publications, presentations, and conference participation.
- Agencies should establish policies that aim to increase the transparency of rulemaking processes.
- Agencies should enhance digital accessibility in the federal rulemaking process
- Invest in a robust federal workforce that is diverse in expertise, experience, race, ethnicity, gender identity, and sexual orientation.
- Enhance accountability regarding interactions between scientists and political officials.
- Ensure that science-based rulemaking is transparent and protected from interference.
- Prevent conflicts of interests in science-informed decisionmaking.
- Create policies that ensure political officials cannot impede the collection or access to federally funded data.
- Prevent the politicization of research funding, to ensure that grant processes are independent and based on scientific merit.
- Create rigorous peer-review policies that protect federal science from political interference.
- Train federal employees regularly on their rights and responsibilities.
- Commit to supporting scientists' work and careers.
- Provide clear, detailed policies/procedures for addressing differing scientific opinions
- Establish procedures for federal employees—and non-federal scientists who contract or are funded by the government—for reporting violations of scientific integrity, without fear of retaliation.
- Prioritize robust, community-focused research and data collection on health disparities.
- Involve communities in decisionmaking earlier and more effectively, especially marginalized communities and those most likely to be affected by new or revised rules.

Sincerely,
Anne Millbrooke

Dear Decision Influencers and Decision Makers:

As a historian of science and technology, I am very concerned about the previous administration's attacks on science and the influence that had on segments of the population. History has shown, repeatedly, consistently, that science can help address the problems facing the nation. Science can help address today's problems, such as climate change, infrastructure inadequacies, wildlife population crashes and species extinctions, water quantity and quality. Science, free from political interference, should guide government policy and programs.

30x30 is a necessary and reachable goal. Science can guide selection of lands for Nature to thrive, particularly wilderness areas on National Forest and Bureau of Land Management lands. Many roadless studies conducted by those agencies have already identified wilderness quality lands, but older studies do not reflect the modern science of landscape scale preservation nor the national needs of 30x30 and the importance of addressing climate change aggressively NOW.

I recommend that all remaining roadless wildlands be designated Wilderness and placed under the protection of the federal Wilderness Act. Science can guide restoration of those pockets needing restoration. But only landscape scale preservation will provide the habitat and habitat corridors necessary for wildlife. Only landscape scale preservation will stop the privatization of our public waters and the transfers of public waters out of basin of origin to users with enough money. These wilderness designations should ban, as the original Wilderness Act of 1964 intended, mechanized tools, toys, and travel, as well as commercial logging (not even under the guise of forest treatment or fire prevention) and commercial livestock grazing (the publicly subsidized extraction of grasses, forage, and water from the arid West for the private profit of a relative few livestock operators).

Soil science and resilience are literally the ground level. Please prioritize soil science and resilience in comprehensive infrastructure legislation and climate legislation. Both grazing and mechanized travel have been scientifically documented as detrimental to soils.

Based on scientific articles that I have seen, commercial livestock grazing on public lands and the associated extraction of public grasses, forage, and water, is inconsistent with science-based conservation of our public lands. Here is a list of scientifically documented harmful effects of commercial livestock grazing on public lands (including holistic, regenerative, restorative, passive season-long, and other livestock grazing). The science should not be ignored to benefit a small percent of livestock raisers made powerful in part by the federal subsidies associated with public land grazing.

Harmful Effects

- introduction of invasive species
- disease transmission
- increase in fire danger
- increased soil exposure, drying, compaction, erosion, and sedimentation
- off-road vehicle trails, with associated noise, speeds, erosion, compaction, sedimentation
- construction of roads
- trucks and other motorized vehicles creating unauthorized roads
- grazing exemptions to mechanized travel create routes for other mechanized users
- construction of facilities, such as cabins, water lines, and fences
- damage to riparian areas, wetlands, and watersheds

- damage to streamflow regimes
- diminished water quantity as well as quality
- surface water pollution
- damage to aquatic habitat and species
- cumulative contributions to the desertification of the public land
- loss of fish and wildlife, both reduction of population and loss of species
- displacement of wildlife
- fragmentation of wildlife habitat
- disruption of wildlife migration
- slaughter of predatory species, such as bears and wolves
- disturbance of bird breeding, roosting and feeding
- removal of native flora species, such as pinyon juniper
- degradation of native plant communities
- reduction of nature's carbon storage capability
- exacerbation of climate stresses and thereby contributing to climate change
- public subsidies for commercial operations on public lands
- unfair advantage given to subsidized operations versus operations on only private land
- unsustainable production of agricultural commodities on public lands
- general over-burdening of fragile arid lands
- exclusion of other uses, including habitat and wildlife conservation
- reduction of public access to public lands
- loss of solitude and foot-powered recreation
- interference with post-fire habitat restoration
- failure of land stewards to document trespass violations, overstocking, and other harms
- politicization of public land stewardship
- commercial marketing of unhealthy diet rich in meat.
- interference with post-fire habitat restoration
- failure of land stewards to document trespass violations, overstocking, and other harms
- failure of land stewards to enforce trespass, overstocking, and other regulations
- politicization of public land stewardship
- cumulative impacts over time
- cumulative impacts of multiple harms
- cumulative impacts of multiple harms over time

Such a list might also be compiled for mechanized travel on public wildlands. As a birder, hiker, camper, I have seen the damage. Mechanized recreation degrades the environment more than non-mechanized recreation, and motorized recreation degrades the environment more than non-motorized recreation. The scientific literature is clear on these points; for examples, see Courtney Larson et al., 2016; Catherine Pickering et al., 2010; and Michael Vandeman, 2004.

Back in the 1960s Edward Abbey proposed an end to road construction in national parks and the reservation of dirt roads for use by only non-motorized traffic. Applying that guidance to public lands in general makes a lot of sense given the population pressures added since then. In no way should we be opening footpaths, some already shared with mountain bikers, to motorized traffic! We should preserve our roadless wildlands as Wilderness — to meet the 30x30 goal but also for the benefit of the people of the nation.

Forester Elers Koch wrote in the 1930s, “Roads are such final and irretrievable facts.” Motorized traffic makes any path a road unsafe for pedestrians and disruptive to birds and

other wildlife. Don't allow ebikes and other motorized vehicles to degrade any more trails through our public lands. The Land and Conservation Fund provides for lands for recreation. We don't need to degrade the remaining wildness of our public lands. Block the expansion of trails open for ebike and other motorized use; personally, I see a motor as a motor, regardless of fuel type.

Public lands are held in trust for the people of the nation. Birds are public wildlife. Public lands and public birds, and other public resources (fish, wildlife, insects, watersheds, carbon storage capability of nature, etc.) should be conserved. These resources are for the benefit of future generations as well as our own. They should not be degraded by motorized recreationists. As the ecologist George Wuerthner keeps reminding us, "Recreation is not conservation." Moreover, restricting the expansion of trails open to mechanized travel in no way diminishes or interferes with the thousands of miles trails already open to ebikes.

In other words, science supports the designation of wilderness to address today's problems of climate change, wildlife population crashes, human population pressures, etc. Science can guide other policy decisions too.

Please protect the integrity of science, provide financial support for science, and integrate science into the decision-making process (not as token voice at the table, but as a key influence).

Sincerely,
Anne Millbrooke

Sources Cited:

Edward Abbey, *Desert Solitaire: A Season in the Wilderness*. New York: Ballantine Books, 1968.

Elers Koch, "The Passing of the Lolo Trail," *Journal of Forestry*, 33/2 (1935): 98–104.

Courtney L. Larson, Sarah E. Reed, Adina M. Merenlender, and Kevin R. Crooks, "Effects of Recreation on Animals Revealed as Widespread through a Global Systematic Review," *PLOS ONE* (December 08, 2016), 21p, doi:10.1371/journal.pone.0167529.

Kenneth V. Rosenberg, Adriaan M. Dokter, Peter J. Blancher, John R. Sauer, Adam C. Smith, Paul A. Smith, Jessica C. Stanton, Arvind Panjabi, Laura Helft, Michael Parr, Peter P. Marra, "Decline of the North American Avifauna", *Science*, (September 19, 2019). 120–124, doi:10.1126/science.aaw1313.

Michael J. Vandeman, "The Impacts of Mountain Biking on Wildlife and People: A Review of the Literature," *Culture Change* (July 03, 2004), >http://culturechange.org/mountain_biking_impacts.htm <;

George Wuerthner, *Thrillcraft: The Environmental Consequences of Motorized Recreation*. Sausalito, CA: Foundation for Deep Ecology, 2007.

Response to the Biden Administration Scientific Integrity Task Force Request for Information to Improve Federal Scientific Integrity Policies

Center for Open Science¹

July 16, 2021

Science demonstrates integrity and earns public trust by being an open, transparent, self-critical social enterprise. Huge majorities of scientists endorse core principles and values for scientific integrity in the service of advancing knowledge such as open and transparent over closed and secret, evaluating research on its own merit rather than by the status of its originators, and organized skepticism over organized dogmatism. Simultaneously, large majorities of scientists perceive the research culture as failing to incentivize those core values leading to a dysfunctional dynamic that often puts what's good for researchers at odds with what's good for science. Researchers are rewarded more for reporting novel, positive, tidy results and less for methodological rigor and transparency leading to publication bias and questionable research practices (occurring intentionally and unintentionally) that undermine the credibility of reported findings. Moreover, lack of rewards for replication and for transparency and sharing research data and materials creates barriers to identifying error and cumulative research. As a consequence, the literature is overrepresented by exaggerated, overconfident research claims and insufficient mechanisms for verification and self-correction (cf. Munafò et al., 2017; Nosek et al., 2015; Open Science Collaboration, 2015).

Improving the research culture by aligning norms and incentives with scholarly values will foster cumulative science and reduce unnecessary friction and waste. Too often, interventions to address and improve research integrity have been conceptualized narrowly on addressing individuals' attitudes, knowledge, and behavior. Training and appeals to personal values have their place, but those interventions will be ineffective if the research culture does not support integrity in its norms, incentives, and policies. That is, improving research integrity is a systems challenge and requires systems level solutions. All stakeholders must contribute to aligning norms, incentives, and policies with the research culture's core values. Improving the research culture will increase research integrity, bolster public trust, and accelerate the pace of scientific discovery of knowledge, solutions, and cures.

We believe that the most critical policy intervention for improving research integrity is **setting the default to open**: open plans (preregistration), open materials, open data, and open outcomes (findings, papers). Setting the default to open will promote science's complementary strengths--innovation and self-correction. Science pushes the boundaries of knowledge with a willingness to pursue high-risk, high-reward possibilities. Transparency and openness foster

¹ The Center for Open Science is a nonprofit research, technology, and culture change organization with a mission to promote openness, integrity, and reproducibility of research. This response was adapted and expanded from congressional testimony delivered by Brian Nosek to the House Committee on Science, Space, and Technology (November 13, 2019) and to the Senate Committee on Homeland Security and Governmental Affairs Federal Spending Oversight Subcommittee (October 18, 2017).

innovation by enabling collaboration and reuse. It is understood that an emphasis on innovation will lead to many false starts. Science addresses this best when it maintains a complementary emphasis on verification and self-correction. Innovation identifies what is possible; Replication and community scrutiny sorts out what is likely. Setting the default to open promotes verification and self-correction by making it easier to understand the basis of new findings, by making the methodology more accessible, and by making it easier to build cumulative evidence with replication and extension.

Lack of transparency creates friction in the pace of discovery and reduces the return on investment of research dollars. For example, in a large-scale replication project of cancer biology research, 193 experiments that attempted to replicate the original findings found that the original papers had enough information to design a complete replication protocol for none and the raw data in public repositories was accessible for just 3 (Errington et al., 2021). Engaging original authors yielded modest improvements in obtaining original data. This effort to replicate the results of 193 previously published experiments was a snapshot. Some culture and policy improvements in recent years might result in incremental improvements, but a sustained shift will require a more comprehensive change in the research culture.

Return on research investments could increase dramatically by promoting greater transparency of a variety of research outputs:

- **Transparency and Openness of Materials:** the protocols, materials, and code that generated the research findings -- will make it easier for others to replicate researchers findings, and build on their research.
- **Transparency and Openness of Data** will make it easier for others to test the robustness of researchers' findings and to reuse the data for new questions or combine it with related data for more precise assessments of the totality of evidence.
- **Transparency and Openness of Research Plans:** registration of the study design, hypotheses, and analysis plans before observing the outcomes, known as preregistration -- will make it easier to discover findings that are never published, particularly negative results that are often ignored, and make clear the difference between confirmatory investigations in which hypotheses are being tested and exploratory investigations in which hypotheses are being generated. Mistaking exploratory analyses as confirmatory tests increases bias and is a threat to the credibility of research claims.
- **Transparency and Openness of Research Outcomes** will make it easier to find all relevant evidence about a research question, and make it easier for researchers, policymakers, and the tax paying public to examine and use the scientific evidence that we all paid to produce.

There is a mature infrastructure of tools and services, like the [Open Science Framework](#) and many other repositories, that make it possible for researchers to do these behaviors. There is also growing awareness within the research community about the importance and value for these transparency promoting behaviors. For example, the [TOP Guidelines](#) policy framework has been adopted by more than 1,000 scientific journals for authors, and some funders are

likewise adapting their policies for grantees. Following the Holdren memo during the Obama administration, many federal agencies have taken steps toward improving policies supporting transparency and reproducibility of research. There is more work to do, but your continuing support for those efforts could have salutary effects on the research culture.

To be specific, concrete behavior changes will dramatically accelerate research credibility and integrity and, ultimately, the pace of discovery. These include:

- **Registration of studies:** Registration involves reporting plans for conducting a study in a public registry. This makes studies discoverable whether or not they are ultimately published. At scale, registration of studies and reporting outcomes solves the problem of publication bias, particularly combating the greater likelihood that positive results are published than negative results (Greenwald, 1975; Rosenthal, 1979; Sterling, 1959).
- **Preregistration of analysis plans:** Preregistration makes clear the distinction between confirmatory analyses that test hypotheses and exploratory analyses that generate hypotheses. Preregistration clarifies which analysis decisions were made a priori and which were made post hoc reducing the likelihood of overconfident interpretations of exploratory results, and confirming the diagnosticity of the hypothesis tests (Nosek et al., 2018; Wagenmakers et al., 2012).
- **Accessibility of data, materials, and code:** Availability of original research materials enables others to conduct replications of the original findings and to reuse or extend the methodology for novel purposes, and makes it possible to test whether the reported findings are robust to variation in the analysis pipeline (Silberzahn et al., 2018). It also enables reuse of data for novel analyses and aggregation with similar datasets.

Each of these behaviors can prompt intellectual humility and improve research integrity. Without registration of studies, it is too easy to dismiss “failed” studies as uninformative or flawed and to become overconfident in focusing attention on only the positive or desired outcomes. With registration of studies, researchers are explicitly confronted with their body of evidence. The public accessibility of all studies can prompt perspective-taking of how an observer might evaluate the strength of evidence and whether they would be as likely to dismiss some of the conducted studies. Without preregistration of analysis plans, it is easy to deploy confirmation bias in exploring the data until evidence consistent with preconceptions is obtained, and easy to deploy hindsight bias after observing outcomes to conclude that such results were anticipated all along. Both of these behaviors lead to overconfidence in reported outcomes. With preregistration of analysis plans, researchers give themselves an external accountability check on their own biases. It can be a rather profound and humbling event to analyze a study, be confident in the outcomes and then check the preregistered analysis plan only to realize that the hypotheses and plans were completely different. The power of these biases is as strong in impact as they are subtle in their influence on reasoning. Finally, without sharing data, materials, and code, it is easy to be a little sloppy, a little haphazard, and a little more flexible with interpretation than the evidence justifies. With sharing data, materials, and code, the commitment to public accountability is strong, even if no one ever actually looks at the content. The knowledge that someone could look is often sufficient to prompt the researcher to be more careful, modest, and calibrated in claims and conclusions.

Registration of studies, preregistration of analysis plans, and accessibility of data, materials, and code address distinct and interdependent aspects of fostering rigor and reproducibility. Broad adoption of these open science behaviors will maximize return on research investment.

Federal agencies can provide complementary support to these policy changes to improve research integrity and credibility by:

- **Supporting replication research:** With a near exclusive emphasis on innovation in research funding, there is very little incentive for verifying important but uncertain claims. This results in a lack of self-correction and creates substantial friction in knowledge accumulation. Even a few percentage points of research budgets going to replication research could have a transformative impact on research efficiency by rewarding replication studies of important findings before translation or huge investments in new programs. Such investments would validate excitement or send up caution signals suggesting closer study before substantial commitments are made to uncertain findings.
- **Supporting metascience:** With these and other changes to improve research integrity, it would be ironic if the research community did not conduct research to determine whether they are working. The emergent metascience research community is conducting science on science to understand better how it works, and to evaluate whether interventions like preregistration and transparency meet their promise. Federal investment in metascience will create a virtuous cycle of intervention, evaluation, and improvement.
- **Sponsoring Registered Reports:** In standard practice, publication decisions are influenced by the research outcomes leading to publication bias and, particularly, lack of reporting of null and negative outcomes. This reduces the credibility of the published literature. [Registered Reports](#) is a publishing model in which journals conduct peer review prior to knowing the research outcomes. If the research question is considered worthwhile and the methodology an effective test of the question, the journal commits to publishing the results regardless of outcome. This eliminates publication bias and focuses peer review on the rigor and quality of research. Introduced in 2013, about 300 journals offer Registered Reports as a publishing format. Federal agencies can conduct intramural research in the Registered Report format and partner with journals to fund research via Registered Reports to maximize research quality and return on research investment.

The United States Federal Government is unique as one of the largest funders, generators, and consumers of scientific knowledge. The TOP Guidelines give specific recommendations for how open data, research materials, preregistrations, and replication research can be supported by a funder and institution engaged in conducting scientific research. But there is also an important role for such considerations to be applied as a consumer of information in evidence-based policy making. Policymakers must use the best evidence available when making decisions, and transparency of such evidence is one metric to include in these considerations. For example, considering whether or not underlying data, preregistrations, or independent replications exist add credibility to proposed regulatory changes alongside evidence of other credibility enhancing features such as validity of measurement, lack of confounding influences, and strength of research design.

Flipping the default from closed to open will foster regulatory framework for the exceptions--when other interests outweigh the goal of transparency. Two common occasions in which competing principles can outweigh the principles of openness and transparency are protecting intellectual property and protecting participant confidentiality for sensitive human subjects research. Sensible policies for managing these competing interests will facilitate the culture shift that is already underway in the private sector and with proactive steps by federal agencies, such as NIH and NSF. Such policy changes will synchronize with ongoing improvements in scientific journals and research institutions and ensure that no single stakeholder becomes the bottleneck for scientific improvement. Setting the default to open will represent a collective step forward that will encourage continued reform in how scholarly work is funded, published, and incentivized.

Also, federal investment in the services and repositories that support research transparency will ensure persistence and accessibility of that content for researchers, policymakers, and the public. Publicly funded research is a public good, and the infrastructure storing and preserving it should be a public good as well.

Finally, there are a variety of technological and methodological innovations that could address goals of transparency and security simultaneously. For example, data enclaves can provide secure storage of sensitive data and workflows for ethical management of reanalysis and reuse without sacrificing that security. Also, there are emerging methodologies that improve privacy by perturbing the characteristics of the underlying data just enough to make it effectively impossible to identify individual data points but still preserve the overall structure of the data for accurate analysis and inference. Supporting such technologies will make it easier to address the otherwise competing principles of transparency and security.

Public investment in science leads to solutions, cures, and unexpected advancements that benefit the national interest. Making open the default for research process, data, materials, and outcomes would transform science, dramatically increase the return on investment from publicly funded research, and accelerate progress.

References

- Errington, T. M., Denis, A., Perfito, N., Iorns, E., & Nosek, B. A. (2021). *Challenges for Assessing Reproducibility and Replicability Across the Research Lifecycle in Preclinical Cancer Biology*.
- Greenwald, A. G. (1975). Consequences of prejudice against the null hypothesis. *Psychological Bulletin*, 82(1), 1–20. <https://doi.org/10.1037/h0076157>
- Munafò, M. R., Nosek, B. A., Bishop, D. V. M., Button, K. S., Chambers, C. D., Percie du Sert, N., Simonsohn, U., Wagenmakers, E.-J., Ware, J. J., & Ioannidis, J. P. A. (2017). A manifesto for reproducible science. *Nature Human Behaviour*, 1(1), 0021. <https://doi.org/10.1038/s41562-016-0021>
- Nosek, B. A., Alter, G., Banks, G. C., Borsboom, D., Bowman, S. D., Breckler, S. J., Buck, S., Chambers, C. D., Chin, G., Christensen, G., Contestabile, M., Dafoe, A., Eich, E., Freese, J., Glennerster, R., Goroff, D., Green, D. P., Hesse, B., Humphreys, M., ... Yarkoni, T. (2015). Promoting an open research culture. *Science*, 348(6242), 1422–1425. <https://doi.org/10.1126/science.aab2374>
- Nosek, B. A., Ebersole, C. R., DeHaven, A. C., & Mellor, D. T. (2018). The preregistration revolution. *Proceedings of the National Academy of Sciences*, 115(11), 2600–2606. <https://doi.org/10.1073/pnas.1708274114>
- Open Science Collaboration. (2015). Estimating the reproducibility of psychological science. *Science*, 349(6251), aac4716–aac4716. <https://doi.org/10.1126/science.aac4716>
- Rosenthal, R. (1979). The file drawer problem and tolerance for null results. *Psychological Bulletin*, 86(3), 638–641. <https://doi.org/10.1037/0033-2909.86.3.638>
- Silberzahn, R., Uhlmann, E. L., Martin, D. P., Anselmi, P., Aust, F., Awtrey, E., Bahník, Š., Bai, F., Bannard, C., Bonnier, E., Carlsson, R., Cheung, F., Christensen, G., Clay, R., Craig, M. A., Dalla Rosa, A., Dam, L., Evans, M. H., Flores Cervantes, I., ... Nosek, B. A. (2018). Many Analysts, One Data Set: Making Transparent How Variations in Analytic Choices Affect Results. *Advances in Methods and Practices in Psychological Science*, 1(3), 337–356. <https://doi.org/10.1177/2515245917747646>
- Sterling, T. D. (1959). Publication Decisions and their Possible Effects on Inferences Drawn from Tests of Significance—Or Vice Versa. *Journal of the American Statistical Association*, 54(285), 30–34. <https://doi.org/10.1080/01621459.1959.10501497>
- Wagenmakers, E.-J., Wetzels, R., Borsboom, D., van der Maas, H. L., & Kievit, R. A. (2012). An agenda for purely confirmatory research. *Perspectives on Psychological Science*, 7(6), 632–638.

From: [Tom Rogers](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Friday, July 16, 2021 12:29:16 PM

Dear OSTP Team:

Re: "Request for Information To Improve Federal Scientific Integrity Policies"
and "Restoring Trust in Government Through Scientific Integrity and Evidence-
Based Policymaking."

Included in your request are profoundly far-reaching potentials for positive effect upon the nation and society in general.

History has recorded the virtually standard steps that have led to both the success and the collapse of nations and empires.

We are dangerously foolish to ignore the lessons that history can teach us.

A major concern regards this very subject of not just ignoring but also purposefully restricting some scientific findings that can have crucial positive impact for both government and society. The following recommendation should not even have to be raised because it is so basic to the integrity of scientific education and research and the new discoveries found thereby. This is a fundamental rule of science that deserves enforcement when necessary, and the addition of clear legalese, notwithstanding the facts that for science with integrity, this should be an obvious "Given." This regards the current unwarranted restrictions against open teaching and sharing, especially in educational institutions, of new scientific evidence that can have far-reaching beneficial effects.

Unfortunately, these restrictions against open discussion regarding new-found scientific evidences, have been imposed by some education leaders in science in the very institutions where new science should be encouraged to develop.

A draft of a rule that should not even have to be written, but obviously does have to be written, could look like this:

"Scientific research and teaching in our educational institutions is hereby allowed and encouraged to follow and explore evidences and discoveries wherever they lead. These evidences can be freely discussed with students and colleagues and publicized without restriction or penalty of any kind. There will be no restriction regarding discussion and application of new evidence for the cure for any disease as opposed to restricting health research to only treatment which must be repeated. The only exceptions to this rule of following the evidence will include restriction on information that can be used toward development of weapons of mass destruction or the development of new contagious disease."

As you are probably aware, you will hear objection to removal of restriction on following the scientific evidence where it leads from those education leaders who have an agenda they want to protect whether it be for personal gain, corporate gain, or other.

This rule of open scientific evidence should be adopted as soon as possible. It could be called,

“The Freedom to Follow the Evidence Rule.”

Please be wary of those who try to block or eliminate this rule.

Sincerely,

Tom Rogers, President

The Atomic Biology Institute

From: [E Graessle](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Friday, July 16, 2021 10:45:23 AM

Good day,

I'd like to comment on this initiative for advancing, protecting, and respecting scientific integrity in federal agencies which exist to protect all Americans, the common goods like water, air and environment which belong to all Americans, regardless of wealth, power, or political affiliation. I support the resolutions proposed by the president to make agencies independent of outside influences which may alter institution structures, operations, decision-making, accountability, and communications on best practice to the public. There should be a means of anonymously reporting lack of transparent, unbiased actions so that people who are fostering ethical actions are not punished or removed for efforts to preserve the integrity of the agency's actions. Agency actions should not be drastically altered to fit the political climate/agendas, but remain faithful to human health, well-being and more equitable sharing of the earth's resources for better community structure and resilience in the face of changing climate. Agencies need to be the voice of reason and advice to unite actions which protect the greater good and promote just actions which contribute the the health of the planet on which we all depend.

Thank you for your attention.

Eileen Graessle

David Gump

Comments submitted to the Scientific Integrity RFI

During my tenure as CEO of asteroid-mining firm Deep Space Industries (acquired by Bradford Space) and president of Astrobotic Technology and LunaCorp, I guided many grant applications to NASA that required maintaining currency with the most recent lunar and asteroid science.

Many lunar science theories were upended during that time. For example, originally scientists were adamant that ice did not and could not exist on the Moon, as the Apollo samples (all from near the equator) were exceedingly dry. Then new satellite data arrived, showing ice definitely exists in polar craters. A new theory emerged: water has been delivered over eons by comets and asteroids, and the molecules bounced around the sunlit surfaces until they came to rest in dark polar cold traps.

However, the latest leading theory asserts that polar ice comes from at least five distinct sources, not just comets and asteroids. Even more disturbing for settled science, only some polar craters have ice, and no one knows why perfectly situated crater floors (deep and never illuminated) are dry while less-well situated craters harbor ice.

The point here is that science is an on-going process of discovery, and accepted theories get overturned. Thankfully, lunar science never came to be ruled by an Accepted Truth, so discovery and debate could continue.

This contrasts with climate studies, where unique among today's scientific endeavors the central issue is now "settled" and immune from examination; only anthropogenic CO₂ can be the reason why the Earth's climate has gradually and beneficially warmed over the past few centuries. This should be the Scientific Integrity's team major focus, because no other scientific integrity question has trillions of dollars controlled by flawed science and flawed scientists.

To arrive at their indisputable and unquestionable consensus, the major players had to deal with embarrassing historical data: the Roman Warm Period and the Medieval Warm Period. If the global climate had warmed to more optimal temperatures in the past without needing any push from SUV emissions, then it would be illogical for them to assert that 100% of today's warming could only be attributed to anthropogenic CO₂.

Therefore, the climate absolutists decided that the RWP and the MWP had to die.

One line of attack minimized these periods as minor regional phenomena, local to England and western Europe. In actual fact, however, dozens of studies have found the MWP heat pulse showing up around the world, including in giant clam shell sediment off the coast of China.¹

Dr. Michael Mann was an initial leader in this effort to bury the MWP. He found a bristlecone pine tree time series² that went back to the Medieval Warm Period that didn't show any impact from the warmth. Other pine tree series were available that *did* show a growth response to the MWP (in the Urals region of Russia³), but they didn't get traction in the scientific journals, so Dr. Mann was able to stick with his handful of "no response" trees.

Mission *almost* accomplished, in a paper published by *Nature*⁴ and then prominently featured in reports from the Intergovernmental Panel on Climate Change and Vice President Gore's "An Inconvenient Truth."

Dr. Mann had a problem, though. During recent decades, when the pine trees should be signaling an ever-warming climate, they instead incorrectly indicated that the climate was cooling. Any researcher with scientific integrity would have abandoned this particular time series as very flawed – it entirely missed the MWP and now it was showing a trend going in the wrong direction.

Instead, Dr. Mann's paper for *Nature* presented a chart where the temperature trend line drawn from the bristlecone pine trees simply stopped, and substituted for it was a line of thermometer readings. All solved! But not with scientific integrity: if you change measurement methods you can no longer distinguish between a change that is real, and a change due to the new measurement methods.

Another example of scientific dishonesty is the constant tinkering with past temperature data to cool it down, all in the guise of quality control. Weather stations are almost always established proximate to some type of human presence – cities, towns and villages. Since 1880 when serious record keeping began in the U.S., villages have expanded to become towns, and towns have become cities. The asphalt and heat-generating activities of civilization have encroached upon the weather stations to the point where many that were in grassy fields are now in parking lots next to air conditioning vents and car engines.

¹ Hong Yan, Willie Soon, Yuhong Wang, "A composite sea surface temperature record of the northern South China Seas for the past 2500 years," *Earth Science Reviews*. (Volume 141, February 2015, pages 122-135). Retrieved July 5, 2021.

² K.R. Briffa and T.J. Osborn, "Seeing the wood from the trees," *Science*, 284, 926-927, 1999. Retrieved July 16, 2021.

³ Stephan Shiyatov, "Reconstruction of climate and the upper timberline dynamics since AD 745 by tree-ring date in the Polar Ural Mountains." Institute of Plant and Animal Ecology, Ural Division of the Russian Academy of Sciences. Retrieved July 16, 2021 from <https://climateaudit.files.wordpress.com/2005/08/shiyatov.finland.pdf>

⁴ Michael Mann, Raymond Bradley, Malcolm Hughes, "Global-scale temperature patterns and climate forcing over the past six centuries," *Nature* 392, 779-787 (1998). Retrieved July 16, 2021.

When budgets and bureaucracy allow, some of the worst encroachments are remedied by a move to more pristine locations. When this happens, the climate record keepers assume that past temperatures were biased too warm, and they cool them down by often undisclosed formulas and assumptions.

The rest of the other rural-to-urban weather stations have been left in place, either due to no funds available for relocation or no one locally taking the initiative to request them. Certainly, an honest appraisal would be that urban encroachment has biased many of the current readings as too high, and that they need to be adjusted downward to be consistent with the readings when those stations weren't surrounded by urban heating.

The major keepers of global temperature data do not make this logical adjustment. Temperatures from encroached stations are regarded as perfectly accurate in the plotting of trends... until one is moved, then its historic record is arbitrarily cooled to provide lower historic temps to make current temps seem high.

Finally, the team should look critically at the term "peer reviewed." In the scientific papers that my research teams had accepted for publication in refereed journals, peer review consisted of having the editor find a couple of volunteers give them a quick read. In my experience, no papers from my teams have ever had a reviewer request access to the underlying data, or even ask questions about the conclusions. This is not a slam on peer reviewers. They are generally academics who are juggling multiple demands on their time – teaching classes, mentoring students, supervising graduate research, writing grant applications, carrying out research, and dealing with time-sucking faculty committee assignments.

"Peer Review" is something that happens quickly, that takes results at face value, and usually lacks time to compare a result with contrary articles, much less actually reviewing the result's supporting data. It is not a reliable system to discover underlying issues with data or conclusions.

Therefore, the best method to ensure scientific integrity is to require that all data and all programs to analyze data be put in the public record. Then an army of graduate students looking for PhD material can attempt to replicate studies. As you know, many studies considered core to their disciplines fail to replicate⁵ when researchers other than the original team repeat their processes.

Some researchers argue that their computer code is proprietary, and the data is the result of years of personal effort that should not be given away. That's fine; if researchers have a private funding source and don't care to influence public policy, then keeping the data and the codes secret is their prerogative. However, if they use public funds and seek to influence public policy, making the data and the analysis programs public is the only way to achieve better quality control. As the replicability crisis shows, peer review is too perfunctory to take on the challenge effectively.

⁵ Maxwell, S.E., Lau, M.Y., Howard, G.S. (2015) "Is psychology suffering from a replication crisis?" *American Psychologist*, 70(6), 487-498. Retrieved July 16, 2021.

From: [R Solomon](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Sunday, July 18, 2021 7:08:56 AM

As a retired community clinical psychologist I have had many years of experience in trying to apply research based information to improve the lives of individuals and their community. I know from first hand experience that the use of science to inform agency decision making must be as unbiased as possible. Additionally, the science utilized should be independent—in other words, free of political, ideological, or financial influence. Independent science helps our government make informed decisions to protect public health and safety, and it enhances public trust when decisions are based on valid, credible processes.

However, as has been the case in recent years political interference in evidence-based policymaking can erode public trust in the federal government. For example, research has found that, while people in the US generally trust scientists more than many other experts, they have less trust for scientists who study issues that have been politicized. One obvious example of this in recent years has been in climate change. Another is the importance of vaccinations in dealing with the Coronavirus epidemic.

The Biden-Harris memo establishes scientific integrity officials at all federal agencies to protect science from undue political interference. These officials should be empowered to effectively implement their agency's policy. This policy should include the following:

- o In the past, scientific integrity officials have generally lacked power to investigate political interference coming from an agency's leadership or outside an agency.
- o Scientific integrity officials should report to an agency's highest-ranking civil servant and work with OSTP on cross-government issues such as open-data initiatives, the implementation of scientific integrity policies, and strategies to investigate and resolve alleged scientific integrity violations.
- o When a violation of scientific integrity allegedly is committed by agency leadership or outside of the agency, scientific integrity officials should be able to inform and work with the inspector general in the investigation of such interference.
- o Empowering scientific integrity officials will give the public and federal employees a trustworthy avenue for reporting scientific integrity allegations.

Please apply these principles to establish scientific integrity in the agencies of the federal government.

Sincerely,

Richard Solomon, PhD
Oakland, California

From: [Mt Ulla Gardens Webster](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Betsy Webster's public comment for SI-FTAC RFI
Date: Sunday, July 18, 2021 9:07:05 AM

This is my plea for the importance of strengthening the scientific integrity of Federal policies.

Science is factual!

Betsy Webster

From: [Bill Vaughan](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Monday, July 19, 2021 11:33:32 AM

Thank you for the chance to comment on ways to improve scientific integrity and for the work of the White House Office of Science and Technology on this issue.

I submit these comments solely on my own, although I am on the Steering Committee of Consumers United for Evidence-based healthcare (CUE), a group of roughly 40 patient and consumer advocates who promote good science in medical research and health decision-making. We support the work of a similar-purpose international effort, The Cochrane Collaboration. I also work with Medicare patients on their medical choices as part of the State Health Insurance Program (SHIP).

Without getting into the sad details of our national struggle with covid-19 in 2020, it is clear that health (and really, all) science needs to be protected better against political interference. Therefore,

1. In scientific agencies (like the FDA, NIH, CDC) there should be only one political appointee: the rest should be civil servants. One political can set the tone and direction of the agency but the agency should not be staffed to micro-manage the scientific staff and their output.
2. Scientific agency press releases should be approved and signed off by the senior civil servant of the unit involved. If there is no such sign-off, there should be an uncensored statement as to why not (i.e., open dissent should be encouraged with the scientific staff).
3. The FDA and NIH should work to provide clear 'warnings' on ClinicalTrials.gov (and elsewhere) when a study is posted that is financed in whole or part by the drug and/or device maker: drug and device companies can fund 'blinded' independent organizations but direct funding is an unending and losing struggle against intellectual corruption of test results. In TV and other ads about drugs, if the efficacy claim is based on research funded by the manufacturer, that fact should be included in the side effects warning.
4. The Federal government should work with educators and professional societies to develop and encourage changes in the nation's science classes to improve the public understanding of why Randomized Clinic Trials are important, how they work, and how to interpret them. Obviously, the public's knowledge of RCT's and vaccine development is grossly inadequate.

CUE on its website offers 'courses' and tutorials on RCTs and why they are the 'gold standard', but we reach a very small audience. Ideally, in the future every public school general science and biology class should dedicate at least a day's instruction to the fundamentals of RCTs, their history, and how to make sense of their results. Just as it is important to help students with driver safety education and the basics of personal and home finance, it is vital that our citizens understand why health anecdote is not health science.

Thank you for your consideration of these ideas.

From: [Craig Stephens](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Monday, July 19, 2021 1:05:54 PM

Science is based on measurements and trajectory modeling and calculation of what-ifs to predict results. The goal of getting to zero carbon energy generation on a reliable and cost effective basis so that all are able to survive extreme weather conditions caused by climate change regardless of wealth or status has to be our agreed goal.

Hydro has been a wonderful energy source with no carbon and established transmission grids such as here in Oregon and Canada with Ontario supplying Vermont but a model for the future must assume little change upward of hydro derived energy while electrical use increases with electric cars and hydrogen generation to replace jet fuel and diesel quite possibly needed on the horizon as many scientists worldwide have entered on their “energy roadmap”.

The US is moving toward more natural gas power plants with some 200 being planned, a 20 percent increase. Natural gas power is reliable and can adjust to required loading and power companies chose it because it can come on line quickly, is cheap to operate and can use the existing grid but obviously increases not decreases the problem of global warming!.

Intermittent renewal power, wind and solar, produce zero carbon power and are wonderful but reliably unreliable and require grid upgrade and extensions. To even out the power dips at night, when the wind stops, when it is too cold or too hot (wind dies in August and wind turbines need to be protected from extreme conditions) intermittent renewable needs to be double or more is peak capacity than actually needed and massive batteries or grid “backup” power provided to fill the gaps. The intial cost is higher than expected because of site acquisition issues, maintenance is high and remote and upgrading the grid to make it “smart” and robust is enormously expensive.

But a battery backup that fills the gaps and acts to release stored energy on demand and produces zero carbon energy is proven and available although expensive and hard to finance for utility companies without federal backing and that is of course nuclear power.

The roadmap must, to have a chance for success without miracle innovation, go through building nuclear power plants. The question is how many, when and what type. The deuterium reactor Canada first developed reduces the fuel storage and waste transportation problem and can convert to Thorium for more safety. We need another 100 reactors, we need to build them adjacent to existing sites and to stop closing plants that simply have high operating costs compared to natural gas and put nuclear and renewable energy workers on a federal payroll as front line workers in combating climate change.

To advance in the war on climate change we need nuclear and the safest nuclear is heavy water (deuterium oxide) reactors as Canada pioneered. We need national centers for deuterium production located where such research is historically done: Oak Ridge, Idaho, Corvallis, Morgantown, etc. Deuterium is also needed for research on fusion energy and nuclear is also needed for medical purposes. Deuterium production is not dangerous but requires research level workers and creates good jobs but most importantly it provides a way to lower the cost of operating reactors that are safer and cannot experience core melt down and can be converted to Thorium at any time. China has shown that heavy water reactors can use spent fuel from reactors that use enriched uranium. (Heavy water reactors are designed to use “natural” non-enriched uranium.

Building heavy water nuclear reactors should be financed by federal funding with a 30 year payback schedule to start when operational and the program administered by the military just as the Manhattan Project was to ensure focus and project mission success in fighting climate change.

With abundant electrical energy the US will maintain its position as a world leader. Conversion to hydrogen power becomes possible only with sufficient non carbon energy generation. With heavy water reactors the waste fuel situation becomes manageable.

Most importantly there will be power to distribute to all living here to use for survival in intense “heat bubbles” and

polar vortex cold snaps that affect the renewable power grid to shut it down at the worst time. Everyone deserves power and the air conditioning, medical care, and heating required to save their lives. Power is derived from natural resources that we all “own” so distributing it on a life saving basis is only just and humane.

The “roadmap” to zero carbon emission described above is consistent with what nuclear scientists worldwide are stating. I am not a nuclear scientist. My thesis was on atmospheric physics and my career has been in semiconductor manufacturing and reliability of manufacturing equipment. Since the 1960’s I have been a champion of first solar energy generation and then wind generation. But analysis of the need for storage and supplemental power and/or load following power with hydro reaching a practical limit forces any scientist to find that as of now intermittent renewable deployment requires at least as large a commitment to nuclear power to “fill the gaps” and sustain reliable power as we all need and expect. The country of Romania, and many others, have been moving ahead for thirty years with CANDU heavy water reactors coming on line. The US has lost, with time and inaction, many of the core nuclear scientists and engineers necessary to recover leadership but of course has continued the military programs. We need to pivot and educate and learn from Canada and Romania and Sweden do the research on deuterium and build new nuclear plants, heavy water or otherwise. It seems that using graphite moderators instead of heavy water saves money but adds risk and less risk is worth the cost.

Thank you!
Craig Stephens

From: [Jim Morrow - NOAA Federal](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: SI-FTAC RFI
Date: Monday, July 19, 2021 4:38:22 PM

To whom it may concern,

The procedures for participation in the peer-reviewed process (i.e., internal review, choosing reviewers, etc.) are either non-existent, or very difficult to find, for NMFS non-research scientists (e.g., regulatory biologists, hydrologists, etc.). This lack of easy to find procedures likely discourages participation in the peer-review process. I believe that development of clear (and easy to find) procedures would encourage participation of non-research scientists in the peer-review process, which would improve knowledge of local ecosystems, complement regulatory and habitat enhancement efforts, and would improve data analysis and communication skills that NMFS non-research scientists need to effectively perform their job duties.

Jim Morrow
National Marine Fisheries Service
Snake River Basin Habitat Office
Boise, Idaho

From: [Ben Hassan](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI Comment
Date: Monday, July 19, 2021 4:58:21 PM

Good afternoon,

I wanted to comment on the public's trust in the government, particularly when it comes to scientific-based policies.

Much of the lack of faith in government comes from people's exposure to media and their ignorance when it comes to the effect that government has on their lives. The previous twenty years of artificial polarization and foreign entanglements has increased the resentment that the average person has towards the government, from progressives who are frustrated by the lack of movement on healthcare and college debt to conservatives who fear that politicians and lobbyists are eating up tax dollars.

Strengthening faith in government requires a combination of increasing the positive interactions that people have with it. This can include policies that directly help people, educational reform that emphasizes critical thought and civic involvement, and a constant public commitment to democracy and justice. There will always be a segment of the population that will oppose the government simply because it's a) the government or b) the political opposition. However, in an imperfect world, I think that striving to do good by the average American while maintaining a ~%60 popularity approval rating like President Biden is doing is a great benchmark for effective government policy.

Thank you for reading,

Benjamin

To: White House Office of Science and Technology Policy
From: William Gorham, Ph.D. retired biologist, member of the public
Date: 19 July 2021
Re: Improving Federal Scientific Integrity Policies

I am writing to convey my strong support for improving federal scientific integrity policies. I was deeply troubled watching the significant and extremely detrimental influence that the Trump administration had on both the integrity and communication of scientific research and results. The ham-handed and grossly uninformed meddling of the administration's political hacks substantially undermined the trust that scientists and the general public have had in information and policies being developed and transmitted by many federal agencies.

In 2017, I retired from a nine-year career in academia followed by a three-decade career in environmental consulting. Since retiring, I have focused my efforts on teaching people about the causes of global warming and ocean acidification, conveying the likely effects of this greenhouse gas pollution, and empowering individuals, particularly the younger generations to become informed, engaged, and active in the fight to minimize the worst aspects of climate change. In these past 4 years, I've seen previously trustworthy and reliable resources such as the US Environmental Protection Agency be prevented from conveying information on climate change. For example, the lack of updating the EPA's climate change related webpages deprived me and others trying to teach our peers, kids, friends, and neighbors – and individuals with “alternative facts” – about the state of our knowledge concerning the causes & consequences of climate change.

This multifaceted censorship of government scientists has left me with the impression that too many of the agency scientists who were leaders in this field have quit their agencies leaving behind less qualified or experienced staff. I know that my impression is shared by many others both scientists and lay persons. This uncertainty about the quality and integrity of the work coming out of the EPA and other federal agencies has diminished the stature of U.S. science, scientists, and scientific policy in the eyes of the world.

In my 30 years as an environmental consultant and in these past 4 years dealing with climate change, I have worked closely with many government scientists and agency staff. Generally, I have been impressed with their skill, integrity, and commitment both to valid science and to open communication of not only their data but also the bases for their decisions. While I am hopeful that this level of integrity will persist with the Biden and future administrations, I support the push to enshrine it in formal policies.

As the Office of Science and Technology Policy undertakes the critical tasks of restoring the integrity of federal scientists and agencies, I urge you to ensure that all scientists can openly share their data, conclusions, and recommendations without the information being filtered, reinterpreted, or changed without the knowledge or approval of the authors. You need to ensure all employees, not just the scientists, are properly trained

in these rights and the consequences of violations of those rights are clearly defined and rigorously enforced. To reestablish the strength and quality of the federal scientific workforce, you must hire, train, support, and promote a well-qualified, diverse array of professionals not only to reflect the diversity of the nation, but also to demonstrate the considerable value of such a diverse workforce. Finally, and maybe most importantly, it is critical that your Office establish policies and procedures to prevent political interference in scientific investigations, reporting, and discussions, particularly when the issues at hand, such as COVID-19 or climate change, have profound impacts on not only the nation but humanity as a whole. We have a responsibility to once again be the shining example we have been in the past.

From: [Lorin Peters](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Public comment re improving trust in science
Date: Tuesday, July 20, 2021 1:18:20 AM
Attachments:

Lorin Peters public comment for SI-FTAC RFI

Regarding effective approaches to improving trust in federal science:

I graduated from UC Berkeley with an AB in Physics, then taught physics in a Catholic high school from 1970 to 1992, using the (Harvard) Project Physics curriculum.

This curriculum definitely improved trust in science when and where it was used. The reason for this is that it gave students a wholistic experience of science, instead of focusing on just the technical details. It integrated the concepts and principles of physics with what the students were learning about history and government and religion and languages, as well as medicine and chemistry and mathematics.

For example, it had a whole chapter on Aristotelian science, and another on the Copernican revolution and Galileo's conflict with the Church. In the chapter on Newton's work, it explained how his discovery that gravitation explained the motion of the planets meant that terrestrial and celestial matter obey the same laws, which led to the idea that all men (and women) are created equal, and thus to democracy and the Enlightenment.

Some rigorous educational research established that its students understood the principles of physics just as well as students using traditional physics curricula, but had much more favorable views of science than did the students of those traditional non-integrated curricula. (Unfortunately, I no longer have a copy of the journal in which this research was published.) One of the consequences of this favorable reputation was that enrollment in my physics classes grew from about 30% of our student body to about 70%.

So one approach to improving trust in science will be to encourage this kind of integrated science education. The Project Physics curriculum (the 'Harvard' was later dropped from the name) was directed by F James Rutherford, Gerald Holton and Fletcher Watson, and published by Holt, Rinehart and Winston. The earlier editions were the best. Later editions edited out some the rich historical and cultural material. Unfortunately, I was forced to change to another curriculum when I was told this one was going out of print about 1992.

Pace e bene
Lorin Peters
2021 July 19

EXECUTIVE OFFICE OF THE PRESIDENT

Request for Information to Improve Federal Scientific Integrity Policies

Opened 06/28/2021. Closes 07/28/2021.

July 21, 2021

Ivan Graff

Program Manager

Respondent Type: Government

U. S. Department of Energy

Office of Science

Office of Nuclear Physics

Note: Views expressed herein reflect those of the author and not necessarily those of the author's colleagues or employer.

4. Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices:

Writing Prompt	Recommendations
Educating and informing employees, contractors, and grantees in scientific and technical positions, as well as those who manage, communicate, or make decisions based on science and technology, of their rights and responsibilities related to agency scientific integrity policies;	<ol style="list-style-type: none">1. Through an OMB memorandum institute an annual training not to exceed one half hour to educate federal employees and their contractors of their responsibilities related to upholding agency scientific integrity policies.2. Through an OMB memorandum, direct agencies to conduct an annual internal review of scientific integrity policies to determine the agency level of compliance with current government-wide policies. Have agencies document the results in their annual performance reports.
Reporting practices that promote transparency in the implementation of agency scientific integrity policies and in the handling of any allegations of misconduct;	<ol style="list-style-type: none">1. Through an OMB memorandum, augment the responsibilities of the Office of General Counsel to in addition to review ethics questions to additionally have resources available to review

Writing Prompt	Recommendations
	science-related ethics questions and allegations of scientific misconduct.
Communicating to the public about alleged lapses in scientific integrity, substantiated violations of scientific integrity policies, and remedial actions taken; and	1. Through an OMB memorandum, direct agencies to include in annual performance reports alleged and substantiated violations of agency scientific integrity policies and remedial actions proposed and taken.
Minimizing conflicts of interest in Federal science and research misconduct.	1. Develop through Grants.gov a government-wide database of grant applicants and proposal reviewers that would facilitate checking for conflicts of interest. This would necessitate standardizing for the database biographical sketches, resumes, or curriculum vitae. OMB could assist with the efficient review and eventual approval of the associated information collections.

5. Other important aspects of scientific integrity and effective approaches to improving trust in Federal science:

Writing Prompt	Comments
Consider also effective practices, in addition to those specified above, that Federal agencies could put in place to improve scientific integrity and public trust in Federal science, including for proactively promoting rigorous, objective scientific research and streamlining implementation within and across Federal departments and agencies.	1. Advance a legislative proposal that would require all grant recipients to acknowledge in reports and other printed materials not just their federal sponsors, a requirement typically found in the award terms and conditions, but also all sponsors; public and non-public; non-profit and for profit.

July 21, 2021

OSTP Director Dr. Eric Lander and OSTP Deputy Director Alondra Nelson
Executive Office of the President of the United States
725 17th Street NW
Washington, DC 20006

**Re: Executive Office of the President Document No. 2021-13640 - Request for Information
To Improve Federal Scientific Integrity Policies**

On behalf of the Union of Concerned Scientists (UCS), we submit this comment to the Office of Science and Technology Policy (OSTP). Our comment provides recommendations on reviewing the effectiveness of federal agency policies aimed at preventing improper political interference in the conduct of scientific research and the collection of data; preventing the suppression or distortion of findings, data, information, conclusions, or technical results; supporting scientists and researchers of all genders, races, ethnicities, and backgrounds; and advancing the equitable delivery of the Federal Government's programs.

With more than half a million supporters, UCS is a science-based nonprofit working for a healthy environment and safer world. Our organization combines independent scientific research and citizen action to support innovative, practical solutions and secure responsible changes in government policy, corporate practices, and consumer choices.

We commend the White House for seeking information on how to improve scientific integrity across all federal agencies. It is crucial that any new policies consider equity in evidence-based policymaking, be clear in their implementation and enforcement, allow scientists to openly communicate with the public and air disagreements, and that policies are consistently reviewed by experts with leadership from OSTP. Below are specific recommendations that should be recognized and accommodated in any future directives from your office.

I. Scientific Integrity Must be Equitable.

We recommend that OSTP and other agencies have strong scientific integrity policies in-place to ensure that evidence-based decisions safeguard underserved communities.

For decades, underserved communities, including communities of color, Indigenous communities, and low-income communities, have fought for the right to live in environments free of toxic waste, pollution, and other hazards (1). The victories of community activists in these hard-fought battles have led to federal programs and policies that help these communities address health, safety, occupational, and quality-of-life concerns (2). Nevertheless, underserved communities continue to face disproportionate harm from environmental pollution, hazardous workplace conditions, industrial activities, a lack of access to health care, and many other threats (3). While listening to community voices is an important part of addressing past and ongoing inequities in public protections, so too is the scientific evidence of these inequities. That

evidence must be explicitly called for, evaluated, and become a routine part of the science that informs government decisions. And sidestepping or sidelining such evidence should be considered a violation of scientific integrity.

Federal agencies can help address such disparities by first combating systemic racism through examining their own internal systems. Agencies cannot adequately protect underserved communities or understand their needs or circumstances when hindered by a system that fails to support a workforce from diverse and underrepresented backgrounds (4). While such internal work may be thought to be organized under the umbrella of “professional ethics” and not “scientific integrity,” we argue that the two are intrinsically linked. Federal agencies must foster and support a safe and professional environment for *all* scientists so that they are able to learn, conduct, research, and communicate science with integrity, respect, and transparency.

Agencies should include in their scientific integrity policies affirmation that discrimination, harassment (including sexual harassment), or bullying constitutes scientific misconduct. The American Geophysical Union has done well incorporating these issues in their scientific integrity policy that we recommend the taskforce review (5). The development of provisions on these issues should adhere to the Biden-Harris administration’s executive orders on diversity and equity as well as combating discrimination based on gender and sexual orientation (6, 7). Scientific integrity policies should explicitly reject discrimination or harassment by any means based on factors such as ethnic or national origin, race, religion, citizenship, language, political or other opinion, sex, gender identity, sexual orientation, disability, physical appearance, age, or economic class. Federal scientists must commit to unbiased reviews and editing of manuscripts, grant proposals, or any other scientific work. Scientific integrity policies also should oppose all forms of bullying that may sabotage ongoing scientific work or the career of a federal scientist, grantee, intern, or contractor. Scientific integrity officials and federal scientists should receive training to identify and report discrimination, harassment, or bullying within their professional environment.

Agencies must also ensure scientific data on health disparities is available and used (8). In open-ended responses to a 2018 survey conducted by the Union of Concerned Scientists and Iowa State University, federal scientists in at least seven agencies reported they were blocked from accessing or obtaining data that could have been used to identify and reduce health disparities (9, 10). Federal agencies should include provisions in their scientific integrity policies affirming that scientists receive requested data within a timely manner if the requests do not violate existing regulations (e.g., the Paperwork Reduction Act of 1980). Scientific integrity policies should also affirm that the public have access to unclassified, disaggregated, federally funded data and information in a timely manner and with appropriate context to enhance public understanding (11). For example, data from federal monitoring programs such as air pollution monitoring networks, satellite observations of Earth systems, and the collection of workplace injury statistics should be publicly available (12). Many environmental justice groups use federal-level datasets on environmental risks, industrial emissions, and climate issues to examine inequities in health, social, and economic outcomes throughout the United States (13).

To ensure that federal data-collection efforts on health disparities are conducted in a scientifically robust and community-focused manner and without political interference, federal

agencies should develop protocols to allow community input throughout the research process. This would not only provide agencies with a mechanism to receive community input on ongoing research, but also help hold agencies accountable for prioritizing the interests of public health (3).

II. Scientists Should be Allowed to Openly Communicate and Disagree

We recommend that scientists be allowed to speak freely about their work with the public and the media, and that agencies develop protocols to allow scientists to voice disagreement with science-based decisions.

Disagreement and open scientific communication are essential components of the scientific process (14). An open discussion of scientific work can help build trust that the researchers involved paid careful attention to best scientific practice. Despite possible disagreement on one or more technical points, federal agencies should still adhere to and openly state that their decisions are guided by the “weight of scientific evidence.” Rather than covering up or excluding contrary evidence, agencies should acknowledge it and clearly express why other evidence is given greater weight.

Federal scientists must be explicitly allowed to publicly speak about their work. Agency scientific integrity policies should ensure that scientists may speak about their research findings with media and the public without prior approval and may receive and respond to media requests about their scientific work directly without being routed through a public affairs office (15). Agencies may be concerned that such a media policy will lead to scientists speaking about federal policy or that scientists will “go rogue.” To be clear, allowing scientists to talk about their research publicly does not provide federal experts an opportunity to opine on policy decisions on behalf of an agency. Furthermore, concerns about rogue scientists worrying the public with misinformation or sharing unclassified data or results is unfounded in agencies that have had such open communication provisions in their scientific integrity policies for years (e.g., the National Oceanic and Atmospheric Administration) (16). The novel coronavirus pandemic clearly illustrated the toll on public health when non-scientists are allowed to control messaging on a science-based issue; therefore, federal agencies should allow scientists to communicate with the public to prevent such devastation in the future (17).

The scientific integrity task force, and any resultant guidance, should mandate that all agencies that rely on scientific information adopt a differing scientific opinions policy. The policy should outline clear, formal steps for individuals to voice differing scientific opinions regarding issues, decisions, or policies on which they are engaged substantively. These steps should be supported by guidance on when such actions are necessary, how the individual should take such actions, and to whom an individual should submit differing scientific opinions. The policy also should establish a mechanism to protect from retaliation any employee who voices differing scientific opinions. Currently only three science-based agencies have a formal mechanism in-place for scientists to issue a differing scientific opinion (the Environmental Protection Agency, the Food and Drug Administration, and the Department of Energy) (8). The Environmental Protection Agency’s (EPA) differing scientific opinions policy was used in 2020 to highlight a scientist’s scientific integrity concerns with the agency’s former “Strengthening Transparency in Regulatory Science” rule that was vacated in 2021 (18).

Even if differing scientific opinions policies are developed, some agencies may issue science-based statements outside of these policies disagreeing with scientific guidance prepared by other agencies or federal advisory bodies. For example, the Department of Justice (DOJ) issued a formal statement in 2021 criticizing a 2016 report on the state of forensic science prepared by the President’s Council of Advisors on Science and Technology (PCAST) (19). Such formal statements can be highly influential – for example, the DOJ statement has already been used by prosecutors in several court cases potentially affecting the guilt or innocence found of those on trial. The DOJ statement criticizing the 2016 PCAST report was unsigned, and it is unclear if scientists were involved in its development or review. In cases where science-based statements are highly influential, agencies should provide the public with information regarding how the disagreement was formed and the scientists involved in its development or review.

III. Scientific Integrity Policy Implementation and Enforcement Should be Clear

We recommend that implementation and enforcement of scientific integrity policies are clear to federal experts and the public, and that they apply to agency employees and political appointees.

There are currently 28 federal agencies, bureaus, and offices with scientific integrity policies that cover thousands of scientists, contractors, and grantees. There are also multiple scientific integrity officials, chief science officers, and scientific integrity liaisons who play various roles in implementing these policies. It is not always clear which agency’s, bureau’s, or office’s policy takes precedence, who it applies to, and who plays what role in implementing the policy.

The implementation of scientific integrity policies may be particularly unclear when policies of offices or bureaus differ from those of their home departments (e.g., Fish and Wildlife Service within the Interior Department). This lack of clarity in implementation can make holding violators of the policy accountable for their actions difficult. For example, an independent investigator was not permitted to interview Department of Commerce (DOC) employees involved in the 2019 “sharpiegate” scientific integrity violation. Crucially, political appointees in DOC did not feel bound by the NOAA policy (20). Federal agency scientific integrity policies in bureaus or offices must apply to their home agencies and to political as well as career staff.

Clarity on implementation of scientific integrity policies is also important because provisions among policies can vary greatly. For example, the Department of Interior (DOI) does not offer detailed guidance about clearance on scientist’s work that occurs outside of the agency (8). The Fish and Wildlife Service, however, explicitly states that supervisors need not review “personal expressions of information (21).” The United States Geological Survey scientific integrity policy requires scientists to receive advance authorization from a division chief before outside work is conducted (22). Three different scientific integrity policies all at DOI with three very different provisions regarding clearance on work outside of a scientists’ agency or bureau. Such variance could make implementation, such as what happened with the investigation of “sharpiegate,” unclear, or leave some scientists confused as to why they are not afforded the same rights as other scientists within their same department.

To effectively restore public trust in evidence-based policymaking, scientific integrity policies, infrastructure, and processes must be clear, transparent, and consistent. The public can lose trust in confusing government processes and suspect that the system can be manipulated for political

goals (23). Scientific integrity officials from different agencies, bureaus, and offices should continue to work together to discuss and work on these issues.

IV. Accountability of Policy Violators

We recommend that agencies adopt mechanisms to hold those accused of violating scientific integrity policies accountable through adverse or disciplinary actions.

Federal employees who violate agency scientific integrity policies must be held accountable for their wrongdoing. In the case of “sharpiegate,” the NOAA investigation found two senior-level employees had violated the agency’s policy, yet neither received any disciplinary or adverse action (20, 24). This sent a message that scientific integrity violations are not taken seriously and that there are no repercussions for violators of agency policy. If this is the case, what would prevent an employee from violating the policy again?

Scientific integrity policies should clearly articulate the disciplinary or adverse actions that could be taken if an individual violates the policy. It should be noted in the policy that federal employees have the right to due process before a federal agency takes an adverse or disciplinary action against them as specified in Chapter 75 of Title 5 in the United States Code. Violations of other federal agency policies include adverse and disciplinary actions such as removal, demotion, reduction in grade, or suspensions of greater than 14 days. A violation of the agency’s scientific integrity policy should also consider being factored into the employee’s annual performance evaluation. A public record of this violation, in accordance with privacy protections, should be noted on the agency’s website.

Federal agencies should issue a final determination for adverse or disciplinary action after the accused has been given the opportunity to respond to a notice of the proposed action. Scientific integrity policies should make clear that the accused have a right to appeal through multiple avenues depending on the decision. Resources should be provided to employees on appeal processes through the Merit Systems Protection Board, the Equal Employment Opportunity process, the grievance/arbitration procedure, and on whistleblower defense.

V. The Role of OSTP

We recommend OSTP continue its leadership on federal scientific integrity for the foreseeable future and continue to review and refine its process for public involvement.

Scientific integrity standards, process, and implementation across federal agencies has historically, and is currently, being overseen by OSTP. This work began under the Obama administration with a significant first step on December 17, 2010, when President Obama’s science advisor, John Holdren, issued a memorandum directing federal agencies to develop and implement scientific integrity policies (25). Given the office’s role in coordinating federal agency scientific processes, OSTP will need to continue its leadership on scientific integrity for the foreseeable future. While the current scientific integrity taskforce has a specific goal to produce a report that may mark its end – OSTP should consider convening a regular annual meeting on scientific integrity with multiple stakeholders (e.g., scientific integrity officials, chief science officers). The meeting should be open to the public.

The office also should work to develop a scientific integrity policy for the White House. Scientific integrity violations do not solely exist in federal offices outside of the White House. During the past four years, in some cases, it was clear that individuals in the White House played a role in a scientific integrity violation (26). However, the implementation and enforcement of scientific integrity policies is unclear if White House officials are involved. OSTP should work to establish its own policy and clarify when White House officials are subject to its own or other agency's policy.

OSTP should also review its ongoing process to fulfill the president's memorandum on restoring trust in government through scientific integrity and evidence-based policymaking (27). One of the key tenets of scientific integrity is that science-based decision-making processes are transparent (8). It is important that the scientific community and public fully understand how federal agencies are using scientific information to inform policy decisions. This same principle of transparency should be applied to OSTP's process on strengthening scientific integrity. The process by which the scientific integrity taskforce and OSTP are determining how to strengthen scientific integrity could be more transparent. For example, scientific integrity task force meetings and minutes have not been made publicly available. Furthermore, it appears there is no federal docket that will make submitted comments publicly available – OSTP should make all comments received to this request for information publicly available.

The office should also review its process for public involvement. It is a unique and great opportunity to provide public input into a process led by the White House – a process that is moving fast. However, some organizations or communities affected by the work of OSTP and the taskforce may need a longer time to provide robust oral and written comments. OSTP should consider more advanced notice and extending comment periods if future public input opportunities are provided.

VI. Additional Resources

The Union of Concerned Scientists has advocated for stronger protections for federal scientists and their work for over a decade. Our organization has published multiple reports and publications that provide recommendations on how to strengthen scientific integrity policies in the federal government – many of which are attached to the email sent with our comment. Further resources can be found on our webpage: [Independent Science | Union of Concerned Scientists \(ucsusa.org\)](https://www.ucsusa.org/independent-science). We appreciate the opportunity to provide input into OSTP's process to bolster scientific integrity and evidence-based policymaking.

Sincerely,

Dr. Jacob Carter, Senior Scientist
Dr. Andrew Rosenberg, Director
Genna Reed, Senior Analyst
Anita Desikan, Research Analyst
Taryn MacKinney, Investigative Researcher

The Center for Science and Democracy, Union of Concerned Scientists

Literature Cited

1. R. Bullard, *The wrong complexion for protection: how the government response to disaster endangers african american communities* (NYU Press, New York, NY, 2012).
2. R. D. Bullard, G. S. Johnson, A. O. Torres, in *Environmental Health and Racial Equity in the United States*. (American Public Health Association, 2011), chap. Chapter 1.
3. A. Desikan, J. Carter, S. Kinser, G. Goldman, "Abandoned science, broken promises: how the Trump administration's neglect of science is leaving marginalized communities further behind.," (Union of Concerned Scientists, Cambridge, MA, 2019).
4. A. Desikan, "Supporting equity and environmental justice: recommendations for 2021 and beyond," (Union of Concerned Scientists, Cambridge, MA, 2020).
5. American Geophysical Union, "AGU scientific integrity and professional ethics," (American Geophysical Union, Washington, DC, 2017).
6. *Executive order on diversity, equity, inclusion, and accesbilitly in the federal workforce* (2021 <https://outlook.office.com/mail/inbox/id/AAQkADA5MjcwNTE5LTl5ZGUtNGY1Yi1iZDE1LWZjOTU5N2JkZWYwNwAQADrWfDeLRa1HhTBXvWslbf4%3D>).
7. *Executive order on preventing and combating discrimination on the basis of gender identity or sexual orientation* (2021 <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-preventing-and-combating-discrimination-on-basis-of-gender-identity-or-sexual-orientation/>).
8. T. MacKinney, J. M. Carter, G. Reed, G. Goldman, "Strengthening scientific integrity at federal agencies," (Union of Concerned Scientists, Boston, MA, 2020).
9. J. Carter, G. Goldman, C. Johnson, "Science under Trump," (Union of Concerned Scientists, Cambridge, MA, 2018).
10. G. T. Goldman, J. M. Carter, Y. Wang, J. M. Larson, Perceived losses of scientific integrity under the Trump administration: A survey of federal scientists. *PLoS One* **15**, e0231929 (2020).
11. Executive Office of the President, *Policies for federal agency public websites and digital services* (2016 <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/m-17-06.pdf>).
12. A. Desikan, Union of Concerned Scientists, Ed. (Office of Management and Budget, Washington, DC, 2021).
13. L. Dillon *et al.*, Environmental Data Justice and the Trump Administration: Reflections from the Environmental Data and Governance Initiative. *Environmental Justice* **10**, 186-192 (2017).
14. The power of disagreement. *Nature Methods* **13**, 185-185 (2016).
15. J. M. Carter *et al.*, Strengthen scientific integrity under the Biden administration. *Science* **371**, 668 (2021).
16. National Oceanic and Atmospheric Administration Administrative Order 202-735D-2: *scientific integrity* (2021 <https://www.noaa.gov/organization/administration/nao-202-735d-2-scientific-integrity>).
17. A. Desikan, T. MacKinney, G. Goldman, "Let the scientists speak: how CDC experts have been sidelined during the COVID-19 pandemic," (Union of Concerned Scientists, Boston, MA, 2020).
18. *The final strengthening transparency in regulatory science rule: differing scientific opinion* (2020 <https://int.nyt.com/data/documenttools/dissenting-scientific-opinion/8fdd7838c67f4c21/full.pdf>).
19. United States Department of Justice statement on the PCAST report: *Forensic Science in Criminal Courts: Ensuring Scientific Validity of Feature-Comparison Methods* (2021 <https://www.justice.gov/olp/page/file/1352496/download>).
20. *An independent assessment of allegations of scientific misconduct filed under the National Oceanic and Atmospheric Administration scientific integrity policy* (2020 https://nrc.noaa.gov/Portals/0/SIC/NOAA%20Final%20Report_scanned_061220.pdf?ver=2020-06-15-074029-673).
21. *Scientific integrity and scholarly conduct* (2011 <https://www.fws.gov/policy/212fw7.html>).
22. *Survey manual chapter 500.25: scientific integrity* (2015 <https://www.usgs.gov/about/organization/science-support/survey-manual/50025-scientific-integrity>).

23. F. D. LoMonte, in *American Bar Association's Human Rights Magazine*. (American Bar Association, Washington, DC, 2021).
24. A. Freedman, J. Samenow, in *The Washington Post*. (The Washington Post, Washington, DC, 2020).
25. *Memorandum for the heads of executive departments and agencies: scientific integrity* (2010 <https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf>).
26. J. M. Carter, E. Berman, A. Desikan, C. Johnson, G. Goldman, "The state of science in the Trump era," (Union of Concerned Scientists, Washington, DC, 2019).
27. *Memorandum on restoring trust in government through scientific integrity and evidence-based policymaking* (2021 <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/>).

OSTP Director Dr. Eric Lander and OSTP Deputy Director Alondra Nelson
Executive Office of the President of the United States

July 28, 2021

Re: Executive Office of the President Document No. 2021-13640 - Request for Information to Improve Federal Scientific Integrity Policies

We, the undersigned science advocates, submit the following to the Office of Science and Technology Policy as it works to improve federal scientific integrity and promote public trust in science-based decisions. We urge the federal government to:

- strengthen communication and publication policies, so that all scientists can openly share their discoveries and we, the public, can be active participants;
- prevent political interference in science and preserve scientific independence, so that scientists can do their work without being unethically influenced by political interests or conflicts of interest;
- train, protect, and empower federal employees, so that all civil servants can do their jobs, report wrongdoings if needed, and remain safe from retaliation;
- prioritize underserved communities, so that environmental laws are enforced thoroughly and equitably and communities can play active roles in research and decisionmaking; and
- invest in a robust, diverse federal scientific workforce, so that our nation's scientists represent, and are invested in, our diverse nation.

Thank you for your consideration.

Sincerely,

Over 9,700 signatories (See Appendix A for names – attached)

Submitted by the Union of Concerned Scientists (UCS), a science-based nonprofit, on behalf of over 9,700 members of the public.

From: [John W Hunt](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI Comments on Scientific Integrity Policy
Date: Wednesday, July 21, 2021 6:51:25 PM

Dear Scientific Integrity Officer,

Thank you for the opportunity to submit comments to improve federal scientific integrity policies. I have the following comments:

1. I applaud the work of the President and the Office of Science and Technology Policy for preparing a sound set of policies to promote the efficient use of scientific information and to reduce the amount of interference by those who would distort the truth for illicit gain.
2. I have no specific comments about the policies as written. I think they go a long way toward protecting scientific integrity and promoting effective government based on evidence rather than hyperbole and misinformation.
3. With any document of this type, I hope the authors and policy reviewers pay serious attention to social scientists in fields such as psychology, cognitive neuroscience, history, and linguistics to pay careful attention not only to what the policies say but how the policies are heard by Americans. The frames of reference for many Americans have changed dramatically over the past three or four decades as a result of repetitive messaging, proliferation of questionable media platforms and unapologetic dissemination of "alternative facts." The people who read and react to policy documents and pronouncements may interpret them very differently than the scientists and social servants who produce them. Very few political constituents have the training and analytical world view possessed by the professionals who write this type of policy, and every effort should be made to speak in a language that is as unambiguous and accessible as possible for an audience that is confused by and skeptical of well-crafted language covering complex subjects.
4. Given my point in #3 above, I suggest that this and other technical policy documents be reviewed by scientists and other experts with experience evaluating the social and mental processes by which language and ideas are perceived by people with different life experiences and different mental frames of reference.

Thank you very much for considering this.

John W. Hunt, Ph.D.
Research Toxicologist
Department of Environmental Toxicology
University of California, Davis

The greatest challenge to any thinker is stating the problem in a way that will allow a solution. - Bertrand Russell

Corrine Ann Dale, PhD

Director/Principal Investigator

Small Diverse Research Institute

Beginning with the grant review protocol, racial and culture inequities has clouded the landscape of scientific inquiry and equity. Lack of an avenue to ensure that African American and Hispanic scientists receive the proper recognition for their contribution to the field has been a historic and current problem that has plagued federal grantors and the scientific community for many years. Assigning and applauding the contributions of those with less than impeccable credentials has resulted in a stagnant scientific system that has forgone original inquiry and innovation. Accepting that one who is considered less than (i.e., less experience, less credentials, and less connections) will not receive credit has been an accepted tradition in the scientific community. However, not only is this view less productive, but it also effects the integrity of the scientific process. Thus, designing a protocol that outlines how inquiry, innovation, and implementation by those ‘less than’ should be treated begins with a conversation that is inclusive, reflecting diversity, and reflective of input that is not framed by fear of judgment by those ‘expert’ in the field.

When I began my research career, I was told I was not properly credentialed. I was without a PhD but I had great ideas, and a desire to contribute. Although I was rebuffed time and again, I pressed on and developed a small research institute that stood idly by as my ideas were passed on to those with more influence, more credentials, and with the vaulted Dr. before their name. I wondered why people like me, who were inspired by science, inquisitive, and unique in their viewpoint, was being shut out of the scientific field. For years, I let the institute lay fallow, while I pursued more practical tasks. I paid the bills through my master level education, while developing and submitting grant projects that were denied for what appeared to be an industry-based policy of denying those who lacked the established credential with little thought to the actual abilities and capabilities of a master’s level investigator. Although I wanted

in badly, I could find no entrance through the front door (government grants) or the back door (mentorship). I eventually decided my deeply held passion for scientific inquiry would need to be fulfilled. So, I went back to school to obtain my PhD.

After obtaining my PhD, I was still considered under qualified. I needed experience, prior examples of my work, which I couldn't get because I had not served an industry prescribed 'servitude'. This is not to say that one could not benefit from a mentor-mentee relationship. However, the lack of such a relationship should not equate to being shut out of the pursuit of science, or the implementation of innovative ideas and seminal research. I think the phrase scientific integrity can sometimes be equated with exclusion, the majority rules, and the ignoring of difference. It has become necessary to screen the screeners. Who is reviewing grant applications, do they have vested interest in keeping others out, what personal standards are involved in their assessment? These are tough questions and may be seen by some as unnecessary but without the appropriate conversation and subsequent investigation we may never get to a point where the scientific community is more reflective of black and brown communities they study.

Thus, starting with the conversation and ending with specific guidelines, it must become policy to include those new to the field (not just saying that's what we are going to do, i.e., early research scientist awards) but actually facilitating the implementation of ideas and the inclusion of diverse groups from reviewers to researchers. Diversity must become a focus in every facet of the scientific community. As such, scientific inquiry should not only be reflective of diverse study populations, but reflective of diverse ideas and innovations. We cannot accomplish this without enlisting those in the field who sit on review boards, who are department heads, and who are grantors. We all must embrace the idea that scientific inquiry need not be white inquiry, that

scientific integrity need not equal minority exclusion, and that scientific research need not equal the majority investigator led studies of minority communities, but a reflection of inclusiveness of those from all walks a life, who simply love and embrace the process of transforming scientific inquiry into public service programs.

COMMENTS OF SUSAN VON STRUENSEE, JD, MPH
to the
Request for Information to Improve Federal Scientific Integrity Policies A Notice by the Executive
Office of the President on 06/28/2021
Document Number:
2021-13640

Thank you to The White House Office of Science and Technology Policy (OSTP) for the opportunity to provide information to improve the effectiveness of Federal scientific integrity policies to enhance public trust in science, an issue so important to all of us.

Our Nation's opioid crisis; the scandal involving Jeffrey Epstein, a sex trafficker; space joyrides by federally funded billionaires while students are crippled by educational loans; and the fact that American Indians and Alaska Natives and people of color are experiencing not only higher rates of COVID-19 infections but also worse outcomes from the infection; are all germane topics to the Request for Information to Improve Federal Scientific Integrity Policies. The RFI states that comments must not exceed 7 pages in 12-point font, alas, I will do what I can.

The press shows widespread concern and loss of trust in the nation's top leaders, including our scientists, due to the Epstein scandal. This loss of trust-in the values of our leaders in science, values that include their acceptance of sex trafficking, is just as critical to discussing loss of public trust due to some aspects of the government's handling of the COVID-19 pandemic and some government scientists' recent politicizing results of climate change research. The RFI mentions strengthening the actual and perceived credibility of government research through, e.g., setting clear standards for governing conflicts-of-interest and adopting whistleblower protections. Whistleblowers follow a statutory process of revealing abuses to their agency's inspector general and then potentially to members of Congress. Some view them as surrogates for the broader public. However, whistleblowers are vulnerable and imperfect surrogates. Those who blow the whistle are invariably subject to retaliation, even though statutes prohibit such responses. What can we do about that?

Epstein's relationships included two recent former US Presidents, federally funded leading universities and a host of eminent scientists, and other celebrated Americans. The confirmation of Eric Lander, the current top US science adviser, of the White House Office of Science and Technology Policy, the Agency who called for this RFI, was delayed in part because of Sen. Maria Cantwell's (D-Wash.) concerns about meetings Lander and his colleagues had with Jeffrey Epstein. The facts cleared Lander of a relationship with the convicted pedophile and indicted sex trafficker. But Lander's reputation remains tarnished with the stain. That's how horrified people are about Epstein's ties to the scientific community.

Public corruption involves a breach of public trust and/or abuse of position by federal, state, or local officials and their private sector accomplices. The relationships of top government officials and top university scientists with sex trafficker Epstein and his disturbing scientific research has longstanding impacts on public trust. What are the values of our leaders in government, including in science? The Jeffrey Epstein Foundation's board included Cecile de Jongh, wife of the former Governor of the United States Virgin Islands, John de Jongh. In 2003, the foundation pledged \$30 million to Harvard University to establish the Program for Evolutionary Dynamics, directed by Martin Nowak, a professor of mathematics and biology. The federally funded University received \$6.5 million of this pledge. The foundation also supported NEURO.tv, a video series featuring experts discussing topics related to the brain, and the OpenCog project, an open-source software initiative for Artificial intelligence. As a

representative of the foundation, Epstein sat on the Mind, Brain and Behavior Advisory Committee at Harvard University, and been involved in the Santa Fe Institute, the Theoretical Biology Initiative at the Institute for Advanced Study at Princeton, and the Quantum Gravity Program at the University of Pennsylvania. Epstein also served on the Trilateral Commission and the Council on Foreign Relations.

Computer scientist and open software advocate Richard Stallman resigned from his position as a visiting scientist at MIT's Computer Science and Artificial Intelligence Lab after describing a victim of sex trafficker Jeffrey Epstein as "entirely willing" in emails sent to a department list. Stallman also stepped down from his roles as president and board director at the Free Software Foundation, the nonprofit he founded in 1985. Stallman has long called for the legalization of child pornography and abolishment of age of consent laws.

The Epstein affair spotlights another serious problem: it undermines the integrity of the nation's research enterprise when wealthy individuals can pick and choose lines of inquiry that appeal to them, whether they are ethical or needed, while American students cannot even get real federal assistance for an education. Instead, they get saddled for a lifetime with crippling debt federally guaranteed to bank behemoths. Or they do not go to college. We do not need this state of affairs for our Artificial Intelligence (AI) National Security initiative to develop AI expertise nationally, we never needed it. Money and avenues toward citizenship are proposed to secure foreign talent in the AI national security plan. What are we doing for American talent ready and willing to learn and serve, who live right here?

Pursuant to the National AI Initiative Act of 2020, passed on January 1 as part of the National Defense Authorization Act of 2021, the White House Office of Science and Technology Policy formally established the National AI Initiative Office on January 12, 2021. The Office—one of several new federal offices mandated by the NDAA—is responsible for overseeing and implementing a national AI strategy and acting as a central hub for coordination and collaboration by federal agencies and outside stakeholders across government, industry and academia on AI research and policymaking.

AI systems that demonstrate significant bias or lower than claimed accuracy, and resulting in individual and societal harms, continue to be reported. Such reports beg the question as to why such systems continue to be federally funded, developed and deployed despite the many published ethical AI principles. There is a need to focus on the funding processes for AI research grants identified as a gap in the current range of ethical AI solutions including AI procurement guidelines, AI impact assessments and AI audit frameworks. Federal funding bodies have a responsibility to ensure investment is channeled towards trustworthy and safe AI systems. Funding bodies need consider procedures they can employ. For instance, they can include a Trustworthy AI Statement section in the grant application form and an example of the relevant guidance. Wider management requirements of a federal funding body for the ethical review and monitoring of funded projects to ensure adherence to the proposed ethical strategies in the applicant's Trustworthy AI Statement also need development. The anticipated outcome for such proposals would be to create a 'stop and think' section during the project planning and application procedure requiring applicants to implement the methods for the ethically aligned design of AI. Funders send the message "if you want the money, then build trustworthy" This should also apply to funding of non-AI projects.

Jeff Bezos's trip to outer space was financed by all the rest of the US taxpayers who paid their taxes when Jeff Bezos didn't have to. Senator Bernie Sanders tweeted: "Am I supposed to be impressed that a billionaire went to space while he's paid zero in federal income taxes some years and the workers at his company struggle to afford their medical bills, rent, and food for their kids? Nope. It's time to invest in working people here on Earth." Massachusetts Senator Elizabeth Warren tweeted: "Jeff Bezos

forgot to thank all the hardworking Americans who actually paid taxes to keep this country running while he and Amazon paid nothing.” ProPublica revealed that Mr. Bezos paid no federal income taxes in 2007 and 2011 by reporting to the IRS that he lost more money than he earned. He claimed and got a \$4,000 child tax credit meant for families making less than \$100,000. At the time in 2011, Mr. Bezos was worth \$18bn. Who are the officials in charge of our Federal Scientific Integrity Policies and what are their values and ethics? What is the tone at the top? Jeff Bezos’s space flight company Blue Origin lost a multibillion contract to Elon Musk’s SpaceX, but Congress is prepping the ground for Bezos to win a contract anyway, ordering NASA to make not one but two awards. The order would come through the Endless Frontier Act, a bill to beef up resources for science and technology research to hand over \$10 billion to NASA — money that most likely would go to Blue Origin. Could any other pressing needs use \$10 billion?

Can federal initiatives in science operate ethically to see that a range of views is represented, that women, indigenous peoples, people of color, diverse investigators at nonelite universities and lower income individuals have a chance? Certainly, some programs can be devised to help people get educated, including about science and AI, without being saddled with life diminishing debt for their lifetimes. They cannot even get decent jobs with benefits in the gig economy, for instance, lawyers nationwide saddled with student debt review documents on temp gigs for \$26.00 hourly or less that are marked up to hundreds of dollars hourly billed to clients by global law firms. These ads circulate daily on theposselist.com While billionaires are hogging more money than they need, can policymakers recognize the importance of addressing college affordability and jobs with pay and benefits? Google does not compensate its largely contractor tech force fairly. Is that how to get best quality data outcomes? The scientific community can and needs to move this issue. Current ideas include a plan that moves toward debt-free higher education. There are also strong proposals for debt-free college from Sen. Brian Schatz (D-HI) and for tuition-free college, including one from Sen. Bernie Sanders (I-VT), as well as calls for free community college championed by Sen. Tammy Baldwin (D-WI) and Rep. Bobby Scott (D-VA). As policymakers contemplate solving college affordability for future students, they must not forget about the tens of millions of borrowers already holding college debt, who forewent a home during the housing crisis, and forewent so many other aspects of the promise of an education. Multiple presidential campaigns have outlined policy proposals that forgive some student loans or make changes to repayment options. Thirty years after graduation is too long to be paying off these loans, while bankers await the high interest federally guaranteed default pay off upon the debtor’s death.

Epstein was a eugenicist whose interests were tied to a delusional notion of seeding the human race with his own DNA. It is disturbing that he focused his largesse on research on the genetic basis of human behavior. Human genetics is an ethically questionable domain where it behooves us to ensure that the highest standards of scientific rigor are in place. The New York Times concluded that researchers at federally funded institutions gave “credence to some of Mr. Epstein’s half-baked scientific musings.” A corrupt sex trafficker socialized with our top government officials and scientists and set agendas affecting research at major federally funded U.S. institutions. It sounds like a conspiracy theory, except it wasn’t. A memo from MIT president L. Rafael Reif previewed some of the findings of the Epstein relationships with the top scientists of this federally funded institution. They are damning. Harvard president Lawrence Bacow released a letter acknowledging the \$6.5 million Epstein gave to Harvard to start the Program for Evolutionary Dynamics, as well as a fellowship Epstein had at Harvard and \$2.4 million in “other gifts” given before Epstein’s conviction. The university will donate the \$186,000 remaining of those funds to groups that help human trafficking and sexual assault victims.

A partial list of the biggest scientific names in Epstein's orbit, according to the New York Times includes "the theoretical physicist and best-selling author Stephen Hawking; the paleontologist and evolutionary biologist Stephen Jay Gould; Oliver Sacks, the neurologist and best-selling author; George M Church, a molecular engineer who has worked to identify genes that could be altered to create superior humans; and the MIT theoretical physicist Frank Wilczek, a Nobel laureate". The New York Times did a deep dive into Epstein's scientific beliefs, and reporters found that Epstein was fixated on "transhumanism", the belief that the human species can be deliberately advanced through technological breakthroughs, such as genetic engineering and artificial intelligence. At its most benign, transhumanism is a belief that humanity's problems can be improved, upgraded, through such technology as CRISPR and artificial intelligence – at its most malignant, transhumanism lines up uncomfortably well with eugenics. Eugenics is the belief that humanity can be improved by controlled breeding, selecting for preferable traits and eliminating less desirable ones. Epstein said he'd be the one "strengthening the gene pool". Starting in the early 2000s, he told people that he wanted to impregnate as many women as he could to distribute his genes as widely as possible. Several acquaintances told the New York Times that Epstein mentioned using his New Mexico ranch as a base of operations to start this colony.

The RFI asks how to support scientists and researchers of all genders, races, ethnicities, and backgrounds; and advancing the equitable delivery of the Federal Government's programs. Ellen Pao's landmark discrimination case against vaunted Silicon Valley venture capital firm Kleiner Perkins Caulfield & Byers turned one of many glaring spotlights on the mistreatment of women in technology and the lack of women in the rarefied world of venture capital. Outside the university where a lot of big federal money resides, we have the greatly federally funded Silicon Valley bro-culture, the venture capital culture, the Biotech start-up culture, the boy-genius culture — all of which exclude women. Silicon Valley would not be Silicon Valley without DARPA, DoD, and many other federal agency contracts. The Department of Defense (DoD) adopted its Ethical Principles for Artificial Intelligence in February 2020, a first for any military organization. These principles build on the foundational work performed by the Defense Innovation Board and is tied directly to one of the pillars of the DoD AI Strategy: Leading in military ethics and safety. The DoD Joint Artificial Intelligence Center leads implementation of responsible AI across the Defense Department. On May 26, 2021, U.S. Deputy Defense Secretary Kathleen Hicks, in a department wide memo enumerated foundational tenets for responsible AI, reaffirmed the ethical AI principles the department adopted in 2020, and mandated the JAIC director, Lieutenant General Michael S. Groen, start work on activities for developing a responsible AI ecosystem. Hicks said in a June 1, 2021 memo "A trusted ecosystem not only enhances our military capabilities, but also builds confidence with end-users, warfighters, and the American public." Forthcoming DoD AI contracts will likely address ethics in the manner mentioned above.

Jeffrey Epstein was a convicted pedophile and died while facing charges of sex trafficking. Why would our nation's top officials and scientists and academic leaders (who receive federal funding) socialize with him? What are their values and ethics? Would they want to be trafficked sexually? Would they want their children to be trafficked? Most child trafficking victims are girls and often between the ages of 12 to 16. Although, when children under 12 are the victim, boys have been found to outnumber girls in some samples. While trafficking often implies "transporting" across borders, trafficking can very often be a domestic matter with little to no transportation. For example, one study found more than 80% of sex trafficking incidents in the United States involved US citizens. Child sex trafficking is a critical issue affecting more than one million children worldwide, many of whom are left to suffer in silence. Some consider human trafficking as the world's fastest-growing crime. Worldwide, about 20% of trafficking victims are children, with up to 100% in some regions. Sex trafficking is the most common form of human trafficking. Globally, an estimated 4.8 million people are forced into sexual

exploitation. The industry produces \$99 billion in profits a year for traffickers. A child can become a victim of commercial sexual exploitation when they are vulnerable, and some of the risk factors include: substance abuse, poverty, exposure to family violence or criminality, running away or told to leave home, abuse and neglect (including sexual abuse), involvement in delinquency, poor mental health, and involvement in child protective services.

What then can we conclude at this point about why our nation's top leaders and scientists cavorted with sex trafficker Epstein? Former Labor Secretary Acosta lost his job over Epstein. He claims he cut that sweetheart deal for Epstein on the pedophile charges because he was told Epstein was an intelligence asset. Jeffrey Epstein was clearly involved in intelligence work but was it just American intelligence? A "Brownstone operation," is a reference to a theory that intelligence agencies, such as the CIA and FBI, engage in utilizing e.g., underage individuals for prostitution purposes with high profile targets, for the purposes of being able to blackmail those high profile individuals later. Generally, the incidents are recorded via videotape. The U.S. Intelligence Community is no Snow White, it goes with the territory, and there are reports on their involvement in drug trafficking, including in this country, and they tolerate the dirty habits of high-value agents or informants. But countenancing onshoring sex trafficking rings for minors on American soil, for years? Epstein likely shared information with intelligence agencies—many criminals do so to buy themselves insurance—but it's implausible that he was mainly working for the Americans.

Federal officials, including top science officials, cannot expect public trust from funding unethical projects and institutions that engage in unethical and illegal behavior and target our people with sex trafficking and opioid crises.

We need our top science and health officials to regulate ethically. The Purdue Pharma case is dauntingly complex, involving what many experts regard as the nation's worst man-made public health crisis. Members of the Sackler family own Purdue Pharma. That's the company that patented and aggressively marketed Oxycontin, an approach that helped bring about the opioid crisis. Between 1999 and 2017, close to 218,000 people died in this country from overdoses connected to prescription opioids, and that does not include the collateral damage. The devastation on our country is akin to a terrorist attack. In 2015, the federal government launched an initiative directed toward reducing opioid misuse and overdose, in part by promoting more cautious and responsible prescribing of opioid medications. In line with these efforts, in 2016 the Centers for Disease Control and Prevention (CDC) published its CDC Guideline for Prescribing Opioids for Chronic Pain to establish clinical standards for balancing the benefits and risks of chronic opioid treatment. In 2017, President Trump established the President's Commission on Combating Drug Addiction and the Opioid Crisis. The commission outlined several priority areas aimed at improving the prevention and treatment of opioid addiction. Coordinated federal efforts to reduce opioid addiction and overdose are ongoing. We can do more and we can do more like this for other public health crises.

Much of the responsibility for the opioid crisis rests with the pharmaceutical industry's promotion of aggressive opioid prescribing. Indeed, in a first-of-its-kind trial against opioid manufacturers, a state court in Oklahoma last year found that the "exponentially increasing rates of addiction," "overdose deaths," and babies born exposed to opioids were caused by "false, misleading, and dangerous marketing campaigns" for opioid medications. The fact that opioid manufacturers disseminated false claims regarding the risks and benefits of opioids for the past 25 years points to a dereliction of duty by the US Food and Drug Administration (FDA)—the federal agency charged with regulating pharmaceutical companies.

The FDA's regulatory failures with respect to opioids have not gone unnoticed. In 2017, the President's Commission on Combatting Drug Addiction and the Opioid Crisis found that the opioid crisis was caused in part by "inadequate oversight by the Food and Drug Administration," and the National Academy of Sciences (NAS) publicly called on the FDA to overhaul its opioid policies. Last year, a former FDA Commissioner rebuked the agency, saying on 60 Minutes that the FDA was wrong to allow promotion of opioid use for chronic pain. Despite this mounting criticism, FDA policies for approving and labeling opioids remain largely unchanged. The FDA has not undertaken a root cause analysis of its regulatory errors that contributed to this public health catastrophe, let alone instituted any major reforms. To the contrary, the agency has adopted a defensive posture and sought to shift blame. For example, in response to a critical letter from Senator Maggie Hassan of New Hampshire, the FDA's top official at the Center for Drug Evaluation and Research since 1994 offered a blanket defense of the FDA's handling of opioids, claiming that the agency has properly enforced the Food, Drug, and Cosmetic Act. Until these past mistakes are understood and corrected, the United States will remain vulnerable to health crises caused by inadequate regulation of pharmaceutical companies. FDA failures to regulate false marketing claims by opioid manufacturers, failures to require adequate and well-controlled clinical trials for opioids and its poor management of conflicts of interest between FDA staff and industry. Understanding how and why the FDA allowed improper marketing of opioids can help us better address the current crisis and improve regulation of pharmaceutical companies in the future, including for the COVID-19 vaccine.

COVID-19 is the most recent example of the vulnerability of American Indian reservations to pandemic disease. Like countless other health conditions, the COVID-19 pandemic has resulted in inequalities. People of color are experiencing not only higher rates of COVID-19 infections but also worse outcomes from the infection. American Indians and Alaska Natives are experiencing COVID-19 infections at higher rates than other groups across several states including Arizona, New Mexico, and Wisconsin.(see attached statements) The Navajo Nation, in particular, has been adversely impacted by COVID-19. The Tribe has had over 9,300 cases with 472 deaths as of August 9, 2020. By May 2020, the Navajo Nation had displaced New York City as having the highest per capita rates of COVID-19 infections in all the United States. The Navajo Nation's COVID-19 infection rate is higher than that of any US state—even New York. The economic and health situation on reservations exacerbates the challenge of responding to the current pandemic. A central policy challenge is to alleviate the continued burden imposed on American Indian tribes by a uniquely complex federal legal structure. The (CARES) Act provides only temporary measures to increase tribal funding. Reducing long-run vulnerability to pandemic disease requires an affirmation of tribal sovereignty along with institution building that enables the tribes to respond to crises. But for federal Indian law, American Indians and Alaska Natives would not have experienced the pervasive inequalities in COVID-19 response and health outcomes. We must correct the negative impact of federal Indian law on health outcomes generally and in the context of offering a specific discussion on the failures of federal Indian law in the context of the COVID-19 pandemic. Without intervention by the federal government, the sad reality is that the impact of these failures will continue to manifest in other forms, including trauma-related conditions. Put the best government minds to work on these issues, not on agendas from the like of Jeffrey Epstein.

Earning public trust requires more initiatives on these issues mentioned from our top officials. Women in STEM fields are paid less, promoted less, and are given fewer opportunities for prestige work. The widespread recent reporting on sexual harassment in the sciences that only scratches the surface. Almost three-quarters of women who experience sexual harassment do not report it, and neither do bystanders who witness it. This past conduct shows a questionable history that needs to be addressed with positive action, to gain public trust.

OSTP Chief Lander led a toast in honor of scientist Dr. James Watson, who discovered the double helix and is known for racist and misogynistic views, during an event celebrating his 90th birthday at the Cold Spring Harbor Laboratory in 2018. Dr. Watson had served as director of that laboratory before being forced to step down more than a decade ago after suggesting that black people are intellectually inferior to white people. Only after the public backlash intensified against those who offered remarks at the event, did Lander describe toasting to Dr. Watson as the “wrong decision.”

Lander can put policies into action now, that show he is the right person for the OSTP job. For years, government leaders claim to ensure that technology and science become more inclusive. The Epstein scandal is a reminder that despite progress, the fruits of our federally funded universities and access to our government is more accessible to a known male sex predator than to most of us hardworking, decent people. Social activism steps in when the government fails to act. Even in authoritarian China, scientists risked their lives and bore arrests to tell the world about COVID-19 when the government forbade it. The spread of COVID-19 misinformation by governments worldwide was significant.

Technology scholar danah boyd chose to talk about Epstein when she was given an award from the Electronic Frontier Foundation. “I am here today in no small part because I benefited from the generosity of men who tolerated and, in effect, enabled unethical, immoral, and criminal men,” boyd said. “Many of us are aghast to learn that a pedophile had this much influence in tech, science, and academia, but so many more people face the personal and professional harm of exclusion, the emotional burden of never-ending subtle misogyny, the exhaustion from dodging daggers, and the nagging feeling that you’re going crazy as you try to get through each day. Let’s change the norms. Please help me,” boyd said.

Pattie Maes, chair of the Media Lab executive committee, said in an email there could be a silver lining to the horrific Jeffrey Epstein scandal with our nation’s top scientists — a renewed focus on making progress in inclusion and equality. Hopefully, OSTP leadership will move the needle and make real progress on the issues mentioned above for the benefit of us all and generations to come.

Respectfully submitted,
Susan von Struensee, JD, MPH

Bibliography

John Horgan, Jeffrey Epstein and the Decadence of Science, Scientific American, November 18, 2019
<https://blogs.scientificamerican.com/cross-check/jeffrey-epstein-and-the-decadence-of-science/>
The Epstein scandal, which embroiled many prominent scientists, is just one of many signs that a gloomy prophecy is being fulfilled

Jeffrey Mervis, What kind of researcher did sex offender Jeffrey Epstein like to fund? He told Science before he died, Sep. 19, 2019 , 4:15 PM at
<https://www.sciencemag.org/news/2019/09/what-kind-researcher-did-sex-offender-jeffrey-epstein-fund-he-told-science-he-died>

Jeffrey Epstein's Harvard Connections Show How Money Can Distort Research - Scientific American,
<https://www.scientificamerican.com/article/jeffrey-epsteins-harvard-connections-show-how-money-can-distort-research/>

Report Regarding Jeffrey Epstein's Connections to Harvard, 2020,
<https://www.harvard.edu/president/news/2020/report-regarding-jeffrey-epstein-s-connections-to-harvard/>

MIT releases results of fact-finding on engagements with Jeffrey Epstein | MIT News | Massachusetts Institute of Technology, <https://news.mit.edu/2020/mit-releases-results-fact-finding-report-jeffrey-epstein-0110>

Navajo Nation, Comments to the Department of the Treasury, Rule, Coronavirus State and Local Fiscal Recovery Funds, 86 FR 26786 (May 17, 2021) (attached)

Alaska Native Health Board, Comments to the Department of the Treasury, Rule, Coronavirus State and Local Fiscal Recovery Funds, 86 FR 26786 (May 17, 2021) (attached)

Dirty money? - ScienceDirect,
<https://www.sciencedirect.com/science/article/abs/pii/S0262407919317646>

How Rich Donors Like Epstein (and Others) Undermine Science | WIRED
<https://www.wired.com/story/the-problem-with-rich-people-funding-science/>

Epstein's \$800,000 MIT donations prompt resignations and investigation,
<https://www.nature.com/articles/d41586-019-01805-3>

Jeffrey Epstein, the academy and questions about male dominance in science - The Washington Post,
https://www.washingtonpost.com/local/education/jeffrey-epstein-the-academy-and-questions-about-male-dominance-in-science/2019/09/17/0b546dd6-d965-11e9-bfb1-849887369476_story.html

Jeffrey Epstein infiltrated science because it was easy to do it - The Verge,
<https://www.theverge.com/2019/9/19/20870858/jeffrey-epstein-science-philanthropy-donation-prestige-mit>

How an Élite University Research Center Concealed Its Relationship with Jeffrey Epstein | The New Yorker, <https://www.newyorker.com/news/news-desk/how-an-elite-university-research-center-concealed-its-relationship-with-jeffrey-epstein>

James B. Stewart, Matthew Goldstein and Jessica Silver-Greenberg, Jeffrey Epstein Hoped to Seed Human Race With His DNA, July 31, 2019, The New York Times, <https://www.nytimes.com/2019/07/31/business/jeffrey-epstein-eugenics.html>

Luke Darby, Private jets, parties and eugenics: Jeffrey Epstein's bizarre world of scientists, August 2019, The Guardian, <https://www.theguardian.com/us-news/2019/aug/18/private-jets-parties-and-eugenics-jeffrey-epsteins-bizarre-world-of-scientists>

Catherine Offord, More Scientists, Institutions with Links to Jeffrey Epstein, The Scientist, (Aug 27, 2019) <https://www.the-scientist.com/news-opinion/more-scientists--institutions-with-links-to-jeffrey-epstein-66359>

Katha Pollitt, Jeffrey Epstein's Science of Sleaze, Epstein's scientist "friends" should have known better than to associate with a crackpot transhumanist. The Nation, August 12, 2019, <https://www.thenation.com/article/archive/epstein-science-sex-abuse-eugenics/>

Daniel Engber, What it was like to be a scientist in Jeffrey Epstein's circle, Slate, Aug 2, 2019, <https://slate.com/technology/2019/08/jeffrey-epstein-science-eugenics-sexual-abuse-researchers.html>

Yin, Tung, Learning from the Jeffrey Epstein Mess: It's Time to Add a Cause of Action for Damages to the Crime Victims' Rights Act (September 7, 2020). Kansas Law Review, Vol. 69, 2021, Available at SSRN: <https://ssrn.com/abstract=3688597>

Patricia Illingworth, An ethicist explains why philanthropy is no license to do bad stuff, (Dec. 5, 2019) <https://theconversation.com/an-ethicist-explains-why-philanthropy-is-no-license-to-do-bad-stuff-127426>

Poco Kernsmith et al, What the Jeffrey Epstein case reveals about female sex offenders, (Sept. 24, 2019) <https://theconversation.com/what-the-jeffrey-epstein-case-reveals-about-female-sex-offenders-123423>

Lawrence Lessig, Epstein at Harvard: We're Not Finished Yet, The Harvard Crimson, April 14, 2021, <https://www.thecrimson.com/article/2021/4/14/lessig-epstein-at-harvard/>

C. Todd Lopez, DOD Takes Phased Approach to Implementing Recommendations on Sexual Assault, Harassment, July 21, 2021, <https://www.defense.gov/Explore/News/Article/Article/2702095/dod-takes-phased-approach-to-implementing-recommendations-on-sexual-assault-har/source/GovDelivery/>

MEMORANDUM TO: MEMBERS OF THE SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION, Apr 23, 2021, <https://www.politico.com/f/?id=00000179-1b42-d22a-affb-fb6b2ed30000>

Gustaf Kilander, Bezos is ‘laughing at every person who paid taxes’: Progressive politicians blast Amazon owner’s spaceflight, *The Independent*, July 21, 2021
<https://www.independent.co.uk/news/world/americas/us-politics/sanders-warren-aoc-bezos-spaceflight-b1887982.html>

Startups experiencing allegations of sexism, sexual harassment, and/or intimidation. Two such startups are Tinder (co-founder sued Tinder for sexual harassment) and GitHub. Sapna Maheshwari, Tinder Settles Fast with Co-Founder in Sexual Harassment Suit, *BUZZFEED NEWS* (Sept. 8, 2014, 4:44 PM), <https://www.buzzfeed.com/sapna/tinder-settles-fast-with-co-founder-in-sexual-harassment-sui> [<https://perma.cc/DLF7-3KSQ>]; Alex Wilhelm & Alexia Tsotsis, Julie Ann Horvath Describes Sexism and Intimidation Behind Her GitHub Exit, *TECHCRUNCH* (Mar. 15, 2014), <https://techcrunch.com/2014/03/15/julie-ann-horvath-describes-sexism-and-intimidation-behind-her-github-exit/> [<https://perma.cc/W82P-8JTR>].

David Streitfeld, Lawsuit Shakes Foundation of a Man’s World of Tech, *N.Y. TIMES* (June 2, 2012), <http://www.nytimes.com/2012/06/03/technology/lawsuit-against-kleiner-perkins-is-shaking-silicon-valley.html> [<https://perma.cc/WV8L-26R2>].

Judgment on Special Verdict, *Pao v. Kleiner Perkins Caufield & Byers LLC*, No. CGC-12-520719, 2015 WL 1726539, at *4 (Cal. App. Dep’t Super. Ct. Apr. 3, 2015).

Larissa Christensen et al, Jeffrey Epstein’s arrest is the tip of the iceberg: human trafficking is the world’s fastest growing crime, *The Conversation*, July 12, 2019, <https://theconversation.com/jeffrey-epsteins-arrest-is-the-tip-of-the-iceberg-human-trafficking-is-the-worlds-fastest-growing-crime-120225>

Alex Thompson, Theodoric Meyer, and Marianne Levine, Biden’s Top Scientist Met Jeffrey Epstein Twice. It’s Now Complicating His Confirmation, *POLITICO* (Apr. 22, 2021), <https://www.politico.com/news/2021/04/22/bidentop-scientist-met-jeffrey-epstein-confirmation-484159>.

Martin Novak Institute, 2012 Meeting at Harvard hosted by Jeffrey Epstein, available at <https://www.documentcloud.org/documents/6346698-2012-Meeting-Martin-Nowak-s-Office.html>.

Fan, Jennifer S., *Innovating Inclusion: The Impact of Women on Private Company Boards* (April 10, 2019). *Florida State University Law Review*, Vol. 46, No. 2, Pp. 345-413, 2019, Forthcoming, Available at SSRN: <https://ssrn.com/abstract=3369841>

Peter Aldhous, Jeffrey Epstein’s Links To Scientists Are Even More Extensive Than We Thought, *BuzzFeed* (Aug. 27, 2019) <https://www.buzzfeednews.com/article/peteraldhous/jeffrey-epstein-science-donations-apologies-statements>

Blake Montgomery, MIT bigwig Richard Stallman dismissed Epstein’s unhttps://www.thedailybeast.com/famed-mit-computer-scientist-richard-stallman-defends-epstein-victims-were-entirely-willingderage victims in emails and defended child pornography on his blog. *Daily Beast*, (Sept. 13, 2019)

Gustaf Kilander, Bezos is ‘laughing at every person who paid taxes’: Progressive politicians blast Amazon owner’s spaceflight, The Independent, July 21, 2021
<https://www.independent.co.uk/news/world/americas/us-politics/sanders-warren-aoc-bezos-spaceflight-b1887982.html>

Ben Geman, Andrew Freedman, Biden administration reinstalls climate official Trump had removed, AXIOS, (May 19, 2021) <https://www.axios.com/biden-climate-change-office-director-trump-b3327db8-4849-4d88-9ec0-0660af5f7870.html>

Tweedy, Ann E., The Validity of Tribal Checkpoints in South Dakota to Curb the Spread of COVID-19 (June 9, 2020). University of Chicago Legal Forum, Forthcoming, Available at SSRN: <https://ssrn.com/abstract=3622836> or <http://dx.doi.org/10.2139/ssrn.3622836>

Deeks, Ashley, Secrecy Surrogates (August 26, 2020). 106 Virginia Law Review, Forthcoming, Virginia Public Law and Legal Theory Research Paper No. 2020-62, Available at SSRN: <https://ssrn.com/abstract=3681450>

Sara Sirota, Ryan Grim, SENATE PREPARING \$10 BILLION BAILOUT FUND FOR JEFF BEZOS SPACE FIRM, (May 25 2021) The Intercept, <https://theintercept.com/2021/05/25/jeff-bezos-blue-origin-senate-bailout/>

John R. Schindler, It Sure Looks Like Jeffrey Epstein Was a Spy—But Whose? The Observer, 07/10/19 5:29pm, <https://observer.com/2019/07/jeffrey-epstein-spy-intelligence-work/>

William Blum, The CIA, Contras, Gangs, and Crack, Institute for Policy Studies, (Nov. 1, 1996) https://ips-dc.org/the_cia_contras_gangs_and_crack/#:~:text=While%20much%20of%20the%20CIA-contradrug%20story%20had%20been,a%20city%20now%20known%20as%20the%20%E2%80%98crack%20

Epstein Victims' Compensation Program, <https://www.epsteinvcp.com/>

Andrew Kolodny, MD, How FDA Failures Contributed to the Opioid Crisis, AMA Journal of Ethics (August 2020) <https://journalofethics.ama-assn.org/article/how-fda-failures-contributed-opioid-crisis/2020-08>

Mongoose: Operation Brownstone — Is CIA Using Children for Pedophilia Blackmail Across the USA? Public Intelligence Blog (July 21,2018) <https://phibetaiota.net/2018/07/mongoose-operation-brownstone-is-cia-using-children-for-pedophilia-blackmail-across-the-usa/>

COVID-19 misinformation by governments, https://en.wikipedia.org/wiki/COVID-19_misinformation_by_governments

Bill Bostock, China Declared Whistleblower Doctor Li Wenliang a ‘Martyr’ Following a Local Campaign to Silence Him for Speaking Out About the Coronavirus, BUS. INSIDER (Apr. 3, 2020), <https://www.businessinsider.com/coronavirus-china-li-wenliang-whistleblower-doctor-martyr-2020-4> [<https://perma.cc/6849-G4VP>]

Sarah Repucci and Amy Slipowitz, Democracy under Lockdown - The Impact of COVID-19 on Global Freedom, Freedom House, (Oct. 2, 2020)

<https://freedomhouse.org/report/special-report/2020/democracy-under-lockdown>

Hoss, Aila, COVID-19 and Tribes: The Structural Violence of Federal Indian Law (August 14, 2020). Arizona State Law Journal Blog, Forthcoming, Available at SSRN: <https://ssrn.com/abstract=3674261> or <http://dx.doi.org/10.2139/ssrn.3674261>

Louise Watt, Taiwan Says It Tried to Warn the World About Coronavirus. Here's What It Really Knew and When, TIME, (May 19, 2020) <https://time.com/5826025/taiwan-who-trump-coronavirus-covid19/>

von Struensee, Susan, Sex Trafficking: A Plea for Action. European Law Journal, Vol. 6, No. 4, December 2000, pp. 379-407, Available at SSRN: <https://ssrn.com/abstract=659124>

von Struensee, Susan, Analyzing Dilemmas Posed by Artificial Intelligence and 4IR Technologies Requires Using All Available Models, Including the Existing International Human Rights Framework and Principles of AI Ethics (June 25, 2021). Available at SSRN: <https://ssrn.com/abstract=3874279> or <http://dx.doi.org/10.2139/ssrn.3874279>

von Struensee, Susan, The Role of Social Movements, Coalitions, and Workers in Resisting Harmful Artificial Intelligence and Contributing to the Development of Responsible AI (June 16, 2021). Available at SSRN: <https://ssrn.com/abstract=3880779> or <http://dx.doi.org/10.2139/ssrn.3880779>

von Struensee, Susan, Mapping Artificial Intelligence Applications Deployed Against COVID-19 Alongside Ethics and Human Rights Considerations, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3889441

The following information is Dyne Immune's perspective on how to improve the effectiveness of Federal scientific integrity policies to enhance public trust in science. Support scientists, researchers and small business innovators of all genders, races, ethnicities, and backgrounds; and advancing the equitable delivery of the Federal Government's programs. Publish gender race statistics semi-annually.

Improve scientific integrity, including in the communication of scientific information, for infectious disease and CBRN threats. Better definition of limit of detection, LOD, matters and directly impacts efforts to identify, control, and contain outbreaks during this pandemic. Various assays report out LoDs in manners that are often difficult to comprehend, for example, TCID₅₀ values that may relate to viral copy numbers in different ways depending on the viral preparation, or units of copies/μL (1 copy/μL = 1,000 copies/mL) or attomolar quantities (1 attomolar = 602 copies/mL). We therefore suggest that viral copies/mL be used as a universal standard metric, so that cross comparison between assays can readily be made. It is clear that viral load matters, and therefore LoD values should be readily evaluable and in the public domain. <https://pubmed.ncbi.nlm.nih.gov/33532847/>

The White House Office of Science and Technology Policy (OSTP) encourage greater innovation in Federal contracting. OSTP has compiled this collection of agency case studies to highlight different models that have been successfully tested by agencies to meet a range of needs related to research, prototyping, and market testing.

The "Incentive prize" tool uses new authorities provided by the America COMPETES Reauthorization Act of 2010

The "rapid technology prototyping" model involves issuance of several contracts for small, inexpensive prototypes to be built within a short period of time and then tested in a relevant demonstration scenario to assess the viability of each prior to making a substantial investment.

The "milestone-based competition" process allows agencies to enter into contractual relationships with a qualified pool of contractors and to issue task orders for a series of clear, technically feasible milestones, each with an assigned deadline and monetary value.

The "challenge-based acquisition" model is designed to explore the market and pay only for a successful solution but is geared towards projects where solutions are likely to already exist as opposed to having to be developed. The key differentiator between challenge-based acquisition and a traditional performance-based acquisition is the firm requirement to demonstrate product performance in real-world conditions prior to a major commitment of resources for full production.

Enhancement of Other Transaction Agreements (OTAs)

OTAs refer to contractual instruments allow agencies and their contracting partners to enter into flexible arrangements tailored to the particular project and needs of the participants. It is pivotal that all OTAs allow for the use of the above tools for innovative technology analysis. The current COVID-19 has exposed many inequities, gaps and vulnerabilities that innovation will overcome. The status quo is unacceptable.

From: [jonesje1](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] The Department of Defense Refusal to Protect Intellectual Property of Small Businesses
Date: Thursday, July 22, 2021 8:00:53 PM

Hello:

The problem with publication of research results and intellectual property is the U.S. Department of Defense. Rules against plagiarism and outright theft of intellectual property appear to no longer have any enforcement. Instead, it appears, based on our experience, to be encouraged by the Department of Defense. We have attended technical meetings, where we made presentations about new and advanced technologies which we have developed, and patented. That information is plagiarized by larger defense contractors, and then used to produce goods and services for the Department of Defense, without license to the patent or our permission to do so. Our experience is that those defense contractors do not contact us, and with complete disregard for intellectual property laws, take the published information and use it to generate profit. This is done with the full knowledge that there are patents protecting the intellectual property. This rampant behavior is a very significant inhibitor with regard to the publication of research and development activities and results.

The Department of Defense appears to be encouraging this type of activity. There are agencies within the Department of Defense, such as the individual state Procurement Technical Assistance offices, which are charged with the responsibility to encourage small business participation in Department of Defense procurement of goods and services. Our experience has been that those offices will not provide any kind of assistance, so it is difficult to identify how the expenditure of their funding is having any effect to support small businesses. Instead of taking any action, our experience was that the only interaction was a referral to a private legal firm, the fees of which were far too expensive for any small business to afford. State governments are providing partial funding for these offices, to help small businesses in their state. Clearly, that is not what those funds are being used for.

In the case of our interaction with the Colorado PTAC, our own corporate attorney found a law which provides that the small business will be reimbursed by the government should a product be delivered to the Department of Defense using our patented technology, without our permission. Also, then, the offending government contractor has to pay a small business triple that amount. A great, and very important law, that the PTAC did not even know existed -- or, at least chose to not tell us about it.

The only alternative we can envision regarding publication of research results, is to not ever publish any of that information. In the past, before this apparent shift by the Department of Defense to no longer protect or assist small businesses, was that any intellectual property, which was protected by patent, could, and should, be published. This has, for decades, been common practice -- and was a great path for stimulating intellectual curiosity and the building of new and advanced technologies on the results of previously published technical information. But, if the safeguards of protecting that prior technology development by patent, is now no longer being respected by the Department of Defense and their contractors, then the only way for technology developers to profit from their inventions is to never publish anything.

The result of that policy, regarding no longer protecting the intellectual property of small businesses by the Department of Defense, will inevitably have a significant dampening effect on the future of technology development. It will also probably result in the United States falling behind the rest of the world in the development of advanced technology. In addition, the publication of and the resulting free exchange of ideas and information, upon which society has for decades depended for rapidly increasing technology information growth, will stop.

The long standing tradition of sharing of new technological advances, through publication of research results, will end, if organizations like the U.S. Department of Defense, continue this behavior of ignoring protections of intellectual property, or making the cost of those protections too expensive for small businesses.

Jerald E. Jones, Ph.D. President
EnergynTech, Inc.

From: [Han Naung Tun](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Friday, July 23, 2021 10:20:39 AM

Hello ,

Here is my comment for “Not to politicize science”

Science is the search to bring truths and evidences for mankind . Originality and autonomy are its lifeblood. Science only becomes science by a bona fide treatment of evidences , facts, and intellectual property on scientific ways .

The politicization of science still make negatively affect academic and scientific freedom, and as a result it is considered taboo to mix politics with **science is a red alert sign to harm the mankind .**

Thanks ,
Dr Han Naung Tun
MBBS, MD
Physician-scientist and Cardiologist
Member of American Physician-Scientists Association

From: [Ashwani K. Gupta](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] "SI-FTAC RFI"
Date: Friday, July 23, 2021 1:05:17 PM

With reference to your seeking comments from individuals and/or organizations, given below are my initial comments, based on my understanding of how they are handled and work on the existing policies to prevent political interference and promote trust at different levels/units. Best regards

ACTIONS and CHANGES for NO.1

State government agencies are mostly directly funded by Federal Government Programs. Work is conducted through administrative, scientific and technical personnel. Administrative personnel acquire the titles of managers more rapidly than they can gain scientific expertise. The administrative personnel or managers distribute projects based on preferences. Direct communication by scientific and technical state personnel on many areas undergoing development and implementation is restricted or inordinately controlled.

In this process, voluntary development of information for future potential improvements can be completely forbidden. This can likely create an artificial barrier for emerging technologies as administrative personnel have long become distant from the scientific and technical development process. Closely involving scientific leaders is critical in contrast to having only the administrators handle it.

The administrative personnel or managers are appointed by those in executive branch without any independence whatsoever. Independence and collaboration on scientific and technical reviews by those in the merit system must be monitored and required. Involve the scientific community in the process for credibility.

2. Analyze instances where communication policies have not been followed.

ACTIONS and CHANGES for NO.2

Communication should also involve workgroups of scientific and technical personnel from the

State and local government merit system independent of administrative and managerial personnel subject to the executive branch.

Approval for voluntary scientific and technical activities of personnel has to come from within the merit system.

These requirements need to be part of the commitment for Federal grants and need to be monitored.

3. Identify effective policies to implement.

ACTIONS and CHANGES for NO.3

Must ensure independence, autonomy, and effectiveness of scientific integrity of state and local officials and that they be monitored and required through the conditions in the existing Federal grants. States and local governments implement programs under Federal funding. This process will help enhance the implementation of the Federal programs. Technologies are changing at a faster pace than ever before, so one must follow them closely in the real world as best as one can.

These are my initial thoughts on your query.. Hopethey will be helpful.

Best regards

--

Ashwani K. Gupta
Distinguished University Professor
University of Maryland
Department of Mechanical Engineering
College Park, MD 20742

From: [Maureen Fairbrother](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Maureen Fairbrother"s public comment for SI-FTAC RFI
Date: Friday, July 23, 2021 6:59:31 PM

The willful, repetitive misrepresentation of scientific data and research by vested interests has dragged scientific facts into doubt among vulnerable members of the public. By all means build up protection of research results and fact-based decision-making but also support and protect science teachers as they give students the critical skills and encourage the reasoning needed to see the deceptive opinions as attempts to mislead and manipulate.
Maureen Fairbrother MD[retired], MSc.

Daniel J. and Julie J. C. H. Ryan

Hon. Dr. Eric S. Lander
Science Advisor and Director
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

Re: SI-FTAC RFI

Dear Dr. Lander:

We are writing you concerning President Biden's request that you seek "information to help improve the effectiveness of Federal scientific integrity policies to enhance public trust in science." We understand that you have decided to convene an interagency task force to prepare a response to the President's request. We are retired academics who also served, at various times, in the public and private sectors. The following comments are directed to, and offered for consideration by, your interagency task force.

We understand science to be our best way of building knowledge of the universe and the processes and natural phenomena within it. We know that, being empirical, science does not result in absolute truth, but seeks temporary theories to explain, predict (or retrodict) outcomes, and, ultimately, to provide a measure of control over natural events and our environment. We believe that, just as the Intelligence Community best informs statecraft when it provides objective, apolitical information, the Scientific Community best serves policymakers when it supplies accurate, valid and reliable information derived using the scientific method absent political influence. Suppressing or distorting evidence in support of political agendas is unacceptable. "Alternative facts," and flawed evidence, methodology and reasoning lead to junk science. The use of junk science leads to bad public policies. The dangers of politically and ideologically driven science are amply illustrated by the history of Trofim Denisovich Lysenko.

Trust is not possible if the integrity of advisors, however credentialed, who are supplying advice and information are biased, ideologically driven, corrupt or subjected to economic, professional or political pressures. It follows that an apolitical vetting process must be used in choosing those scientists who will be relied upon to provide scientific guidance to policy makers. Since politicians and policy-makers are not themselves sufficiently educated, trained and experienced in all the scientific disciplines from which they need information, they will necessarily have to rely on panels of disinterested evaluators having the relevant scientific education, training and experience to vet the

candidates who would supply such advice, analogous to the process by which candidates for judicial positions are vetted by the American Bar Association. The National Academies of Sciences, Engineering and Medicine might provide such vetting. Candidates must not be appointed based on other criteria such as political compatibility with the policymakers they are to advise, or their willingness to shape their advice to preconceived notions among those policymakers. Independence and integrity are essential.

Americans inherently distrust their government. To promote public trust in science, transparency and accountability are essential. The government must, to the maximum extent possible without compromising national security, maintain open, freely available access to the processes used in research and development, acquisition of scientific and technical knowledge, and application of the resulting knowledge to solving society's problems. When problems arise, as they will, the government must ensure prompt, visible consequences when the problems are perceived to be the result of bias, negligence, malfeasance or corrupt behavior.

Unfortunately, our educational system has not produced citizens who are well-grounded in science, civics or critical thinking. It is incumbent, therefore, upon the government to use its extensive powers to inform and educate the public as to the nature and validity of the scientific and technical information upon which it relies, and how that information informs and guides the development of public policies. Every effort must be made to correct the tendencies so prevalent in our society to accept fake news and espouse conspiracy theories. It is important that the information provided by the government be coherent and consistent. Mixed or contradictory messages from the administration lead to confusion and rejection of what should be a favorable consensus among members of the the public regarding public policies promulgated by the government.

This is not to say that legitimate disagreements concerning the scientific bases of policies should or must be suppressed. On the contrary, transparency demands that such disagreements be aired in public and the various positions and their rationales be elucidated. Trust requires that the reasons for ultimate decisions be clearly explained, and that the level of certainty in the correctness of the chosen course be stated in understandable terms. The Intelligence Community has developed admirable processes for presenting its conclusions, along with minority doubts and the relative degrees of certainty in its conclusions. The forensic sciences are developing methodologies for explaining in-court testimony together with the degree of assurance with which the evidence presented should be taken by finders of fact. Similar approaches should be used in informing the public as to the reliability of the science upon which public policy is based.

Nor are we suggesting that consensus is needed or even appropriate *within* the scientific community. The history of science is replete with examples of consensus within the scientific community that turned out to be wrong — the earth was the center of the solar system, continents couldn't drift, electromagnetism requires a medium (aether) in order to propagate, and so forth. It is a fundamental principle of science that

conclusions are always tentative and subject to revision based on new evidence. The consensus we seek is the belief among members of the public that the best available science is being used in the development of public policy. This is fundamental to restoring trust.

Needless to say, leadership is vital. President Biden's Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking (2021 Memorandum) of January 27th provides an admirable start, indicating that leadership will flow from the very top, as it must. Obviously, the role of the Office of Science and Technology Policy will be key. But appropriate leadership must be fostered in every agency and at every level of government. Especially with regard to public policy related to contracting for research and development of science and acquisition of technology, peer review, and publication of results.

Academic integrity must be rigidly enforced, with penalties imposed for research misconduct and academic fraud, including fabrication or manipulation of data, unauthorized collaboration, misstated authorship and attribution, and plagiarism. Conflicts of interest must be avoided or punished. Informed consent must be required when human subjects are involved. Nothing undermines trust so surely as surfacing of integrity problems or failure to punish them if they do arise.

Sufficient funding must be provided by the government. Such funding must provide balanced support for both basic research and for research targeted on developing specific technologies. Experience has shown that funding from sources in the private sector, not-for-profit nongovernmental organizations, and even some government agencies, too often has a specific outcome in mind, so the resulting efforts are biased and suspect. We use double-blind studies in medicine to reduce bias. We suggest that double-blind studies are appropriate in other areas of scientific research and development as well. For example, if disinterested funding sources are insufficient or unavailable, money from multiple sources could be pooled so that researchers don't know the source of their funding. Trust requires blinded, nonpartisan funding mechanisms.

Public interests are not entirely compatible with academic interests, which focus on obtaining tenure, being first to publish, retention of rights to intellectual property, and which deemphasize confirmation of results. Too often, the government's rights to the use of and benefits from research it has sponsored and funded have been lost because protections have not been properly included in contracts. Especially when new and unusual science or technology is concerned, the government should be prepared to let multiple, parallel competing contracts that require peer review and independent verification of results, dictate simultaneous publication of results, and which provide that intellectual property rights are reserved for the public.

The use of simulations and mathematical models are mainstays of modern research and development. Their use can certainly clarify differences among policy options. But they must be used with caution. As representations of reality, simulations and models

are limited abstractions. The real world is complex, and no model can fully capture that complexity. As Alfred Korzybski reminds us, “The map is not the territory.” Data sets may be incomplete, and uncertainty of data input values may compound the difficulties of constructing and validating the model. Choices among elements and relationships, initial parametric values and boundary conditions are necessary. In keeping with a double-blind approach, those choices must be independently reviewed, ideally by a Verification & Validation contractor. When the simulations and models are run, those choices must be varied in order to observe the effects of mistaken, poorly chosen, superfluous or missing elements or relationships. The advantages and limitations of simulations and models are well-understood, but careful contract drafting requiring rigorous adherence to best practices is essential.

Most of our regulatory schemes today are partially or wholly dependent on scientific and technological advice for their effective development and implementation. Special care must be taken in developing and promulgating regulatory schemes based on such advice, since trust is easily destroyed by the arrival of unintended consequences. Scientific advisors must anticipate possible negative outcomes if their advice is used in developing regulations and include suggested mitigations with their advice. Regulators, for their part, must seek and use those mitigations.

Science is international in scope. Current challenges — global warming, pollution, public health, etc. — make it abundantly clear that isolationist policies are not tenable. Soft power depends upon how the United States is perceived. Trust must be restored among our international allies as well as here at home. We must be fully engaged with other nations and an active participant in international partnerships at both the scientific and policy levels. The United States should actively seek visits from and offer visas and green cards to talented STEM researchers in order to encourage innovation and to staff our laboratories. And we should welcome international entrepreneurs with STEM backgrounds who wish to start businesses in the United States, or to join our high tech companies, and to live and work here.

Closely related to the issue of international relationships and partnerships are the issues of foreign students who wish to study STEM disciplines in our universities. Those students enrich and energize our educational institutions. Living, studying and working with people from other cultures improves the educational experience of our own students. And we should actively seek to retain talented students who obtain advanced degrees in STEM subjects, not send them home.

It will be difficult to regain the trust of the American people after many years of apathy within the scientific community, confusing and often contradictory statements from the government, polarization along partisan lines, and inherent anti-intellectual and anti-science strains in our society. This requires that the government be open, transparent and accountable in its use of science in policy making. The focus must be on establishing processes that are and are seen to be fair and rational. The vast resources of government for informing and educating the public must be directed at showing the

public that the government is relying on the best available objective science after thoroughly weighing alternative ideas.

It is not, of course, possible to cover in a few pages every issue and detail entailed by the mandate from the President, nor to provide the examples and extensive citations needed to fully develop these ideas. We hope these abbreviated comments are useful.

Thank you for your attention. If we can be of further assistance, please contact us.

Respectfully,

Daniel J. Ryan
Professor (Ret.)

Julie J. C. H. Ryan
Professor (Ret.)

Daniel J. Ryan is a lawyer, a businessman and an academic. He served as a Senior Executive in the Department of Defense and the CIA, as a corporate executive in private industry, and as a Professor in academia. He holds Masters degrees in mathematics and business administration, and the degree of *Juris Doctor*.

Julie J. C. H. Ryan graduated from the United States Air Force Academy and received a Masters degree from Eastern Michigan University and her Doctorate from George Washington University. She served as an Air Force officer, as a civilian member of the Intelligence Community, as an executive in private industry, and as a Professor in academia. She has served on and chaired Boards and led workshops for the National Academies of Sciences Engineering and Medicine.

The opinions expressed herein are solely those of the authors, and do not represent the opinions or policies of any other person, entity or organization.



Response of The MITRE Corporation to the OSTP RFI to Improve Federal Scientific Integrity Policies

July 26, 2021

For additional information about this response, please
contact: Duane Blackburn
Center for Data-Driven Policy
The MITRE Corporation

Introduction

The MITRE Corporation is a not-for-profit company that works in the public interest to tackle difficult problems that challenge the safety, stability, security, and well-being of our nation through the operation of multiple federally funded research and development centers and labs, and participation in public-private partnerships. Working across federal, state, and local governments, as well as industry and academia, gives MITRE a unique vantage point. MITRE works in the public interest to discover new possibilities, create unexpected opportunities, and lead by pioneering together for public good to bring innovative ideas into existence in areas such as artificial intelligence, intuitive data science, quantum information science, health informatics, policy and economic expertise, trustworthy autonomy, cyber threat sharing, and cyber resilience.

MITRE is constantly advancing, assessing, leveraging, and communicating to a variety of audiences about a wide range of science & technology (S&T) capabilities and issues impacting numerous Federal agencies. Ensuring the integrity of these activities is foundational to our existence, and these experiences serve as the primary basis for this response.

MITRE also initiated a 2020 research effort¹ through its Great Power Competition strategic initiative, in collaboration with the National Science and Technology Council's Joint Council on the Research Environment, that focused on risks posed to the nation's S&T enterprise due to foreign collaboration and influence. Recommendations on this front inherently interact with those for ensuring integrity of S&T practices, so MITRE recommends taking an integrated planning approach that meets both objectives.

Q1: The effectiveness of Federal scientific integrity policies in promoting trust in Federal science

One aspect of accurately measuring the public's trust in Federal science is the availability of quantitative data, which has been hampered by current measurement limitations. For example, several studies measure the construct using single questions along the lines of "How much do you trust the things that scientists say about the environment?" A research project² by MITRE, working in collaboration with external partners, sought to develop a more advanced tool that could also be useful for baseline assessments, ongoing monitoring of trust in science, and as a "post-test" tool for assessing the impact of interventions (or, for that matter, societal and natural events).

More generally, the work underscored both the need and the feasibility of understanding different facets and drivers of trust in science, along with how this relates to other aspects of the information environment (e.g., conspiracy theories, social identities, cognitive styles, and personality). Future efforts to enhance and leverage these types of tools would enhance the government's assessment capabilities, leading to more effective practices.

¹ Improper Influence in Federally Funded Fundamental Research. 2021. MITRE, <https://www.mitre.org/sites/default/files/publications/pr-20-3351-improper-influence-in-federally-funded-fundamental-research.pdf>.

² Hartman, R., Dieckmann, N., Sprenger, A., Stastny, B. and DeMarree, K. Modeling Attitudes Toward Science: Development and Validation of the Credibility of Science Scale. 2017. Basic and Applied Social Psychology, <https://www.tandfonline.com/doi/abs/10.1080/01973533.2017.1372284?journalCode=hbas20>.

Q2: Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information

After a formal, in-depth review in 2018, MITRE provided recommendations to clarify ambiguities, address deficiencies, and streamline an agency's scientific integrity policy and guidance.³ These recommendations can serve as a starting point for government-wide policies.

A predominant recommendation within this effort was for the agency to develop and implement a policy for the production of fundamental research communications (FRCs). The new policy would identify applicable agency scientific integrity policy, definitions, principles, scientific activities, code of conduct, and code of ethics, and conform with direction in the parent Department's policy on public communications. The intent was for the new policy to strengthen and clarify the criteria for distinguishing an "agency-initiate" FRC from an FRC that presents an individual staff member's "personal viewpoint or opinions." The new policy must also strengthen and clarify the standard notation for identifying and distinguishing the use of "research" versus "operational" data in FRCs, and the implications of using research or operational data in specific products. Similar requirements throughout the Federal S&T enterprise, combined with toolkits to properly guide agencies in the development of these policies and practices, would help agencies ensure accurate representation of new S&T knowledge and how agencies are using that knowledge within their programs.

MITRE also recommended the agency develop and widely disseminate a Peer Review Handbook for fundamental research communications (FRCs). The handbook should comply with the Office of Management and Budget's Information Quality Bulletin for Peer Review. It should (1) explain how to apply the criteria for "influential" categories (Influential Scientific Information [ISI] and Highly Influential Scientific Information [HISI]), which require more stringent peer-review; (2) outline roles and responsibilities for all steps in the peer review processes for ISI, HISA, and other FRCs; (3) provide a detailed description of the agency's peer review processes (including the more stringent ISI and HISI reviews); and (4) require peer review plans for ISI and HISI communications be publicly-available in advance of the peer review process.

MITRE has also recommended the agency develop and implement procedures for mission-specific data management, including authoritative definitions of "research" and "operational" data and its associated software code and documentation. This recommendation also included developing or updating policy on research and development transitions. The update should (1) simplify concepts and processes for transitioning research and development output to operations, application, and commercialization; (2) clarify the definition of mission-specific data records and specify the types of data that are included (or not included) in this definition; and (3) define maturity levels for this type of data, with the goal of defining two levels of maturity: research and operational. Finally, this recommendation includes producing a procedural document that consolidates, integrates, simplifies, and describes official processes for the end-to-end data-management life cycle. The new procedural documents should explain, in detail:

³ Baggeroer, A., et al. Assessment of National Oceanic and Atmospheric Administration Scientific Integrity Policies and Procedures. 2018. MITRE, <https://www.mitre.org/sites/default/files/publications/MITRE-DoC-NOAA-Assessment-Report.pdf>.

- When and how data records are transitioned from research to operations, with the goal of consolidating initial operational capability and full operational capability into a single operational stage
- When and how operational data is archived in the agency's data centers
- When and how operational data and its associated software code and documentation are monitored, maintained, and updated
- When and how both research and operational data are made publicly accessible, with clear indications of their nature as either research or operational and the associated implications

Q3: Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce

The Federal scientific workforce spans numerous agencies and occupations that have overarching needs, as well as unique occupational requirements. A strategy that addresses the scientific workforce includes planning future needs and filling essential talent gaps, advancing recruitment and selection processes that efficiently results in the hiring of qualified individuals, identifying training and development plans in technical and core competencies, examining compensation structures, and supporting employees through cultural foundations.

To support professional development of Federal scientists and to support scientists of all genders, races, ethnicities, and backgrounds and advance the equitable delivery of the Federal Government's programs, MITRE recommends conducting a formal workforce assessment with an interagency pilot of up to 12 scientific occupations across the Federal workforce, with an emphasis in two areas: 1) developmental needs assessment; and 2) diversity, equity, inclusion, and accessibility (DEI&A).

To address the first area of developmental needs of the scientific workforce, the assessment will identify skill gaps that build the foundations for advancement. A high-level road map to address these gaps should be developed, including both specific strategies to grow the workforce in a manner that not only creates equal opportunities for all segments of American society, but also mitigates factors that discourage entry into and retention in scientific occupations by historically disadvantaged groups. Starting with a complete assessment of a small number of scientific occupations in the Federal workforce will create immediate opportunities in making both evidence-based decisions in investments in development of the scientific workforce and also in creating a more equitable environment that better recruits and retains diverse talent in a cost-effective manner. The assessment should provide a holistic view of these occupations with predicted gaps in both workforce size and competency.

Addressing DEI&A will also expand the supply of individuals that make up the scientific workforce. MITRE specifically recommends adding fields around disabilities (e.g., autism, physical disabilities) to the list of considerations for measuring and creating equity. MITRE's experience with developing and sustaining a diverse scientific workforce includes many studies that predict future demand will surpass future supply of scientific talent and also that—although some scientific fields, such as biotechnology, tend to be made up equally of men and women—

others, such as quantum, are 70% or more men. Moreover, scientific occupations in the Federal Government, like the private sector, tend to be dominated by White Americans, with Black, Indigenous, and People of Color unrepresented, and those qualified to perform a job but with disabilities dramatically underrepresented.

MITRE's previous work across the Federal Government with scientific occupations, and also with topics relevant to DEI&A in the scientific community, have shown that addressing these challenges from a holistic approach can help to prevent the many redundant programs from stovepipes in the Federal Government.³ For example, many Federal agencies focus on the same small subset of Historically Black Colleges and Universities (HBCUs) despite their being 100 HBCUs in the United States. Furthermore, MITRE's work with individuals on the autism spectrum has shown that these individuals are often more capable in STEM professions, solving problems many times faster than neurotypical individuals, but traditional hiring practices disadvantage them in the hiring process and typical development activities do not meet their developmental needs in the workplace⁴. These efforts will increase the supply of qualified scientific professionals.

Key policies and practices for developing a scientific workforce have been identified through MITRE work examining facets of the Federal workforce. These policies would address lessons as described in the below tenants.

- ***Use a holistic approach to understand the needs of the scientific community in the Federal Government:*** For example, use of designations in STEM fields to identify application of work across occupations (e.g., as is done in cyber) would allow for better workforce planning, creation of communities of practice, more efficient training needs analysis, and a greater sense of belonging in the Federal Government, especially for scientists at agencies with few individuals in their specialties.
- ***Expand the pool of applicants for scientific positions:*** Recruit with intention using evidence-based practices, including tracking the return-on-investment of recruiting initiatives. This should include interventions such as efforts to target neurodiversity, recruitment from HBCUs beyond the D.C. metro area, developing and supporting a skilled technical workforce, removing educational requirements no longer relevant as industries mature (e.g., when a PhD is no longer necessary and lower-level degrees or work experience are sufficient to fully demonstrate proficiency, or graduates with non-traditional but related STEM degrees).
- ***Attract and retain talent*** through the recruitment and selection processes that efficiently result in the hiring of qualified individuals. This will include key practices relevant to the scientific Federal workforce such as:
 - ***Branding around meaningful work.*** The Federal Government can compensate for the pay differential with the private sector by advertising the unique, complex scientific challenges solved by the Federal Government; the importance of civil service to the safety and security of the nation; the work-life balance offered by Federal positions; student loan repayment programs; and the affordability of many

⁴ For more information on the GEAR Center Neurodiverse Federal Workforce pilot program see <https://www.performance.gov/blog/mitre-neurodiversity-pilot/> and <https://nfw.mitre.org/>.

Federal job locations outside of Washington, D.C. Attracting employees based on engagement with the mission will also improve retention.

- ***Influencing policies to increase stay-rates of foreign-born scientists:*** Stay-rates have been dropping in critical scientific areas, especially among doctoral recipients. Our research identified both a need to address improper foreign influence while also retaining the “best and brightest,” including foreign-born scientists. Policies should work to address both.
- ***Streamlining efforts:*** The Federal Government’s workforce efforts in STEM are both stove-piped and redundant across Federal agencies, resulting in both gaps in coverage and duplicative efforts. As such, the Federal agencies compete with each other for the same talent while other talent pools are neglected. A holistic inventory of recruiting efforts would enable more efficient recruiting by increasing the size of the talent pool and the likely acceptance rate.
- ***Modernize the compensation system where necessary:*** Pay for the person, not just the position. Conduct a compensation study to determine whether a new, government-wide Alternative Pay Systems for scientific careers deemed hard-to-fill or hard-to-keep, would assist with recruiting and retention. FDA Cures is an exemplar.
- ***Explore reskilling and upskilling opportunities:*** Address key workforce gaps through upskilling and targeted approaches (e.g., fellowships). MITRE recommends using a combination of public-private partnerships such as Intergovernmental Personnel Act (IPA) assignments, as well as building upon lessons learned from existing Federal reskilling programs, such as the Federal Cyber Reskilling Academy and best practices from the private sector.⁵ Although many reskilling programs are unsuccessful,⁶ selecting candidates with both aptitude and interest in the new field, then supporting them from job placement through full proficiency in the role can help to increase both performance and retention in the new role.

Q4: Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices

Improving scientific integrity and transparency requires identifying and addressing integrity-related competencies across levels and roles in an agency. Moreover, training on scientific integrity should be targeted to different audiences and needs to address key competency needs. Such targeting is not only more cost effective, but also provides staff with skills they can apply on the job in their roles, which increases the efficacy of the training in changing behaviors. For example, we worked with a federal agency to enhance a data upskilling program to improve the data science capacity and capabilities of their workforce. The agency’s goal was to build a data science-fluent workforce that addresses the evolving need for data science and analytics

⁵ Weber, L. Why Companies Are Failing at Reskilling. 2019. Wall Street Journal, <https://www.wsj.com/articles/the-answer-to-your-companys-hiring-problem-might-be-right-under-your-nose-11555689542>. Accessed July 16, 2021.

⁶ Ibid.

capabilities. MITRE supported this work by identifying critical data science competencies (e.g., research methods, statistics, ethics), conducted a gap analysis to identify data science gaps in its workforce, and developed a strategy for closing key gaps through formal training, experiential activities, capstone projects, mentoring, and on-demand learning. While the program was mostly targeted towards upskilling scientific staff, during the gap analysis MITRE also found the need for the program to upskill leaders and non-scientific staff to have some proficiency in data science competencies (beyond those in scientific positions). This work included research of leading practices in data science upskilling. This methodology would be effective in addressing the integrity needs of the scientific community.

Q5: Other important aspects of scientific integrity and effective approaches to improving trust in Federal science

Enhancing the public's trust in Federal science requires two thrusts: (1) ensuring the integrity of the science itself (including how it is communicated to other scientists and used in operations) and (2) ensuring the science is being explained properly to *nonscientific audiences*.⁷ The majority of the government's prior scientific integrity endeavors, and indeed this RFI, predominantly focuses on the first thrust. That is an understandable first step as it is foundational to the effort. But going forward, MITRE recommends significantly enhancing efforts on the second front as well, as this is the part that the public actually sees and drives their individual analyses. While the Federal Government cannot dictate how this is done, it can serve as an example for others to follow. Discussion of three common concerns and actions the Federal Government can take to help overcome each is provided in the following paragraphs.

S&T knowledge is often conveyed in diametric terms; *this is what the science says, you should believe it* (or not). In reality, science is neither true nor false but instead has graduated levels of consensus.⁸ “The very nature of scientific discovery is a series of hits and misses, then arguing about those hits and misses until the learned community coalesces around a solidly proven idea. Sometimes, though not very often, that proven consensus ends up being disproven decades later!” Scientists (and science agencies) that convey more certainty in their findings than is warranted are contributing to the public's distrust of science when those findings are later shown to be false or are only accurate in specific conditions. Going forward, the government should not only state the new finding but also convey where that finding stands within science's evolutionary process.

Discussing the role of science within policymaking also, unfortunately, suffers from similar diametric messaging: either the policymaker “trusted the science” in their decisions (if the author agreed with the decision) or they were “anti-science” (if they did not). In most every situation of *actual policymaking*, which differs significantly from lobbying or advocating for preferred policy outcomes, there are many considerations beyond just the science. Consider our recent history with COVID-19 as an example. The recommendation from a pure science aspect would have been to completely shut everything down and isolate everyone until the threat passed. But doing

⁷ Blackburn, D. When and How Should We “Trust the Science?” 2021. MITRE, https://www.mitre.org/sites/default/files/publications/pr-21-1187-when-and-how-should-we-trust-the-science_0.pdf.

⁸ Ibid, p.3.

so would have created extremely negative consequences for the nation's financial and security considerations, not to mention increasing other types of health issues. Policymakers had to find the right balance amongst all of these considerations, adjusting over time as conditions changed. The same analysis and balancing occur in all actual policy decisions, which is not normally reflected in government communications—and certainly not within the reactions of those advocating from a single perspective. Proper scientific analysis should play a large role in these debates but overplaying its hand by promoting its infallibility or dominance is wrong—in fact, it is downright unscientific. The Federal Government needs to better explain all influences within these policy decisions, and how they determined the role and proper influence science should properly have held at the time of the decision.

Finally, S&T has become weaponized within partisan politics, by politicians from both political parties as well as by outcome-focused advocacy organizations. Each occurrence, no matter if their statement is positive or negative towards S&T, generally leaves half of the population that hears it reactively distrustful of the message being conveyed. It is easy to conjecture how this is having a negative impact on the public's trust of S&T and its use by Federal agencies. S&T is inherently apolitical, and it is in the nation's interest for it to be treated as such by everyone. While Federal S&T agencies cannot directly influence these partisan efforts, they can take actions to minimize their impact by proactively providing descriptive information about its findings that is understandable to the nonscientific community. For example, in addition to publishing a formal technical report or journal article, agencies could also produce a flyer tailored to general audiences that explains the findings, the certainty of those findings, and the meaning or potential impact of the findings. The availability of this non-partisan, readily understandable material will help interested citizens accurately understand the S&T without it being provided through the lens of influencer operations.

From: [Sandy S](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Monday, July 26, 2021 2:30:37 PM

Thank you for the opportunity to comment. My comment is directed at item 3 "Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce."

I strongly urge the Federal government to include as part of scientific integrity supporting all scientists and researchers regardless of gender, race, ethnicity, disability status, and background, and to make STEM a truly open space where people of all backgrounds are invited and encouraged to participate. Diversity of backgrounds brings diversity of ideas, and with all the problems facing us today -- the climate crisis, pandemics, species extinction just to name a few -- we need all the creative minds we can tap. We also need to make sure that government scientists are not muzzled, regardless of which political party is in power. I urge you to make it clear that harassment of any kind is not to be tolerated.

Thank you for the opportunity to comment.

Sincerely,
Sandra Scholar
Rockwood, Maine

Alondra Nelson
Deputy Director
Office of Science and Technology Policy
The White House

Jane Lubchenco
Deputy Director
Office of Science and Technology Policy
The White House

July 26, 2021

Dr. Nelson and Dr. Lubchenco:

Our organizations represent thousands of journalists whose work includes seeking honest and timely answers from government agencies on matters that are important to the members of the public these agencies represent. We are hoping to meet with the White House Scientific Integrity Task Force to discuss crucial ways to protect against federal interference in this work.

Our job is intentionally hindered by the U.S. government in many ways, including barring government scientists, issue specialists and other government employees from communicating directly with reporters and even refusing to allow interviews of such scientists or specialists, even with oversight by a public information officer. These barriers to obtaining accurate and authoritative information [are now widespread](#), prompting dozens of groups to call for change in [letters](#) to Congress and past presidential administrations.

A comprehensive [analysis](#) by First Amendment attorney Frank LoMonte found that existing controls are unconstitutional and that many courts agree.ⁱ And no less than seven surveys from 2012 to 2016 have shown controls have become common at federal, state and local levels, in health, education, environment and science, and — perhaps most chillingly — in police departments where information has become increasingly important to ensure all members of the public are treated equitably.

We would like to see the task force recommend that agencies:

- eliminate restrictions on employees speaking to reporters without notification of authorities, especially before but also after the contact;
- credential journalists to enter, without escort, any area of federal facilities where most employees are allowed to enter;
- and make it standard policy that when reporters voluntarily contact public information offices, they are allowed to speak to the people they request.

These changes would eliminate restrictions and policies that have become pervasive in federal agencies but that are relatively new. For much of President Joe Biden’s Washington career they were either nonexistent or not nearly as stringent. Sadly, they have now become the norm.

In just one shameful example, with pandemic deaths mounting in 2020, [emails show](#) that Centers for Disease Control and Prevention officials told press office staff that one disfavored news outlet should probably not be granted interviews and that, “Just because there are outstanding [press] requests or folks keep getting asked to do a particular interview does not mean it has to be fulfilled.”

This is a nuanced situation. We are advocates for the free flow of information but also realists. We emphasize to the task force that journalists understand that sometimes some information must remain confidential and that public information officers can be and often are helpful to journalists.

However, scientific integrity is threatened when rules pressure people not to speak without controls or notification of people in power. Agencies that control the public scrutiny of themselves can develop critical weaknesses and be subjected to political interference.

For more information or to schedule a meeting, please contact Jennifer Royer, SPJ communications director

Again, we welcome the opportunity to discuss and improve this troubling situation.

American Society of Journalists and Authors
Associated Collegiate Press/National Scholastic Press Association
Center for Scholastic Journalism at Kent State
Colorado Press Women
Colorado State University
Defending Rights & Dissent
International Society of Weekly Newspaper Editors
iSolon.org
Media Freedom Foundation and Project Censored
National Association of Black Journalists
National Association of Hispanic Journalists
National Federation of Press Women
National Newspaper Association
National Press Photographers Association
National Writers Union
Native American Journalists Association
News Leaders Association
North American Agricultural Journalists
Open the Government

Radio Television Digital News Association
SABEW – The Association of Business Journalists
Society of Environmental Journalists
Society of Professional Journalists
Student Press Law Center
The Tully Center for Free Speech

Cc:

Dr. Francesca Grifo
Scientific Integrity Official
Environmental Protection Agency

Dr. Anne Ricciuti
Deputy Director for Science
Institute of Education Sciences
U.S. Department of Education

Dr. Craig Robinson
Director
Office of Science Quality and Integrity
U.S. Geological Survey,
Department of the Interior

Mr. Jerry Sheehan
Deputy Director
National Library of Medicine
National Institutes of Health

ⁱ LoMonte's longer discussion is in a [Kansas Law Review](#).

From:
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Monday, July 26, 2021 4:49:08 PM

Trust and accountability are integral to the scientific research establishment, and every day our government uses science to shape decisions that affect every American. Sharing of scientific information, fact-based information, transformed into meaningful information, drives policy-making for Americans. Science and the scientific processes should inform and guide public policy decisions on a wide range of issues, from infrastructure to public health, protection of our natural resources to our environment, as well as the protection of the American People to national security. The public must be able to trust the science and scientific process informing public policy decisions. Science, the scientific process, and the communication of science should be free from politics, ideology, and financial conflicts of interest.

Policies and procedures that ensure the integrity of the conduct and communication of publicly funded science are critical to ensuring public trust, and federal agencies that fund, conduct, or oversee research should promote and maximize the communication and open exchange of data and findings to other agencies, policymakers, and the public of research conducted by individual employed or contracted by the Federal Government.

Federal agencies that fund, conduct, or oversee research should work to prevent the suppression or distortion of the scientific data and findings.

First, a definition is necessary to help ensure a shared understanding. That is, *science* is the pursuit and application of knowledge and understanding of the natural, physical, or social world following a systematic methodology based on facts and evidence that includes objective observation, measurement and data, induction or reasoning to establish general rules or conclusions drawn from facts. It is repetitive and is peer-reviewed in such a manner that a consensus is realized and confirmed.

Scientific integrity shall be demonstrated by those engaged in research or development, and these individuals shall not engage in dishonesty, fraud, deceit, misrepresentation, coercive manipulation, or other scientific or research misconduct. Individuals shall not work to suppress, alter, interfere with, or otherwise impede the timely release and communication of fact-based findings. Individuals will not attempt to intimidate or coerce an individual in an effort to alter, censor, or retaliate against an individual for failure to alter or censor, scientific or technical findings, or implement institutional barriers to cooperation and the timely communication of scientific or technical findings.

A covered agency may require a covered individual to, before disseminating scientific or technical findings, submit the findings to the covered agency so that the agency may conduct a review of the data and findings for technical accuracy and compliance. If a covered agency does not complete the review of data and findings submitted by a covered individual within 30 days of the submission, the submission shall be deemed approved by the covered agency; and the covered individual may proceed with plans to disseminate the scientific or technical findings.

A covered individual may sit on scientific advisory or governing boards; join or hold leadership positions on scientific councils, societies, unions, and other professional organizations; contribute to the academic peer-review process as reviewers or editors; and participate and engage with the scientific community.

Whenever a covered agency seeks to make a public statement about the conclusions of basic or applied research in science or engineering conducted by a covered individual, the covered individual shall have the opportunity to review the public statement for technical accuracy; and if an inaccuracy is discovered as a result of the review, the covered agency and the covered individual shall jointly revise the public statement.

A covered individual may respond to media interview requests regarding their scientific or technical findings from research conducted by the individual without prior approval from the covered agency supporting the research of the covered individual, but the covered agency may require the covered individual to report the subject of any such interview.

In the event a covered agency supporting the research of a covered individual receives a media interview request regarding that research, the covered agency shall, offer the covered individual the choice of responding to the interview directly; or provide a knowledgeable spokesperson who can, in an objective, nonpartisan, and articulate manner, describe and explain the scientific and technical findings.

A covered individual may present viewpoints in an interview and that extend the viewpoint beyond the scientific or technical findings, as an expert or personal opinion only. Any covered individual presenting viewpoints shall disclose any apparent, potential, or actual financial conflicts of interest or non-financial conflicts of interest.

The head of each covered agency shall develop, adopt, and enforce a scientific integrity policy; and submit the scientific integrity policy to the Director of the Office of Science and Technology Policy and Congress.

A scientific integrity policy shall be consistent with the principles established and specifically address what is and what is not permitted or recommended under that policy: the term *agency* has the meaning given the term in [section 551 of title 5](#), United States Code.

Covered agency: the term *covered agency* means an agency that funds, conducts, or oversees scientific research.

Covered individual: the term *covered individual* means a federal employee or contractor who is engaged in, supervises, or manages scientific activities; analyzes or publicly communicates information resulting from scientific activities; or uses scientific information or analysis in making bureau, office, or agency policy, management, or regulatory decisions.

Public statement: the term *public statement* means any communication that is intended for, or should reasonably be expected to have, broad distribution outside the Federal Government, including public speeches, news releases and advisories, news conferences, broadcast appearances, and interviews or discussions with journalists; public writings, such as articles or papers in publications or other writings distributed through mass-mailing, e-mail, or posting on a website or social media platform; materials and presentations for public educational instruction, lectures, conferences, seminars, and similar venues; and public distribution of audiovisual works, such as slide sets or presentations, podcasts, online video, and exhibits.

Covered agency: the term covered agency has the meaning given the term in section 1009 of the America COMPETES Act ([42 U.S.C. 6620](#)), including procedures; be applied uniformly throughout the covered agency; and be publicly accessible and widely communicated to all employees, private contractors, and grantees of the covered agency.

Scientific conclusions shall not be made based on political considerations; the selection and retention of candidates for science and technology positions in the covered agency are based

primarily on the candidate's expertise, scientific credentials, experience, and integrity; no covered individual shall suppress, alter, interfere, or otherwise impede the timely release and communication of scientific or technical findings; personnel actions regarding covered individuals, except for political appointees, are not made based on political consideration or ideology; covered individuals cannot intimidate or coerce others to alter or censor scientific findings; covered individuals adhere to the highest ethical and professional standards in conducting their research and disseminating their findings; the appropriate rules, procedures, and safeguards are in place to ensure the integrity of the scientific process within the covered agency; scientific or technological information considered in policy decisions is subject to well-established scientific processes, including peer review where appropriate; procedures, including any applicable whistleblower protections, are in place as are necessary to ensure the integrity of scientific and technological information and processes on which the covered agency relies in its decision making or otherwise uses; and include enforcement processes consistent for an administrative hearing and an administrative appeal.

Each scientific integrity policy adopted shall apply to all individuals.

Each covered agency shall appoint a Scientific Integrity Officer, who shall be a career employee at the covered agency in a science and professional positions; have substantial technical knowledge and expertise in conducting and overseeing scientific research; and direct the activities and duties of individuals.

Each covered agency shall adopt and implement an administrative process and administrative appeal for dispute resolution consistent with the covered agency's scientific integrity policy; provide a training program on scientific integrity and ethics training to employees and contractors of the covered agency; provide new covered employees with training within one month of commencing employment; provide information to ensure that covered individuals are fully aware of their rights and responsibilities regarding the conduct of scientific research, publication of scientific research, communication with the media and the public regarding scientific research; and provide information to ensure that covered individuals are fully aware of their rights and responsibilities for administrative hearings and appeals established in the covered agency's scientific integrity policy. Each Scientific Integrity Officer appointed by a covered agency shall post an annual report on the public website of the covered agency and shall include the number of misconduct cases filed for administrative redress for the year covered by the report; the number of misconduct cases petitioned for administrative appeal for the year covered by the report; and the number of cases still pending from years prior to the year covered by the report, if any.

Each scientific integrity policy, process, and report produced by a covered agency under this section shall be submitted to the Committee on Commerce, Science, and Transportation of the Senate; the Committee on Science, Space, and Technology of the House of Representatives; the Office of Science and Technology Policy; and be made available to the public on the website of the covered agency.

The Office of Science and Technology Policy shall collate, organize, and publicly share all information it receives in one place on its own website. In addition, the Director of the Office of Science and Technology Policy shall, on an annual basis, convene the Scientific Integrity Officer of each covered agency to discuss best practices for implementing the requirements of this section.

From: [Andrew Hartley](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Comment for SI-FTAC RFI - from Andrew Hartley, PhD
Date: Monday, July 26, 2021 7:44:45 PM

Hello, I hereby submit the following comment in response to the “Request for Information To Improve Federal Scientific Integrity Policies” dated 28 June 2021.

I believe that the public’s trust in scientific integrity is not as high as it could be, partly because the public doesn’t always interpret statistical results properly.

In particular, many among the public don’t understand how standard statistical methods measure and report the uncertainties (probabilities) associated with those results.

Some recent discussion in the scientific literature attempts to elucidate and ameliorate this problem, such as the American Statistical Association’s 2016 statement on p-values:

<https://www.amstat.org/asa/files/pdfs/p-valuestatement.pdf>.

That statement has been viewed more than 150,000 times,

<https://www.amstat.org/asa/News/ASA-P-Value-Statement-Viewed-150000-Times.aspx>

and has spurred other papers, and debates in scientific conferences,

<https://rss.onlinelibrary.wiley.com/doi/10.1111/1740-9713.01505>.

Common misinterpretations of statistical results include concluding that, once experimental data are analyzed,

- a. the probability of obtaining the same results in another similar experiment (predictive reliability) is the p-value,
- b. the probability of the tested hypothesis (inference following testing) is the p-value, and
- c. the probability that a quantity of interest (population parameter) lies within its corresponding 95% confidence interval (inference following estimation) is 95%.

Questions of reliability, and of inference following testing and estimation are, indeed, of great interest among the public; therefore, unless scientific reports address those questions, one should not be surprised to see some of the public misinterpreting these statistical results as addressing them.

Some Bayesian statistical results, on the other hand, do address those questions and, thus, are less likely to be misinterpreted. Bayesian prediction can measure the probability of results similar to observed results. Bayesian inference can identify probabilities of hypotheses and probabilities that parameters are in given ranges. Consequently, I suggest publishing these, and related, Bayesian results, where possible, in public-facing reports.

Andrew Hartley, PhD (Statistics), member of the public

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From: [Jeff Angers](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Monday, July 26, 2021 10:23:25 PM
Attachments: [image001.png](#)

White House OSTP Leadership

TWIMC,

Our particular area of concern is NOAA Fisheries and the inherent conflicts of interest in its Science and Statistical Committees of the Regional Fishery Management Councils.

I offer two comments to this RFI to Improve Scientific Integrity Policies received July 21, 2021 requesting comments by July 28, 2021:

1. OSTP does not take scientific integrity seriously and cannot possibly expect a one-week turnaround to address conflicts of interest among scientists affecting policy and the industries involved in America's Blue Economy.
2. We have reviewed existing rules and regulations on conflicts at NOAA Fisheries, and we note they are infrequently applied, which leaves them almost ineffective. See Comment 1. NOAA does not take seriously conflicts of interest.

Sincerely,

Jeff Angers

Jeff Angers
President
Center for Sportfishing Policy

As scholars, educators, and administrators in the field of research integrity and responsible conduct of research (RCR), we appreciate this Request for Information from OSTP. The current national interest in scientific integrity presents an opportunity to describe how the federal government could bolster the country's commitment to science and science education. Based on decades of experience related to teaching and performing research in RCR along with administering RCR education programs in accordance with institutional and federal policies, we offer the recommendations listed below. Some context for the recommendations follows afterward; additional rationale and justification for the recommendations can be provided upon request.

Recommendations

We propose that the U.S. Government:

1. Provide greater clarity within federal policies regarding the specific definitions of scientific integrity, research misconduct, research integrity, and responsible conduct of research (RCR), and how these concepts are intended to be related to one another.
2. Promote greater harmonization across federal agencies in terms of their requirements for RCR education.
3. Expand requirements for RCR education across *all agencies* that sponsor research.
4. Provide sufficient funding to federal agencies and grant awardees to develop and implement effective programs in RCR education.
5. Mandate that every organization receiving a federal award to conduct research must dedicate a percentage of the award to support RCR education and related activities. The amount should be significant enough to support an ongoing, comprehensive, and robust RCR education program at the organization, while taking into account the size of the organization and its research portfolio.
6. Craft a policy statement articulating the importance of adhering to best practices in RCR education. These best practices include:
 - Providing educational activities that are interactive (using active learning techniques) and synchronous; while asynchronous online learning can be useful, it is not sufficient by itself
 - Providing RCR research ethics education and training for faculty and research staff as well as students and other trainees
 - Involving research faculty, supervisors, and staff in RCR education activities for trainees
 - Ensuring that RCR education is ongoing (and not just a one-time event); as much as possible it should also be integrated into the settings where research takes place
 - Evaluating the effects of RCR education activities on research practices

- Encouraging institutional administrators to promote a culture of ethics and research integrity

Terminology and Policy

The above recommendations are motivated by two main categories of concerns. The first pertains to terminology in federal regulations and policies. When the phrase “scientific integrity” emerged within federal policy in the 1980s, the term usually related to honesty in research, also referred to as research integrity, responsible science, or responsible conduct of research. Internationally, direct translations of “scientific integrity” are used in many other languages to capture this range of English terms.

Over time, the meaning of scientific integrity at the federal level has shifted in scope; it now might include notions of research integrity but is not limited to research-related activities only. According to the White House’s January 27, 2021 Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking, scientific integrity typically pertains to efforts to “*...ban improper political interference in the conduct of scientific research and in the collection of scientific or technological data, and that prevent the suppression or distortion of scientific or technological findings, data, information, conclusions, or technical results.*”

Clarification of the definitions and scope of scientific integrity and research integrity is needed in part because numerous policy implications stem from their relationship, and how similar or different these concepts are intended to be. Adding complexity to the relationship between scientific integrity and research integrity is whether the federal government intends “undue foreign influence” to be understood as a potential violation of scientific integrity and/or research integrity.

Uncertainty and the lack of definitional clarity can generate inconsistencies in the application and enforcement of policy, including at academic institutions. For example, it is unclear, from a federal perspective, whether research misconduct is also considered to be a scientific integrity violation. Within its Federal Research Misconduct Policy in 2000, OSTP set forth a definition of research misconduct but parameters for identifying and handling a scientific integrity violation have not yet been established. Complicating this situation is that current policies and procedures for investigating a research misconduct allegation vary across federal agencies. Will federal agencies have different approaches to addressing scientific integrity violations as well?

Along related lines, debate persists among scientific communities and others as to whether terms such as “research integrity” (used by the federal Office of Research Integrity within the Department of Health and Human Services), “responsible conduct of research” (typically used by the National Institutes of Health), and “responsible and ethical conduct of research (RECR)” (used by the National Science Foundation) are intended to mean the same thing and if not, what the distinctions are.

Our goal is not to propose specific terminology or its proper use. Rather, it is to emphasize that clarity and consistency of terminology are essential starting points for effective policies and guidance. Definitions matter and should be stated as clearly as possible in policy and procedural documents.

Harmonizing and Bolstering Research Ethics Education

The second main concern pertains to what federal agencies require in terms of research ethics education and training at the organizations that they fund. For our purposes here, the terms research integrity, RCR/RECR, and research ethics will be used interchangeably.

Much could be said about how evidence-based, robust research ethics education is crucially tied to the country's standing as a leader in science, engineering, and technology. We will summarize some main points here. Research ethics education fosters the development of future professionals' knowledge and skills. Although it may not be discussed consistently enough in STEM education, ethics is embedded in the decisions that each person makes as a professional both at the micro scale (for example, is it safe to allow a student to use this chemical in an experiment?) as well as at the macro scale (for example, will the public benefit from this research?). Decisions about which research questions to investigate, how to collect data, when to share them, and with whom are intertwined with ethical values, including considerations of potential benefits and harms.

The National Science Board's Vision 2030 report articulates four main goals to guide the US's approach to science and engineering:

- Foster a global science and engineering community
- Expand the geography of innovation
- Develop STEM talent for America
- Deliver benefits from research

Ethical values are interwoven inextricably in selecting, addressing, and achieving all four of these goals. The country's efforts to stay at the forefront of science and engineering are connected to how seriously the federal government, the scientific community, and other stakeholders embrace ethics and ethics education (with scientific integrity and research ethics specifically being important parts of that equation).

However, improvements in the current state of research ethics education are needed, and the federal government could play a vital leadership role here. At present, the National Science Foundation (NSF), National Institutes of Health (NIH), and the US Department of Agriculture (USDA) through its National Institute of Food and Agriculture (NIFA) Program have policies requiring some categories of extramural researchers to have at least some form of RCR training. Among the complexities with the RCR policies from NIH, NSF, and USDA NIFA is that they contain different requirements. Since RCR requirements are not the same across different federal funding sources, expectations in terms of training vary widely.

Variations include the content of the RCR education and training, who needs to be trained, how much training they need, and how often training should occur. This variability can generate inconsistencies within and across academic institutions in terms of what trainees are taught and learn. Furthermore, the federal policies lack consensus on an RCR training requirement for faculty, which arguably is crucial if faculty are going to be effective mentors for the next generations of scientists and engineers. Moreover, at least some institutions interpret current federal RCR policies as permitting them to outsource some, if not all, of their educational responsibilities rather than dedicating meaningful resources to the effort. Overall, these issues send the problematic message that ethics is separate from research, and that ethical knowledge and standards of practice are not highly valued within the STEM community.

In sum, we strongly encourage the OSTP to take this opportunity to help preserve a robust US research enterprise by harmonizing and strengthening definitions, policies, and resources for scientific integrity, research integrity, and related concepts.

Signed [listed in alphabetical order]*

Stephanie J. Bird

Jason Borenstein

Samuel V. Bruton

Jiin-Yu Chen

Karin Ellison

William L. Gannon

Kenneth W. Goodman

Elizabeth Heitman

Michael Kalichman

Sergio Litewka

Kathryn Partin

Trisha Phillips

Dena Plemmons

Debra Schaller-Demers

* All signatories are members of the Association for Practical and Professional Ethics Research Integrity Scholars and Educators (APPE RISE) ConsortiumSM. The views expressed here are our own and do not necessarily represent the views of our institutions or APPE.



July 27, 2021

Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, DC 20504

Submitted electronically to ScientificIntegrityRFI@ostp.eop.gov

Re: Request for Information to Improve Federal Scientific Integrity Policies (86 FR 34064)

The American Association for the Advancement of Science (AAAS), Association of American Medical Colleges (AAMC), Association of American Universities (AAU), Association of Public and Land-grant Universities (APLU), and Council on Governmental Relations (COGR), collectively the “Associations,” appreciate the opportunity to provide feedback to the White House Office of Science and Technology Policy (OSTP) to help improve the effectiveness of Federal scientific integrity policies in enhancing public trust in science.

The Associations strongly support the efforts of the White House in addressing issues of federal scientific integrity and public trust in science. We further appreciate the swift issuance of the Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking and establishment of the Scientific Integrity Task Force. These actions seek to formalize and standardize scientific integrity through an all-of-government approach. Protecting the integrity of science and ensuring the use of evidence in policymaking should be a national priority across administrations.

These efforts come at a critical time for the United States. Public trust in federal science has been shaken by anti-science rhetoric, lack of transparency, and questions about the integrity of science conducted and supported by the federal government. At the same time, building and maintaining trust in this science has never been more important as we confront continuing threats, including a global pandemic and climate change. The importance of addressing these challenges is further fueled by vaccine hesitancy, and the threat of natural disasters, and growing mistrust in whether recommended responses are supported by credible scientific evidence.

We are pleased to address the following areas to inform the work of OSTP in confronting and addressing these issues.

1. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science

The existence of scientific integrity policies alone may not measurably increase public trust in science but can establish the foundation and set in place the guardrails for protecting scientific inquiry from improper interference or misuse. It is the demonstrable impact of such policies that will restore trust in science and research, not the words the policies contain.

Within the research community, such policies will be deemed to be effective when research funding, scientific conduct, data collection, and dissemination of research results are explicitly tied to established mechanisms for determining scientific merit, such as peer review of grants and publications. In one key recent counterexample, proposed rulemaking¹ from the Environmental Protection Agency sought to limit the science the agency could consider in critical rulemaking activities to those studies for which all underlying data were publicly available for analysis, which the scientific community strongly opposed. While purporting to increase transparency in science, many saw this rule as an attempt to tie the hands of the agency, ensuring that key research studies on the impacts of air or water pollution on human health would be excluded when the agency made policy decisions about limiting particulate matter in the air or protecting waterways from toxic waste.

In a [joint letter to the EPA](#) in July 2018 in response to the proposed rule, AAMC, AAU, APLU, and COGR wrote:

The proposed rule does not advance the type of sound, evidence-based policymaking that is essential for every agency, and particularly important for the EPA, whose activities and regulations have a profound impact on air, land, and water quality, and thus the health of all Americans. This proposal thwarts the promise of evidence-based policymaking, squarely contradicting the requirement that the EPA use the ‘best available science’ to make its regulatory decisions. Basing decision-making on only those studies with publicly available data would drastically curtail the use of key information and studies in the policymaking process and ignore the entire body of scientific evidence built up over years of inquiry.

While the finalized rule is no longer in effect, vacated by a U.S. District Court ruling February 1, 2021, and not proposed anew by the agency, that assault on science in the name of transparency has had far-reaching impacts on the research community and demonstrated how vulnerable science may be made through political interference. That is exactly why the proposed policies are needed.

Strengthening policies on scientific integrity is a good start, but ensuring that these policies are adhered to, and evaluating outcomes from their implementation, should be a key part of the process to improve scientific integrity. The evaluation metrics should be included in the policies themselves

¹ EPA-HQ-OA-2018-0259-0025, Strengthening Transparency in Regulatory Science

so that OSTP, the agencies, and the broader public will know when scientific integrity policies are achieving their intended outcomes.

2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information

The COVID-19 pandemic has highlighted challenges in fact-based communication to the public on emerging scientific issues and ensuring that scientific research and analysis and the evidence-base that underlies policies and decisions, is reflected accurately in any subsequent dissemination of this information. Engaging scientists as part of the communication process and having them publicly available to discuss their work, particularly new or complex findings, can go a long way toward building trust. In addition, many scientific and higher-education institutions conduct [science communication courses and workshops](#) that the federal government should utilize in training government employees in effective communication of complex topics.

It is also important to communicate to the public the processes built into the process to ensure oversight, review, and ethical standards which guard against political interference in the way science is funded or conducted. Understanding how information is most readily consumed and understood is essential for effective communication to the public. A notice in the Federal Register has no chance of effectively opposing scientific misinformation spread through social media. Communicating scientific information through multiple channels including social media accounts, engagement of community and state groups, proactive engagement with journalists, and updating easily found and navigated websites can broaden the message. The vaccine information sites www.vaccines.gov and www.vacunass.gov are good examples of sites that are working to get clear information to the public in multiple languages and are being communicated through social media and physicians' offices.

We also note that the link between federal funding of basic research and the resulting knowledge, products or technologies that improve human health, strengthen energy security, expand our understanding of climate change, and protect national security interests are too rarely understood or discussed. Federal agencies, with the support of OSTP, should work to ensure that when the outcomes of federal funding and research are discussed, the role of the government in that research is made clear and reiterated. At a more fundamental level, policies that promote public understanding of the scientific process, including the fact that science is not static and therefore conclusions may change based on analysis of new data and scientific information, are essential to increasing public trust in scientific efforts. Such policies should target not only scientific education at the K-12 level but engage the broader public as well.

Additionally, existing open access policies affecting federal funding agencies, such as the NIH and NSF, may warrant further review to ensure that they meet their intended objectives of providing equitable and fulsome access to publish and disseminate research output while promoting the reproducibility and integrity of scientific research and protecting national security. At the same time, consideration should also be given to balancing the administrative burdens and costs of compliance carried by researchers and institutions.

3. Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce

The scientific research enterprise is expanding to include new fields of research and inquiry and growing participation of communities and ordinary citizens who may not have traditionally been engaged in science. Any existing scientific integrity policies should be applied equitably and consistently to these situations. The federal government has a key role in growing and broadening the diversity of the scientific workforce, and programs to support scientists should be built with a lens of equity and inclusion.

The concept of scientific integrity is broad and, in some cases, has been solely equated with research integrity or research misconduct. Research misconduct is appropriately defined in federal regulations as fabrication, falsification, or plagiarism in federally funded research. We urge OSTP to clarify in its guidance to agencies that while research misconduct is a threat to the integrity of the scientific record, protecting the integrity of science extends far beyond this precise but focused definition. There are many other issues that could affect the integrity of research, from the environment in which researchers work to willful interference in the scientific process, to violations of rules related to conflicts of interest or the protection of human subjects that should be addressed through mechanisms that could broadly be captured with the term “scientific integrity” but should not be newly defined as a facet of “research misconduct.”

4. Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices

Ongoing and effective training of federal employees, contractors, and grantees is an essential component of implementing standards and guidelines for scientific integrity. We note that academic institutions have developed robust research integrity programs, including training and responsible conduct of research, that could be better leveraged and incorporated into federal policies and training. In this respect, the promotion of consistency in agency policies and processes that address scientific integrity would make the provision of such training easier. Finally, when there are issues regarding scientific integrity or policy violations, the federal government should be as transparent as possible about the process, findings, and any subsequent action taken.

5. Other important aspects of scientific integrity and effective approaches to improving trust in Federal science

The overall goal of scientific integrity efforts directed at the Federal agencies should be to create a research environment that promotes and protects a rigorous scientific research enterprise and the incorporation of this evidence-base into the policymaking process. Applying policies consistently and streamlining implementation across federal departments and agencies is a key part of achieving this goal, as is making sure that policies are clear in their scope and desired effect. This effort should

also identify and build on the substantial efforts that some agencies have already undertaken to communicate the value, integrity, and impact of federal science.

It takes an enormous amount of effort to build and sustain public trust in science, and federal policies and actions are an essential component of this endeavor. Trust in science impacts not only the federal government itself, but the entire scientific enterprise and every federal grantee.

We stress that building trust requires the engagement of the communities whose trust you hope to gain. For a discussion of why trust needs to be built with, rather than at, communities, please see the newly released [Principles for Trustworthiness](#) from the AAMC Center for Health Justice. This commitment to stakeholder engagement was also articulated in APLU's [Public Impact Research: Engaged Universities Making the Difference](#), which outlines five action steps for the public university community and stakeholders to advance research that has a societal impact.

We appreciate the opportunity to put together comments in response to this RFI and to participate in the associated listening sessions. Broad engagement, as well as partnering with the appropriate community organizations so that information about these opportunities is disseminated to a diversity of audiences, is essential for a complete understanding of these issues.

Our associations, both directly and through our broad constituent base that spans the scientific research community, are committed to working with OSTP on these priorities and improving federal scientific integrity policies to facilitate public trust in science. We look forward to further engaging on the issues in discussed in this letter.

American Association for the Advancement of Science (AAAS)

Contact: Joanne Carney,

Association of American Medical Colleges (AAMC)

Contact: Anurupa Dev,

Association of American Universities (AAU)

Contact: Contact: Tobin Smith,

Association of Public and Land-grant Universities (APLU)

Contact: Deborah Altenburg,

Council on Governmental Relations (COGR)

Contact: Kristin West,

The American Association for the Advancement of Science (AAAS) is the world's largest multidisciplinary scientific society and the publisher of the Science family of journals. Its mission is to advance science, engineering, and innovation throughout the world for the benefit of all people or – put more simply – to advance science and serve society. The Association of American Medical Colleges (AAMC) is dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members comprise all 155 accredited U.S. and 17 accredited Canadian medical schools; more than 400 major teaching hospitals and health systems; and more than 70 academic societies. The Association of American Universities

(AAU) is an association of 64 U.S. and two Canadian preeminent research universities organized to develop and implement effective national and institutional policies supporting research and scholarship, graduate and undergraduate education, and public service in research universities. The Association of Public and Land-grant Universities (APLU) is a research, policy, and advocacy organization with a membership of over 200 public research universities, land-grant institutions, state university systems, and affiliated organizations in the U.S., Canada, and Mexico, that is dedicated to strengthening and advancing the work of public universities. The Council on Governmental Relations (COGR) is an association of 190 research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions.

From: [Rizwan Siddiqi](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] RE: "SI-FTAC RFI" - Comments
Date: Tuesday, July 27, 2021 10:24:33 AM
Attachments:

Good Morning,

I serve as a Commissioner on Maryland Transportation Commission (MTC) and would like to offer my comments based on my understanding of how they are handled and work on the existing policies to prevent political interference and promote trust at different levels/units:

1. Consider if existing policies prevent political interference and promote trust;

ACTIONS and CHANGES for NO.1

State government agencies are mostly directly funded by Federal Government Programs. Work is conducted through administrative, scientific and technical personnel. Administrative personnel acquire the titles of managers more rapidly than they can gain scientific expertise. The administrative personnel or managers distribute projects based on preferences. Direct communication by scientific and technical state personnel on many areas undergoing development and implementation is restricted or inordinately controlled.

In this process, voluntary development of information for future potential improvements can be completely forbidden. This can likely create an artificial barrier for emerging technologies as administrative personnel have long become distant from the scientific and technical development process. Closely involving scientific leaders is critical in contrast to having only the administrators handle it.

The administrative personnel or managers are appointed by those in executive branch without any independence whatsoever. Independence and collaboration on scientific and technical reviews by those in the merit system must be monitored and required. Involve the scientific community in the process for credibility.

2. Analyze instances where communication policies have not been followed.

ACTIONS and CHANGES for NO.2

Communication should also involve workgroups of scientific and technical personnel from the State and local government merit system independent of administrative and managerial

personnel subject to the executive branch.

Approval for voluntary scientific and technical activities of personnel has to come from within the merit system.

These requirements need to be part of the commitment for Federal grants and need to be monitored.

3. Identify effective policies to implement.

ACTIONS and CHANGES for NO.3

Must ensure independence, autonomy, and effectiveness of scientific integrity of state and local officials and that they be monitored and required through the conditions in the existing Federal grants. States and local governments implement programs under Federal funding. This process will help enhance the implementation of the Federal programs. Technologies are changing at a faster pace than ever before, so one must follow them closely in the real world as best as one can.

Please let me know for any questions and I can be reached on my cell number provided below.

Regards,

Rizwan A. Siddiqi, PE* | President & CEO
EBA Engineering, Inc.

* licensed in DC and MD

- Commissioner, Maryland Transportation Commission ([MTC](#))
- Past President, American Council of Engineering Companies of Metro Washington ([ACEC/MW](#))
- Advisory Board Member, Department of Civil Engineering, University of the District of Columbia ([UDC](#))
- Inaugural Member, DC Water's Business Diversity and Inclusion Advisory Council ([DCWater](#))

From: [Chris Lish](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI -- Improve federal scientific integrity and promote public trust in science-based decisions -- Request for Information: Improve Federal Scientific Integrity Policies (Document ID: OSTP-2021-0002-0001)
Date: Tuesday, July 27, 2021 11:25:55 AM

Tuesday, July 27, 2021

Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

Subject: SI-FTAC RFI -- Improve federal scientific integrity and promote public trust in science-based decisions -- Request for Information: Improve Federal Scientific Integrity Policies (Document ID: OSTP-2021-0002-0001)

To White House Office of Science and Technology Policy Director Dr. Eric Lander and Operations Manager Stacy Murphy:

As the Office of Science and Technology Policy works to improve federal scientific integrity and promote public trust in science-based decisions, I strongly encourage the federal government to:

- strengthen communication and publication policies, so that all scientists can openly share their discoveries and we, the public, can be active participants;
- prevent political interference in science and preserve scientific independence, so that scientists can do their work without being unethically influenced by political interests or conflicts of interest;
- train, protect, and empower federal employees, so that all civil servants can do their jobs, report wrongdoings if needed, and remain safe from retaliation;
- prioritize underserved communities, so that environmental laws are enforced thoroughly and equitably and communities can play active roles in research and decisionmaking; and
- invest in a robust, diverse federal scientific workforce, so that our nation's scientists represent, and are invested in, our diverse nation.

Thank you for your consideration of my comments. Please do NOT add my name to your mailing list. I will learn about future developments on this issue from other sources.

Sincerely,
Christopher Lish
San Rafael, CA



MICHAEL D. RICH
PRESIDENT AND
CHIEF EXECUTIVE OFFICER

1776 MAIN STREET
P.O. BOX 2138
SANTA MONICA, CA
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July 27, 2021

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White House Office of Science and Technology Policy

Attn: Ryan Donohue

Executive Office of the President

Eisenhower Executive Office Building

1650 Pennsylvania Avenue

Washington, D.C. 20504

Sent via electronic mail

RE: Request for Information to Improve Federal Scientific Integrity Policies
86 FR 34064 (June 28, 2021)

The RAND Corporation (RAND) respectfully submits these public comments in response to the White House Office of Science and Technology Policy Request for Information to Improve Federal Scientific Integrity Policies (the RFI).

RAND is a nonprofit research organization that develops solutions to public policy challenges to help make nations and communities throughout the world safer and more secure, healthier and more prosperous. RAND was established over 70 years ago to strengthen public policy through research and analysis. Over seven decades, our research teams have answered the difficult questions and generated actionable insights by combining the very best analytical tools and methods with a distinct, interdisciplinary approach. The federal government supports approximately 85% of RAND's research through either contracts or grants.

The RFI requests public comment on the following topic:

"The effectiveness of Federal scientific integrity policies in promoting trust in Federal science: Information about the strengths and weaknesses of Federal scientific integrity policies, including where additional efforts are needed to meet the broad ambition to establish trust in Federal science by protecting against: Political or other improper interference in the conduct of scientific research, the collection of scientific or technological data, and the utilization of science in decision-making; suppression or distortion of scientific or technological findings, data, information, conclusions, or technical results; disproportionate harm to Federal scientists and researchers from groups that are historically underrepresented in science, technology, and related fields; or equitable delivery of the Federal Government's programs."

Federal scientific integrity policies are established pursuant to the Presidential Memorandum of March 9, 2009 (Scientific Integrity) and the Director of the Office of Science and Technology Policy's Memorandum of December 17, 2010 (Scientific Integrity), which together specify the mandatory elements of each federal agency's scientific integrity policies. While an analysis of every agency policy is beyond the scope of this public comment, the commonality imposed by the 2009 and 2010 memos allow for a set of broad recommendations:

- **Publication of research**. RAND believes strongly that publication and dissemination of research are essential to scientific integrity. Publication helps ensure the quality of research by allowing for public and expert scrutiny. Moreover, a commitment to publish *all* research,

regardless of outcome, gives the public confidence that a federal agency is not selectively releasing research results.

While the 2009 and 2010 memos note the importance of transparency in federal research, they do not impose any specific requirements. As a result, to the extent the agency scientific integrity policies mention publication of research at all, they include broad caveats such as "to the extent feasible." Some federal agencies, such as the Department of Education, regularly include restrictive clauses in research contracts that give the agency the power to limit the release and use of taxpayer-funded research results.

OSTP should update the 2010 memo to require that publication of research conducted or commissioned by a federal agency be the rule, not the exception. Permissible exceptions should be specific and narrow, such as an exception for research that has been properly classified for national security reasons. Agencies should be prohibited from using contract terms to otherwise restrict publication rights of research organizations, as well as be prohibited from declining to award subsequent contracts, grants, or task orders to external researchers or the organization with which they are affiliated solely because the researchers or organization pursued publication of their research.

It is critical that the right to publish research extend to methods and data, not merely the analysis and findings. High-quality research depends on reproducibility of results by other researchers; this is not possible unless the underlying data and methodology is made public. In situations where the data and/or methods are sensitive, agencies should be required to adopt least-restrictive alternatives to open publication.

Potential improper classification of research for national security purposes is a unique challenge due to the inherent lack of transparency (the public cannot question the classification of a study they don't know exists) and general deference to federal agencies on national security matters. For these very reasons, classification of research should be limited and subject to specific guidelines and oversight. Agency scientific integrity policies should provide clear standards for classification of scientific research, as well as the opportunity for federal employees or contractors to seek independent review of classification they believe may be inappropriate.

Other critical aspects of publication of research include:

- **Timeliness.** While it is appropriate for an agency to be provided an opportunity to review research performed under contract prior to publication for the purpose of correcting errors or requesting clarifications, an undue delay by an agency undermines public confidence in the research and can be used to reduce its impact. Scientific integrity policies should require that any agency review conclude within a 30 or 60 day time period, after which the contractor will publish the research. Requests by agencies to delay the publication of research longer than the period specified in the policy should be approved by the agency director or designee. Such a requirement would inhibit an agency from informally pressuring a contract research firm to "voluntarily" delay publication of their research.
- **Accessibility.** Agencies should be required to publish links to all federally funded studies, as well as a list of ongoing research. Additionally, federally funded research should be accessible for free, not behind "paywalls."

- Spokespersons. While many agency scientific integrity policies address the importance of knowledgeable spokespersons and of permitting federal employee scientists to speak freely, such policies are not a substitute for the unfettered right to publish scientific research in its entirety.
- **Scope of persons and activities covered by scientific integrity policy.** As noted by the Congressional Research Service, agency scientific integrity policies vary significantly on the question of whether contractors and grantees, in addition to federal employees, are covered by agency scientific integrity policies. See CRS report R46614, updated April 16, 2021.

It is essential that OSTP clarify that all federally funded research is covered by these policies, regardless of whether the research is performed by a contractor, grantee, or federal employees. This prevents agencies from shifting sensitive research to contractors or grantors in order to bypass integrity policies. Such a rule would also prevent a “race to the bottom” by which contractors and grantors compete to offer agencies terms that the agency perceives as favorable because they allow more control over research findings and and/or the public release of those findings. While the agency might perceive such terms as favorable because, for example, they could allow the agency to influence research results or allow the agency to suppress public release of the research findings, such terms deprive the taxpayer of high quality, reliable research. Moreover, organizations such as RAND generally refuse to perform research under such restrictive terms, thereby depriving the public of the best available research talent.

- **Data.** RAND has observed a trend among federal agencies to limit data available to the public. In some cases, this includes removing data from the public domain that was previously available. See, for example, the work of the Environmental Data and Governance Initiative, documenting scientific data related to the environment that were removed from public websites between 2016 and 2020.

Denying the public access to data is contrary to the principles of scientific integrity. Unless the data is private and cannot be anonymized, or properly classified for national security reasons, there is generally little public interest in withholding data that has been collected and/or produced at taxpayer expense. In contrast, public access to such data has far-reaching and unpredictable benefits to the scientific community and, by extension, to the American public. As technology develops and “big data” analysis becomes more affordable and accessible, even historical data that was thought to be of minimal value can be compiled and analyzed in new and revealing ways.

It is critical that agencies be required to adopt scientific integrity policies that protect the public’s right to data access. OSTP should impose clear standards for when data may be withheld, such as when the data includes Protected Health Information or Personally Identifiable Information and it is impossible (not merely inconvenient) to anonymize the data. If the data would be sensitive if released to foreign audiences, it could be labeled appropriately and restricted to United States citizens.

Agencies should also be required to post lists of datasets that have been withheld from the public domain, along with the rationale for doing so. Finally, agencies should be prohibited from simply removing data from websites without notice – if data is removed, the agency



should be required to retain the URL and provide a notice to the public that the data was removed, as well as the rationale for removal.

As a nonpartisan, nonprofit institution dedicated to helping improve policy and decisionmaking through research and analysis, RAND appreciates the opportunity to provide input on federal scientific integrity policies. We look forward to continuing to engage with OSTP and other federal agencies on implementation of the January 27, 2021 Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking.

Sincerely,

A handwritten signature in black ink that reads "Michael D. Rich". The signature is written in a cursive, flowing style.

MDR:db

27 July 2021

BY ELECTRONIC SUBMISSION

Scientific Integrity Fast-Track Action Committee (SI-FTAC)
Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, NW
Washington, DC 20504

RE: American Institute of Aeronautics and Astronautics Response to OSTP Request for Information To Improve Federal Scientific Integrity Policies (86 FR 34064)

Dear Members of the SI-FTAC,

The American Institute of Aeronautics and Astronautics (AIAA) commends the Administration for its efforts to support scientific integrity and enhance public trust in science, and we appreciate the opportunity to respond to this request for information (RFI).

AIAA—the world’s largest aerospace technical society—brings together industry, academia, and government to advance engineering and science in aviation, space, and defense. Since the dawn of aviation and through the advent of the space age, the United States has been the world leader in aerospace technologies. The Federal Government has played an important role in supporting research and development efforts by academia, industry, and government labs leading to a myriad of scientific discoveries and innovations.

With regards to the Administration’s interest in improving the effectiveness of Federal scientific integrity policies to enhance public trust in science, we have responded to the following questions posed in the RFI:

1. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science:

- The scientific community will always police itself regarding scientific integrity.
 - o Professional and scientific organizations, like AIAA, play a role in reinforcing professional ethics, including those around scientific integrity.
 - o Trust in federal science needs to be repaired. The Federal Government should have an informed response to any media coverage that is misreported. This will help minimize the misinterpretations of scientific results.
- When releasing scientific information to the public, Federal agencies should ensure that subject matter experts assist with the crafting of those public messages.
 - o Consider working with independent organizations, like AIAA, to validate or reinforce scientific integrity.

2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information:

- Scientific input to be used for policy decisions should be reviewed by nonpartisan scientific and technical organizations who follow similar scientific integrity practices. This should identify any overt political bias; however, it will be up to the policymaker to make their own determination about how to apply the scientific input.
 - o All scientific disciplines relevant to a policy issue and the range of scientific perspectives regarding findings in those disciplines should be considered when creating a digest of relevant scientific insights for use by policymakers.
 - o Subject matter experts should digest the scientific information into concise inputs for policymakers without filtering of the information based on political considerations. Nonpartisan scientific and technical organizations should be part of this process.
 - o Prioritization of information to be included in a digested result can be performed based on careful consideration of what policymakers need to know to address current policy issues in an informed manner.

3. Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce:

- Scientific advisory boards created under the Federal Advisory Committee Act (FACA) should use politically untainted standards for selecting members.
 - o The goal is to provide the best possible scientific input to the agency responsible for a board.
 - o The quality of a board candidate's subject matter expertise should be a primary selection consideration.
 - o The ability of a board candidate to work well with peers should also be a selection consideration.
 - o A willingness to reject scientific findings based on political considerations should be reason to exclude a board candidate from selection consideration.
- Federal agencies should ensure the integrity of the data being generated and make data-driven decisions.
 - o Conduct independent peer reviews of data generated prior to release or publication.
 - o Maintain the highest standards for generation of data particularly for contentious issues.

4. Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices:

- Federal agencies should encourage its scientific staff to engage or participate in scientific professional organizations, such as AIAA, which encourage and reinforce best practices, overall scientific integrity, and professional ethics.

5. Other important aspects of scientific integrity and effective approaches to improving trust in Federal science:

- Scholarly publishers, like AIAA, are deeply committed to supporting scientific integrity and trust in science by building and maintaining infrastructure that enables the widespread production and communication of validated and reliable reports on scientific research.
 - o This includes scientific journals and staffing editorial boards with experts that read and evaluate thousands of submitted manuscripts for quality and relevance.
 - o Publishers also make important investments to ensure that the version of record is distributed and discoverable to readers around the world.
 - o There is an urgent need for stakeholders that support scientific integrity to work together and uphold the role of objective, trusted information in a democratic society.
 - o As OSTP considers its policies related to scientific publications, it is important to recognize the role of peer-reviewed journals in supporting scientific integrity.
 - It is also essential that any policies related to publications ensure that scientists and publishers can continue producing and disseminating the trusted, peer-reviewed version of record of scientific articles.
- It is critical that Federal public access policies continue to promote open science through flexible frameworks that uphold the value of the version of record and empower researchers from all backgrounds to publish high-quality works.
- Per AIAA's submission dated 4 March 2020, responding to the previous Administration's RFI (FR Doc. 2020-06622) on public access, we continue to support OSTP's current policy that does not mandate the free distribution of peer-reviewed manuscripts earlier than one year after publication (reflecting the position of Congress in the 2010 America COMPETES Reauthorization Act – Sec. 103(b)(9) – that the Administration must “take into consideration the role that scientific publishers play in the peer review process in ensuring the integrity of the record of scientific research, including the investments and added value that they make.”).
 - o We remain concerned that requiring articles to be freely available immediately upon publication in a journal would directly result in a reduction in either the quantity or quality (or, more likely, both) of peer-reviewed journal articles produced by hundreds of organizations like ours. While government funding of research covers the resulting data and required reports, it is the publishers' private efforts that add significant value to the data through peer review, editing, dissemination, and indexing of the works.
 - o Historically, aerospace engineering articles receive a significant proportion of their lifetime usage over several years, maintaining their value over time.
 - o AIAA supports and encourages agencies to educate and inform authors about how they can use grant money for open access publishing, possibly for multiple works (e.g., one grant can result in 5–10 published works).
- Publishers are important government partners in promoting scientific integrity and maximizing the value and impact of investment in research.

In closing, AIAA looks forward to working with the Administration to help improve the effectiveness of Federal scientific integrity policies to enhance public trust in science. Political interference must never distort or influence scientific findings and inputs. Additionally, we must emphasize the importance of professional societies and publishers in ensuring integrity across the scholarly communications system, as well as the importance of a robust system for equitably communicating science and scholarship to support evidence-based decision making.

Thank you again for the opportunity to submit these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Dan Dumbacher". The signature is fluid and cursive, with the first name "Dan" being more prominent than the last name "Dumbacher".

Dan Dumbacher
AIAA Executive Director



Paige C. Magness
Senior Vice President
Regulatory Affairs

July 27, 2021

Via Electronic Submission

White House Office of Science and Technology Policy

ScientificIntegrityRFI@ostp.eop.gov

Re: White House Office of Science and Technology Policy Request for Information to Improve Federal Scientific Integrity Policies (86 Fed. Reg. 34,064, June 28, 2021).

Altria Client Services Inc. ("ALCS"), on behalf of Philip Morris USA Inc. ("PM USA"), John Middleton Co. ("JMC"), U.S. Smokeless Tobacco Company LLC ("USSTC"), and Helix Innovations LLC ("Helix"),¹ submits these comments in response to the above-referenced request for information ("Request").

The Request outlines the Biden Administration's policy "to make evidence-based decisions guided by the best available science and data, recognizing that scientific and technological information, data, and evidence are central to the development and iterative improvement of sound policies..."² We applaud the Administration's policy to rely on science and evidence, and believe it should apply equally to the development of tobacco policies across the federal government.

With increasing adult smoker demand for potentially reduced risk, non-combustible products, a commitment to science and innovation, and an appropriate regulatory framework, we have the opportunity to make more progress on reducing the harm caused by combustible cigarettes in the next 10 years than we have in the past 50 years. At Altria, our 10-Year Vision is to responsibly lead the transition of adult smokers to a non-combustible future.

At the same time, we recognize the controversy that surrounds tobacco products. It is precisely for this reason that in 2009, Congress, as part of the Family Smoking Prevention and Tobacco Control Act ("TCA"), established the Food and Drug Administration ("FDA") as the Agency to

¹ PM USA, JMC, and USSTC are wholly owned subsidiaries of Altria Group, Inc. ("Altria"). Helix is a wholly-owned subsidiary of Altria Enterprises II LLC, which is a wholly owned subsidiary of Altria. PM USA manufactures cigarettes and is licensed to sell and distribute IQOS® and HeatSticks® in the United States and JMC manufactures cigars and pipe tobacco. USSTC manufactures smokeless tobacco products and oral tobacco-derived nicotine products. Helix manufactures oral tobacco-derived nicotine products. ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" are used throughout to refer to PM USA, JMC, USSTC, and Helix.

² Request at 34,064-5.

Altria Client Services LLC
601 E. Jackson Street
Richmond, Virginia 23219
(804) 335-2353
Paige.C.Magness@altria.com

regulate tobacco products, and why this Request is especially relevant. Altria was the first manufacturer to support industry regulation, believing that a properly regulated marketplace, led by science and evidence, could ultimately bring innovative lower risk products to adult smokers who cannot or will not quit tobacco use. Thus, Congress established FDA as an independent, science-driven regulatory agency that could review the evidence and weigh the risks and benefits of innovative products to public health. It is essential that FDA continues to base decisions on the best available science and evidence.

Dr. Lander, Director of the White House Office of Science and Technology Policy (“OSTP”), considers “OSTP’s mission [] to maximize the impact of science and technology to advance health...”³ We agree with this goal and believe science-backed tobacco harm reduction policies, led by FDA, are critical for America’s 33.5 million adult cigarette smokers,⁴ over half of whom are interested in less harmful alternatives to smoking.⁵

Below we provide suggestions on how the OSTP could work with various federal agencies to ensure that tobacco policies are guided by the best available science and evidence.

FDA Should Make PMTA Determinations on Science and Evidence Presented in Applications

The success of tobacco harm reduction in the United States hinges on a regulatory framework that allows manufacturers to offer adult tobacco consumers potentially reduced-risk tobacco products. Thus, the TCA charges FDA with executing a science-and-evidence based premarket review process.⁶

FDA is currently reviewing product applications under the Premarket Tobacco Product Application (“PMTA”) pathway from hundreds of manufacturers for potentially millions of products to determine which of those products will be available to adult consumers.⁷ Science must remain the driver of this process.

The PMTA pathway is intended to be a comprehensive science-and-evidence based examination of new tobacco products where manufacturers must demonstrate that the marketing of a new tobacco product is “appropriate for the protection of the public health.”⁸ This is a high standard, and we understand and welcome the scientific rigor needed to satisfy this requirement.

A selection of PMTA requirements includes: assessment of the impact of the product on tobacco use initiation by non-users, including youth; the pharmacological profile of the product, including nicotine; studies of consumer perception and intent to use it; toxicological profile of

³ U.S. Senate Unanimously Confirms Dr. Eric Lander to Become Director of the White House Office of Science and Technology Policy. May 28, 2021. Available at <https://www.whitehouse.gov/ostp/news-updates/2021/05/28/u-s-senate-unanimously-confirms-dr-eric-lander-to-become-director-of-the-white-house-office-of-science-and-technology-policy/>.

⁴ 2019 National Health Interview Survey data set. Available at <https://www.cdc.gov/nchs/nhis/data-questionnaires-documentation.htm>.

⁵ Data provided by the Population Assessment of Tobacco and Health (“PATH”) Study. PATH is a national longitudinal study of tobacco use and how it affects the health of people in the United States. People from all over the country take part in this study. PATH, Home, <https://pathstudyinfo.nih.gov/UI/HomeMobile.aspx>.

⁶ TCA § 910(c)(4).

⁷ Update on FDA’s Application Review: PMTA List Posted, Progress Metrics Updated. May 20, 2021. Available at <https://www.fda.gov/tobacco-products/ctp-newsroom/update-fdas-application-review-pmta-list-posted-progress-metrics-updated>.

⁸ TCA § 910(c)(4).

the product which may include preclinical testing for genotoxicity, carcinogenicity, and literature reviews of reproductive toxicity; information about how consumers actually use the product and switch from more harmful tobacco products; assessment of inherent and relative risks of the new tobacco product, and detailed descriptions of quality control, hazard assessment, and manufacturing.⁹

For context, the PMTA application for our *on!*® nicotine pouch product included over 65,000 pages of scientific evidence and 6 original studies. Similarly, the PMTA and Modified Risk Product Application for *IQOS*® and *HeatSticks*®¹⁰ included over one million pages of scientific data and 97 scientific studies,¹¹ while FDA’s authorization and justification for the PMTA included more than 120 pages of scientific analysis.¹²

Following the science and making evidence-based decisions on product applications is critical in the face of sometimes heated debates surrounding non-combustible tobacco products. OSTP should ensure that the policy of the Biden Administration “to make evidence-based decisions guided by the best available science and data”¹³ applies equally to tobacco product policies and product authorization decisions.

Stakeholders Should Work Together to Advance Tobacco Harm Reduction Science

The President recognizes that OSTP’s effort will require us to “bring together our brightest minds across academia, medicine, industry, and government.”¹⁴ FDA’s work shaping and executing tobacco policies depends upon these various stakeholders, whose research informs marketing orders, guidance documents and the rulemaking process.¹⁵ FDA’s policymaking, like all federal agencies, should “be subjected to well-established scientific processes,” and we believe should rely on data that has undergone “peer review where feasible...”¹⁶

Since advocating for and receiving FDA regulatory oversight, industry has invested billions to research and develop novel tobacco products. At Altria, we employ over 140 scientists, spanning a broad range of disciplines, who are committed to reducing the harm caused by smoking. Our scientists have extensively published in peer-reviewed journals and presented at scientific conferences. They welcome the scrutiny and dialogue with peers that can lead to harm reduction breakthroughs.

⁹ Premarket Tobacco Product Applications and Recordkeeping Requirements 84 Fed. Reg. 50,566, Sept. 25, 2019, <https://www.govinfo.gov/content/pkg/FR-2019-09-25/pdf/2019-20315.pdf>.

¹⁰ PM USA has an exclusive agreement with Philip Morris International to commercialize *IQOS*® and *HeatSticks*® in the United States.

¹¹ 10 facts about the FDA’s modified risk tobacco product authorization of *IQOS*. November 3, 2020. Available at <https://www.pmi.com/our-science/FDA-modified-risk-tobacco-product-authorization-of-IQOS-10-facts>.

¹² See Technical Project Lead for *IQOS* and *Heatsticks*, May 15, 2017. <https://www.fda.gov/media/124247/download>. Altria’s companies have an exclusive licensing agreement with PMI to sell *IQOS*® and *HeatSticks*® in the United States.

¹³ “Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking” (“Memorandum”) (86 Fed. Reg. 8845, February 10, 2021). Available at <https://www.govinfo.gov/content/pkg/FR-2021-02-10/pdf/2021-02839.pdf>.

¹⁴ Letter to Dr. Eric S. Lander, the President’s Science Advisor and Director of the Office of Science and Technology Policy. January 15, 2021. Available at <https://www.whitehouse.gov/ostp/news-updates/2021/01/15/a-letter-to-dr-eric-s-lander-the-presidents-science-advisor-and-director-of-the-office-of-science-and-technology-policy/>.

¹⁵ FDA Rules, Regulations and Guidance. Available at <https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance>.

¹⁶ Memorandum at 8845.

In fact, the National Institutes of Health (“NIH”) recognizes that more research needs to be done on non-combustible products, not less; “[r]egarding more recently introduced tobacco products (e.g., electronic nicotine delivery systems), there are currently insufficient data on their potential utility as either harm reduction or tobacco cessation products.”¹⁷

At the same time the National Institutes on Drug Abuse (“NIDA”) discourages industry participation in tobacco harm reduction research, in conflict with its parent Agency’s goal. NIDA warns grant applicants not to accept funding from the tobacco industry and that doing so may impact their likelihood of receiving funding.¹⁸ The justifications put forth by NIDA do not question the strength of industry-sponsored tobacco harm reduction research. Instead, NIDA argues that a researcher who receives industry funding may compromise their perceived objectivity. With over a decade of regulation behind us, this antiquated view represents bias against industry without basis in its present day research. It undermines the pressing need for even more high quality, peer-reviewed research. OSTP should work with the NIH and NIDA to change this policy as some journals and scientific conferences may be misguided by it.

Indeed, some journals¹⁹ and scientific conferences which serve as critical inputs to FDA’s scientific decision making have shut the door to industry-executed tobacco harm reduction research without any justification in the quality of the research. For example, the Society for Research on Nicotine and Tobacco (“SRNT”), a premier forum for tobacco harm reduction research and information sharing, recently “ban[ned] employees of the tobacco industry from attending SRNT’s annual conference.”²⁰ This is the incorrect path at a significant moment in tobacco product research. Rather, all stakeholders should commit to scientific exchange and sharing expertise that can ultimately shift smokers away from cigarettes.

A new generation of researchers understands the benefit to tobacco harm reduction research when all perspectives are considered. Alarmed with polarization in e-vapor science, a group of young researchers raised their concerns in a recent publication: “Journals may further fuel polarized views on e-cigarettes by providing platforms predominately to those who have extreme viewpoints and therefore limiting the diversity of information to which trainees are exposed.”²¹

They caution that this polarization weakens tobacco harm reduction science. “Divisive, dominant perspectives on e-cigarettes move the field of nicotine and tobacco science away from scientifically rigorous discourse on this important public health topic, which involves millions of lives at stake.”²²

Most strikingly, the authors cautioned that “researchers self-segmenting into smaller, niche conferences or organizations that only highlight one perspective are a disservice to the field and have the potential to undercut public health.”²³

¹⁷ *Id.*

¹⁸ Points to Consider Regarding Tobacco Industry Funding of NIDA Applicants. Available at <https://www.drugabuse.gov/about-nida/advisory-boards-groups/national-advisory-council-drug-abuse-nacda/points-to-consider-regarding-tobacco-industry-funding-nida-applicants>.

¹⁹ Why Tobacco Control still won’t publish tobacco industry funded work, even if the funding is laundered through PMI’s new ‘independent’ foundation October 23, 2017. Available at <https://blogs.bmj.com/tc/2017/10/23/why-tobacco-control-still-wont-publish-tobacco-industry-funded-work-even-if-the-funding-is-laundered-through-pmis-new-independent-foundation/>.

²⁰ SRNT Society News, Letter to Colleagues, July 6, 2021. Available at <https://t.e2ma.net/message/o2yp5h/8xggtm>.

²¹ Polarization Within the Field of Tobacco and Nicotine Science and its Potential Impact on Trainees. *Nicotine & Tobacco Research*, 2021, 36–39 doi:10.1093/ntr/ntaa148. Received October 18, 2019; Editorial Decision July 28, 2020; Accepted August 5, 2020.

²² *Id.*

²³ *Id.*

We believe limiting scientific debate and discourse, as well as possibly outcome-driven manuscript review, stand in stark contrast to the President’s call to “bring together the brightest minds” and adhere to “well-established scientific processes.”²⁴ OSTP can help foster greater scientific integrity by partnering with FDA to evaluate how journals and publications with a distinct, polarized viewpoint, who actively censor industry-conducted research, are considered in the development of rules and guidances.

We hope OSTP agrees that the time-tested scientific principles of transparency, unbiased data review, direct researcher engagement and open dialogue would allow scientific inquiry to prevail over preconceptions and would better inform policies that reduce the harm of tobacco products. We welcome good-faith scrutiny of industry-provided science.

Ultimately, an open dialogue between all stakeholders will improve the scientific data upon which FDA relies. Under the TCA, Congress and the FDA placed tobacco manufacturers at the center of tobacco product science development. We seek to meet this obligation through investing in world-class analytical, pre-clinical, clinical, population and modeling research and constructively engaging with the FDA and the broader scientific community in support of tobacco harm reduction. FDA relies on industry science and data in its review of PMTAs.²⁵ However, we believe that for the best science to reach FDA and broadly inform public health, journals and conferences have roles to play in good-faith review. The principle of making “evidence-based decisions guided by the best available science and data”²⁶ is most needed in areas of controversy.

OSTP Should Work with FDA and CDC to Develop Strategies to Communicate Scientifically-Accurate Information to Adult Smokers About the Risks of Nicotine and Relative Risks of Different Tobacco Products

The President asked OSTP to develop strategies for “improving the communication of scientific facts”²⁷ to the public. We believe the success of tobacco harm reduction depends upon a regulatory framework that provides consumers with scientifically accurate information about the role of nicotine and the relative risks of non-combustible tobacco products compared to smoking.

FDA recognizes that nicotine is not directly responsible for the harms associated with tobacco use,²⁸ and there is a public health consensus that non-combustible tobacco products, while not risk-free, present substantially less harm to the user than combustible tobacco products. While nicotine is addictive, it is the exposure to smoke from combustion – not nicotine – that causes most tobacco-related disease. At the same time, many adult smokers do not understand the role of nicotine.²⁹

²⁴ Memorandum at 8845.

²⁵ TCA § 910.

²⁶ Memorandum at 8845.

²⁷ *Id.*

²⁸ Protecting American Families: Comprehensive Approach to Nicotine and Tobacco. July 28, 2017. Available at <https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017>.

²⁹ See, Nicotine: The Addictive Chemical in Tobacco Products, August 28, 2020. Available at, <https://www.fda.gov/tobacco-products/health-information/nicotine-addictive-chemical-tobacco-products>.

A 2016 study analyzing data from the Health Information National Trends Survey found that 73 percent of people “either incorrectly believed that nicotine is the main substance in cigarettes that causes cancer or were unsure about the relationship between nicotine and cancer.”³⁰ This entrenched misperception is not limited to adult smokers. For example, a recent study found that more than 80% of surveyed physicians, an important source of health information for consumers, “strongly agreed” that nicotine directly contributes to the development of cardiovascular disease, COPD and cancer.³¹

Collectively, these misperceptions could result in smokers rejecting non-combustible alternatives simply because they contain nicotine.³² This demonstrates a clear need for improved “communication of scientific facts”³³ to correct these misperceptions. Despite a commitment from FDA to “reframe the conversation around nicotine and harm reduction,”³⁴ adult tobacco consumers and other important stakeholder groups, like physicians, remain uncertain about the role of nicotine in, and the differential risks of, non-combustible tobacco products.

To reframe the conversation, factual scientific information from trusted sources must be made available to adult tobacco consumers and physicians. Building on its reported success in other targeted communication campaigns,³⁵ and aligned with FDA’s goal of “maximizing the effectiveness of messages and strategies for reaching targeted audiences,”³⁶ we urge OSTP to work with FDA and CDC to conduct a communications campaign focused on correcting nicotine misperceptions among targeted audiences, particularly adult cigarette smokers.

Science and Evidence Can Lead Us to a Non-Combustible Future

FDA’s 2017 Comprehensive Plan for Nicotine and Tobacco Regulation envisioned a world where “less harmful alternative forms [of nicotine], efficiently delivering satisfying levels of nicotine, *are available* for those adults who need or want them.”³⁷ While developing reduced risk products is an important first step, adult smokers must actually choose to use them in the place of combustible cigarettes to achieve net public health benefits.³⁸ To that end, smokers must have

³⁰ O'Brien, E. K., Nguyen, A. B., Persoskie, A., & Hoffman, A. C. (2016). U.S. adults' addiction and harm beliefs about nicotine and low nicotine cigarettes. *Preventive Medicine*, 96, 94-100. doi:10.1016/j.ypmed.2016.12.048

³¹ Steinberg, M.B., Bover Manderski, M.T., Wackowski, O.A. *et al.* Nicotine Risk Misperception Among US Physicians. *J GEN INTERN MED* (2020). <https://doi.org/10.1007/s11606-020-06172-8>.

³² “The misperception of the risks of these products results in smokers rejecting them, misperceptions that arise from inaccurate information and sensational media headlines. Public health officials are misinformed by these sources as well, plus they buttress their opposition to tobacco harm reduction products with unsubstantiated fears of youth addiction. These barriers will need to be addressed if tobacco harm reduction is to make the maximum impact on the tobacco endemic.” O’Leary, R.; Polosa, R. Tobacco harm reduction in the 21st century. *Drugs and Alcohol Today*. Apr. 20, 2020. DOI [10.1108/DAT-02-2020-0007](https://doi.org/10.1108/DAT-02-2020-0007).

³³ Memorandum at 8845.

³⁴ Scott Gottlieb, M.D., and Mitch Zeller, J.D., Advancing Tobacco Regulation to Protect Children and Families: Updates and New Initiatives from the FDA on the Anniversary of the Tobacco Control Act and FDA’s Comprehensive Plan for Nicotine (August 2, 2018), *available at* <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/advancing-tobacco-regulation-protect-children-and-families-updates-and-new-initiatives-fda>.

³⁵ Press Release, FDA launches new, comprehensive campaign to warn kids about the dangers of e-cigarette use as part of agency’s Youth Tobacco Prevention Plan, amid evidence of sharply rising use among kids (September 18, 2018). *Available at*, <https://web.archive.org/web/20190119201459/https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620788.htm>.

³⁶ 86 Fed. Reg. 12,953 (March 5, 2021).

³⁷ Protecting American Families: Comprehensive Approach to Nicotine and Tobacco, July 28, 2017. Available at <https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017> (emphasis added).

³⁸ Abrams D, Glasser A., Pearson J., Villanti A., Collins L., and Niaura, R. 2018. Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives. *Annual Reviews of Public Health*. 39:193–213.

access to satisfying reduced harm products with sensory experiences that meet their expectations.³⁹

We know that adult tobacco consumers are increasingly seeking new options, including those that reduce risk, and their preferences are evolving rapidly. With knowledge of adult tobacco consumer expectations, we aim to provide them with FDA-authorized products that meet these reduced risk preferences and provide accurate information about those risks.

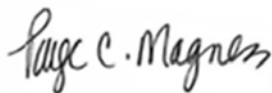
Today, the range of non-combustible tobacco products is expanding with options such as the IQOS® heated tobacco product, on!® nicotine pouch products and e-vapor products, each of which may interest different adult smokers. By providing a range of reduced harm alternatives for adults, and accurate information about them, we believe that they will ultimately choose less harmful products.⁴⁰ In fact, our marketplace data over the past five years show a growing proportion of adult tobacco consumers are choosing exclusive smoke free product use versus smoking. This is exactly the type of change we seek in our Vision to responsibly lead the transition of adult smokers to a non-combustible future. This is also the type of “market-driven change” that OSTP supports in other fields.⁴¹

Conclusion

Congress put FDA at the center of tobacco regulation because it believed that tobacco policies should be made by public health experts using the best available science and evidence. Following the science and making evidence-based decisions for the benefit of public health is most critical in the face of controversial issues.

At Altria, we will continue to focus on delivering quality research to FDA and stakeholders, while seeking out those willing to engage in productive scientific exchanges that advance efforts to reduce the harms caused by combustible tobacco products. We appreciate your consideration of our suggestions on this important public health opportunity and we welcome the occasion to discuss this further.

Sincerely,



³⁹ Researchers have confirmed the importance of nicotine levels for smokers with high nicotine dependence. In another study, smokers indicated higher motivation to quit smoking after choosing to vape e-liquids with a higher concentration of nicotine. Harvanko et al., 2018, Devito et al., 2019, Weaver et al., *in press*.

⁴⁰ Offering Adult Smokers More Choices. Available at <https://www.altria.com/moving-beyond-smoking/offering-adult-smokers-more-choices?src=topnav>.

⁴¹ Letter to Dr. Eric S. Lander, January 15, 2021.

From: [Matthew Tenan](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Scientific Integrity Comments
Date: Tuesday, July 27, 2021 1:23:04 PM

Name of Person Filing Comment: Matthew Tenan PhD ATC
Respondent Type: Non-Academic Scientist

I have spent numerous years working as a Government Civilian Scientist (4 years) or as a Contractor Scientist (7 years). It has been my experience that Scientific Integrity in Government research has comparable integrity to that seen in Academia and Industry. That is to say that integrity is OK, but there is substantial room for improvement.

All Science would benefit from a public pre-registration process (<https://www.cos.io/initiatives/prereg>) which clearly defines the goals of the work, whether it is exploratory or confirmatory and the research plans. In this way, any results can then be contrasted with the original goals to determine if HARKing or other questionable research practices seem to have occurred (<https://en.wikipedia.org/wiki/HARKing>). Furthermore, it can also be quantified how many Government studies are pre-registered but then result in no defined outcome. While the lack of a result or publication resulting from a pre-registration are many, patterns may emerge where projects are started but never completed (pointing to poor management or lack of ability to retain personnel), potentially contentious results which are not released for reasons of bias/political interference, or the "file drawer problem" which is well-known in the scientific community (<https://www.discovermagazine.com/mind/psychologists-throw-open-the-file-drawer>).

The second adjustment to ensure scientific integrity in Government research is to REQUIRE that all publications be made publicly available if Federal funding is obtained. While it is already widely accepted that a copyright cannot be assigned to works of Federal Employees (https://en.wikipedia.org/wiki/Copyright_status_of_works_by_the_federal_government_of_the_United_States). This statute seems to currently have too many "loop-holes" for wide enforcement. For example, when I was a Civilian Scientist with the U.S. Army Research Laboratory, any of my published research was in the public domain as long as none of my Contractor or Academic Collaborators were co-authors on the paper. If they were co-authors, the argument was made that one could not disentangle the "government works" from the "non-government works". The resolution to this legal conundrum is simple: As a contractual stipulation for working for or with government personnel, collaborating individuals should be required to assign any copyrights to collaborative works to the government, which then places all of that work in the public domain. This can be written into any CRADA or contractual agreement. Furthermore, any Academic who is funded by Federal Dollars, either through direct NIH/NSF/DOT/etc. funding or indirectly through Pell Grants or Stafford Subsidized Loans to their students can be designated an "officer of the government" as those funds are providing for their official duties of publishing research. Unless research publications which are directly or indirectly funded by the Government are available to the Public, integrity cannot be ensured and validated.

Thank you for the opportunity to comment on this topic. I would love to work with OSTP in the future, particularly as it pertains to Research Integrity and Open Science. I look forward to the continued work of the Biden Administration.

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Matt Tenan, PhD ATC FACSM

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From: [Richard Nadler](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Tuesday, July 27, 2021 1:47:17 PM

If we seek to improve federal scientific integrity policies, we must first have better educated citizens. We need the average person to understand basic scientific principles. This starts with improving science education in grades K-8. How can we expect meaningful input from an ignorant population?

As a science educator for 42 years, particularly grades K-8, I have seen science education and teaching shunted aside because of the emphasis on reading and mathematics and the lack of adequate training of teachers to teach the subject. Teachers are not required to take more than an introductory course in science when in college. They do not receive comprehensive instruction, in college, in utilizing a constructivist approach to teaching hands on science. Constructivism is 'an approach to learning that holds that people actively construct or make their own knowledge and that reality is determined by the experiences of the learner' (Elliott et al., 2000, p. 256). Constructivism's central idea is that human learning is constructed, that learners build new knowledge upon the foundation of previous learning. This prior knowledge influences what new or modified knowledge an individual will construct from new learning experiences (Phillips, 1995).

Constructivism has been a major influence on work undertaken in science education over several decades but has not been properly instituted in American schools. Constructivism has informed pedagogy and curriculum development, as well as being the dominant idea in research. Science has become reading out of the textbook or watching a video. Teachers receive very little in the way of training to improve their own scientific understandings and to utilize constructivism as a method of teaching science. Teachers generally received less than 10 hours of such training a year.

When teachers are told they will be graded on the improvement their students make in reading and math their will to teach anything else is sapped. When they are told their salary increases will be tied to this same improvement, they lose the desire to teach anything else. Combine this with the fact that many K-8 teachers lack the necessary knowledge and training to provide significant science education to their students, we have a lose-lose situation for science education.

Why is this important? What everyone seems to be missing is that good science education would result in better reading and math skills. Forming a hypothesis is similar to decoding a reading passage and in Math it's figuring out the procedure to apply. The observation skills taught in science class would help young learners better identify new words and see the patterns that Mathematics consists of. For example, learning how to follow procedures would increase students' ability to learn how to sound out words or recognize rules related to the sounds that letters make, such as, c followed by the letters e or i sounds like an s but followed by a, o, or u sounds like a k. In Mathematics it would allow students to use the rules for solving problems step by step. All K-8 Math basically consists of procedures for solving the

problem presented. The procedures change only for the specific type of problem that they apply to. For example, when we add fractions with the same denominators, we add the numerators and leave the denominators alone ($1/3 + 1/3 = 2/3$). Drawing conclusions obviously relates to reading and is a needed skill to allow us to make better decisions by interpreting the facts we have read. In Mathematics it serves us as a check on the work that was done.

What I am trying to say here is that we have damaged the ability of our citizens to understand and interpret fact from falsehoods and distortions in order to make scientific policy because good Science education has been totally neglected in our K-8 schools. In order to remedy this, we must: 1) Have colleges offer more required Science courses for teaching candidates. These courses must include basic biology, earth science, physics, and ecology as well as methodology courses relating to the implementation to teach Science utilizing a constructivist approach. 2) Funding for supplies and equipment used to teach science. Materials such as chemicals and batteries do not last forever. 3) An emphasis or requirement that Science be taught every day for at least 45 minutes. 4) Group planning sessions to support the use of materials and sequence of subjects being taught. 5) Better supervision of the teaching of Science.

I can only hope this short message reaches those who can do something to improve the Science understandings of our citizens. The students I taught over the years truly loved Science. Many still communicate with me and explain how my teaching changed their lives. If there is anything I can do to be of service, just let me know.

Richard Nadler

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Texaco Teacher Training Institute in Science, Math and Technology, Lead Teacher



Defending the scientific integrity of conservation-policy processes

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Abstract: *Government agencies faced with politically controversial decisions often discount or ignore scientific information, whether from agency staff or nongovernmental scientists. Recent developments in scientific integrity (the ability to perform, use, communicate, and publish science free from censorship or political interference) in Canada, Australia, and the United States demonstrate a similar trajectory. A perceived increase in scientific-integrity abuses provokes concerted pressure by the scientific community, leading to efforts to improve scientific-integrity protections under a new administration. However, protections are often inconsistently applied and are at risk of reversal under administrations publicly hostile to evidence-based policy. We compared recent challenges to scientific integrity to determine what aspects of scientific input into conservation policy are most at risk of political distortion and what can be done to strengthen safeguards against such abuses. To ensure the integrity of outbound communications from government scientists to the public, we suggest governments strengthen scientific integrity policies, include scientists' right to speak freely in collective-bargaining agreements, guarantee public access to scientific information, and strengthen agency culture supporting scientific integrity. To ensure the transparency and integrity with which information from nongovernmental scientists (e.g., submitted comments or formal policy reviews) informs the policy process, we suggest governments broaden the scope of independent reviews, ensure greater diversity of expert input and transparency regarding conflicts of interest, require a substantive response to input from agencies, and engage proactively with scientific societies. For their part, scientists and scientific societies have a responsibility to engage with the public to affirm that science is a crucial resource for developing evidence-based policy and regulations in the public interest.*

Keywords: endangered species act, external peer review, science communication, scientific advocacy

En Defensa de la Integridad Científica de los Procesos de Política de Conservación

Resumen: *Las agencias del gobierno que enfrentan decisiones políticas controversiales comúnmente rebajan o ignoran la información científica, ya sea de empleados de la agencia o científicos no gubernamentales. Los desarrollos recientes en la integridad científica (la capacidad de desempeñar, usar, comunicar, y publicar*

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ciencia libre de censura o interferencia política) en Canadá, Australia y en los Estados Unidos demuestran una trayectoria similar. Un incremento percibido en los abusos a la integridad científica provoca presiones conjuntas por la comunidad científica, lo que lleva a esfuerzos por mejorar las protecciones de la integridad científica bajo una nueva administración. Sin embargo, las protecciones se aplican continuamente sin consistencia y están en riesgo de una regresión bajo administraciones públicamente hostiles a la política basada en evidencias. Comparamos los retos recientes para la integridad científica para determinar cuáles aspectos de la contribución científica a la política de conservación están en mayor riesgo de una distorsión política y qué puede hacerse para fortalecer los salvoconductos contra dichos abusos. Para asegurar la integridad de las comunicaciones salientes de los científicos del gobierno al público sugerimos que los gobiernos fortalezcan las políticas de integridad científica, incluyan el derecho a hablar libremente de los científicos en los acuerdos de negociaciones colectivas, garanticen el acceso del público a la información científica, y que fortalezcan la cultura de la agencia apoyando a la integridad científica. Para asegurar la transparencia y la integridad con la cual la información de los científicos no-gubernamentales (por ejemplo, los comentarios entregados o las revisiones de política formal) informa los procesos políticos sugerimos que los gobiernos amplíen el enfoque de las revisiones independientes, aseguren una mayor diversidad de contribuciones de expertos y transparencia con respecto a los conflictos de interés, requieran una respuesta sustanciosa a la contribución de las agencias, y que participen de manera proactiva con las sociedades científicas. Por su parte, los científicos y las sociedades científicas tienen la responsabilidad de comprometerse con el público para afirmar que la ciencia es un recurso crucial para desarrollar las políticas basadas en evidencias y las regulaciones en el interés público.

Palabras Clave: ciencia, comunicación, defensa científica, ley de especies en peligro, revisión de colegas externos

Introduction

Effective conservation outcomes depend in part on the degree to which policy and management strategies are supported by scientific evidence (Sutherland et al. 2004). However, government agencies faced with politically controversial decisions often discount or ignore scientific information received from agency staff or nongovernmental scientists. We compared recent challenges to scientific integrity in conservation policy making in Canada, Australia, and the United States to determine what aspects of scientific input into policy are most at risk of political distortion and what can be done to strengthen safeguards against such abuses.

We defined *scientific integrity* as the ability to perform, use, communicate, and publish science free from censorship or political interference (Goldman et al. 2017). This definition encompasses the ability of government scientists to speak freely about their research and the transparency and integrity with which information from nongovernmental scientists (e.g., consultations, submitted comments, or formal policy reviews) informs the policy process.

Although scientific integrity abuses arise under all political parties, they are accentuated under administrations that publicly question the value of science and the validity of widely accepted scientific knowledge (Goldman et al. 2017). The 2016 election of Donald Trump as U.S. president alarmed much of the scientific community given his administration's attempts to silence government scientists from speaking with the media and his rhetoric disparaging accepted scientific concepts, including climate change (Ritchie et al 2017).

Recent developments in the United States are reminiscent of issues that arose when political appointees of George W. Bush (2001–2009) prevented federal scientists from publicly sharing their research and manipulated scientific reports to justify policy decisions (Doremus 2008). Similar violations occurred in Canada in the latter years of the Harper administration (2011–2015), when federal scientists were systematically prevented from communicating their work to the public (Noël 2016). Scientific integrity became a key issue in Canada's 2015 election and contributed to the election of a prime minister publicly committed to strengthening scientific integrity. In Australia, scientific-integrity violations became a prominent political issue under the Howard administration (1996–2007) (Khan 2017). When the opposition Labor party took power in 2007, it publicly endorsed the right of government scientists to speak freely about their work (Price 2009).

Canada, Australia, and the United States are all examples of developed economies with common-law systems. Although this is only one of many socioeconomic contexts for conservation, comparison of these 3 nations illustrates the challenges to scientific integrity that arise when a longstanding legal and societal commitment to conservation confronts a perceived tension between conservation and economic activities. The 3 nations demonstrate a similar trajectory concerning scientific integrity: a perceived increase in abuses precipitates concerted pressure by the scientific community followed by efforts to improve institutionalization of scientific-integrity protections under a new administration. However, continued violations and inconsistent application of new policies remain even as those administrations publicly endorsed

Table 1. Types of policy reform discussed in this review for strengthening the scientific integrity of 2 categories of scientific communication.

<i>Communication type</i>	<i>Suggested reform</i>
Outbound communication from government scientists to public	<ol style="list-style-type: none"> 1. Strengthen scientific integrity policies 2. Include scientists' right to speak freely in collective bargaining agreements 3. Guarantee public access to scientific information 4. Strengthen agency culture supporting scientific integrity
Inbound communication from independent scientists to government policy processes	<ol style="list-style-type: none"> 5. Broaden the scope of independent reviews 6. Ensure greater diversity of input with transparency regarding conflicts of interest 7. Require substantive response to input by agencies 8. Engage proactively with scientific societies and organizations

reforms (Goldman et al. 2015; Ritchie et al. 2017). With the recent advent of a U.S. administration more publicly hostile to science than previous administrations, even inconsistently applied reforms appear vulnerable to abrogation through regulatory changes designed to undermine the role of science in policy (Goldman et al. 2017).

We took a step back from recent crises to identify problems that transcend administrations and geography and examined how institutional safeguards of scientific integrity can be made more robust. Although it may seem impractical to propose strengthening scientific-integrity policies under unsympathetic administrations, we believe a defense of existing protections must be coupled with a focus on necessary improvements to ensure long-term success in institutionalizing a culture of scientific integrity in conservation-policy processes.

We built on other recent reviews of emerging scientific-integrity issues (e.g., Goldman et al. 2017) by focusing specifically on how science informs conservation policy. We examined commonalities and contrasts across the 3 nations to determine which reforms are limited to specific contexts and which are broadly relevant. We considered reforms that address distinct threats to 2 types of communication related to scientific integrity (Table 1). First, outbound scientific communications from government scientists to the public and media are threatened by restrictive policies that limit scientists' latitude to publish or publicize their research findings. Public access to websites or other sources of government scientific data have also been curtailed in some instances. These limitations on the free flow of information from government scientists to the public undermine the ability of citizens to be informed about and involved in debate on science-based policy questions.

Second, politicians have sought to restrict or ignore inbound scientific communication through which nongovernmental scientists inform policy. Although science is only one source of influence on policy, democratic processes are undermined when policy makers conceal how and to what extent decisions are based on science. Lawmakers in the United States have included in environmental statutes formal opportunities for nongovernmental scientists to inform the policy-making process via peer review of draft decisions. In Australia, such opportu-

nities arise primarily via informal consultation or material submitted during the public-comment period.

Censorship in Communication between Government Scientists and the Public

When government scientists conduct research, the policy implications of their results are often unpredictable. Scientific integrity requires not only a rigorous and unbiased research process, but also the ability of scientists to speak openly about their findings. In surveys of scientists across 8 U.S. federal agencies in 2005–2007, 60% of respondents reported incidents of political interference in their work, and 7% reported they had been directed to “provide incomplete, inaccurate, or misleading information” to the public (Goldman et al. 2017).

In a 2013 survey of Canadian government scientists, 25% reported being asked to exclude or alter information for nonscientific reasons (Professional Institute of the Public Service of Canada 2013). Under the Harper administration, government scientists communicating their work through the media faced lengthy approval processes. Media minders often sat in on scientist's interviews and even followed scientists at conferences to discourage spontaneous commentary. These restrictions stimulated sustained public protests by Canadian scientists (Noël 2016).

In Australia, even after the advent in 2007 of a new administration's public commitment to scientific integrity, authorization was still often required (and sometimes denied) before government researchers could speak publicly about their research (Ritchie et al. 2017). Commissioned research was routinely subject to contractual clauses allowing governments to prohibit publication of research or modify language in scientific papers (Kyprri 2015). Recently, news of the rediscovery of a plant species thought to be extinct for 200 years (*Hibbertia fumana*) was reportedly suppressed by the New South Wales Office of Environment and Heritage until after a development at the site where the plants were found was approved (Hannam 2017) (Fig. 1). At the federal level, the Australian government successfully requested that the UN Educational, Scientific and Cultural Organization remove mention of the climate-change threats



*Figure 1. Species that provide examples of challenges to the scientific integrity of conservation-policy processes. Political considerations delayed protection of the wolverine (upper left) in the United States (photo by U.S. National and Park Service) and the shortnose sturgeon (lower right) in Canada (photo by U.S. Fish and Wildlife Service [USFWS]). The U.S. recovery plan for the Northern Spotted Owl (upper right) (photo by USFWS) was revised to correct deficiencies identified in a review by 3 scientific societies. News of the rediscovery of the shrub *Hibbertia fumana* (lower left) (photo by A. Orme) in Australia was delayed until a development at the site of rediscovery had been permitted.*

to Australian World Heritage areas in their 2016 report on at-risk sites (Markham et al. 2016). Climate scientists were also recently restricted from submitting comments based on their results during public processes (Salleh & Borschmann 2017).

Reforms to Safeguard the Scientific Integrity of Outbound Communications

Institutionalize Protections via Scientific Integrity Policies

Publicity surrounding scientific integrity violations in the United States led the Obama administration to issue a Memorandum on Scientific Integrity that directed federal

agencies to develop policies that would strengthen safeguards on the integrity of the scientific process (Holdren 2010). Twenty-seven executive branch departments and agencies developed policies to guide and protect the process by which agencies use and publicly communicate science, including use of nongovernmental scientists for peer review and federal advisory committees. Many agencies also put in place officials to oversee enforcement of the policies. This system appears to work best when a full-time scientific-integrity official reports to the highest ranking civil servant in the agency and the person is close to agency science activities and removed from political appointees. These new policies and continuing pressure from the scientific community have resulted in a

reduction in reported cases of inappropriate interference in government decision-making processes (Goldman et al. 2015).

In Canada, the incoming Trudeau administration declared that federal researchers could speak publicly about research within their area of expertise without prior approval in most cases (Government of Canada 2016). The government also established the new position of chief science advisor, whose mandate includes safeguarding scientific integrity and accelerating shifts toward more transparent communication of federal scientific research to the public.

To date, institutionalization of scientific integrity reforms in Australia has been more limited than in Canada and the United States. Although several federal and state institutions have issued statements committing the organizations to a rigorous unbiased research process (ARC 2015), their policies do not generally encompass transparency in communication between agencies and the public. In many agencies scientists still need approval before they can speak publicly about their research.

Strengthen Collective Bargaining Agreements

Although the adoption of the 2016 directive increased public engagement by Canadian government scientists, the new open-communication policies were not uniformly applied. Government scientists are employed under different contracts, and protections varied widely among agencies. In response, the union representing government scientists successfully negotiated for the contractual right of scientists to speak publicly about their research. Protections under this agreement will be difficult to reverse even if a future administration decides to modify the communications directive. Although collective bargaining agreements are an effective means of insulating government scientists against loss of the right to communicate their work, alternative methods exist that strengthen such protections where such agreements are not feasible.

When the Australian Labor party took power in 2007, it promulgated charters for some public research organizations that sought to protect the right of scientists to speak out and to ensure scientific publications presented information free from political interference (Price 2009). To address perceived shortcomings of the new policy, Australia's Community and Public Sector Union, which represents staff at government research organizations, campaigned for a stronger Science Integrity Charter based on several principles: open communication, dissemination, and internal and external debate of scientific work; acknowledgment of the contestability of uncertain science; and independence of public-sector institutions and their staff (CSIRO Staff Association 2012). To our

knowledge, the proposed charter has not been implemented to date.

Safeguard Public Access to Scientific Information

Open access to scientific information allows the public to have confidence in conclusions from scientific research and to engage as informed citizens in policy debates. Administrations vary in their commitment to public access to scientific information produced by government agencies. During the Obama administration, public access to scientific information was expanded via new scientific-integrity policies and new statutes. The FOIA (Freedom of Information Act) Improvement Act of 2016 increased public access to government scientific documents and communications, and the Whistleblower Protection Enhancement Act (WPEA) of 2012 increased protections for federal scientists who expose censorship of scientific and technical information. Similarly, the 2016 Directive on the Management of Communications committed the Canadian Government to principles of open government including access to data. In Australia, some state governments (e.g., New South Wales) have publicly committed to transparency and open access to data (NSW OEH 2016).

Despite new protections enacted in the United States, dismissal of the scientific underpinnings regarding climate change by Donald Trump has raised fears that public access to government climate data and other scientific data will be curtailed. In response, scientists at several major universities developed tools and organized data-rescue events to rapidly archive government scientific data on nongovernmental servers to ensure continued public access (Holthaus 2016). Although efforts such as DataRefuge (<http://www.ppehlab.org/>) provide a defense against loss of public access to government data, they are not a substitute for stronger institutional safeguards that would mandate continued access and collection of new data.

Bias and Lack of Transparency in Considering Input from Nongovernmental Scientists

Informed debate and provision of robust scientific evidence for decision making requires comprehensive access to available science, much of which is not done by government scientists. The extent to which and ways in which science produced by nongovernmental scientists informs conservation policy decisions differs among the 3 nations. Consequently, reforms necessary to ensure that independent scientific input is solicited and considered without political bias also differ. Environmental statutes in the United States contain extensive requirements for science-based decisions. For example, the U.S. Endangered Species Act (ESA) (16 U.S.C. §1532 4(a)(1)) requires listing and delisting decisions for certain species

be based solely on scientific data (Doremus 2004), and agency policy requires external scientific peer review of draft decisions to ensure scientific integrity. The U.S. courts play a prominent role in adjudicating policy disputes, and litigation often hinges on whether an administrative agency's decision follows from the available science.

In Canada and Australia, few statutes require independent scientific input into conservation policy, aside from the public-comment period. However, the Canadian Species at Risk Act formalizes the role of an independent scientific advisory body (Committee on the Status of Endangered Wildlife [COSEWIC]) to assess species at risk. The committee conducts independent scientific reviews on the status of species at risk and makes the results publicly available, whether decisions support or reject listing (Hutchings et al. 2017).

Much authority for conservation policy, especially in Canada and Australia, resides at the state and provincial rather than the federal level, and the role of science in policy often differs between the 2 levels. For example, in New South Wales, Australia, listing of threatened species and ecosystems is decided by an independent scientific committee, whereas at the federal level, although an analogous committee exists, its recommendations must be approved by the minister for the environment (Nicholson et al. 2015).

To illustrate key reforms to protect the integrity of independent scientific input into policy, we examined several recent agency decisions related to the ESA, the main statute designed to protect biodiversity in the United States (Fig. 1). We considered the ESA because it contains clear requirements that policy makers incorporate independent scientific input, yet 73% of staff survey respondents at the U.S. Fish and Wildlife Service (FWS), one of 2 agencies that implement the ESA, thought improper political pressure remained too high despite the ESA's science mandates (Goldman et al. 2015). We linked our suggested reforms to examples from Canada and Australia where possible.

Reforms to Safeguard the Scientific Integrity of Inbound Communications

Broaden the Scope of Information Solicited from Independent Scientists

Agencies are constantly faced with the policy question, should we act? This initial decision is often heavily influenced by an agency's scientific evaluation of the facts. However, in many agencies only the decision to take proactive action is subject to peer review. For example, the ESA requires 2 federal agencies (FWS and the National Marine Fisheries Service) to make determinations about adding or removing species from the law's lists of protected species. Currently, external peer review of

decisions to list a species as endangered or threatened is required but external review is not required for decisions not to list a species.

The wolverine (*Gulo gulo*), a mid-sized carnivore, is threatened by loss of snow-covered denning habitat (Fig. 1). Although FWS scientists concluded that threats to the wolverine from climate change qualified the species for listing as threatened, FWS leadership overruled these conclusions and declined to list the wolverine. A federal court subsequently concluded that the decision to deny protections was not consistent with the best available science and was likely due to "immense political pressure" by states that opposed listing (*Defenders of Wildlife v. Jewell*, U.S. District Court for the District of Montana, CV 14-246-M-DLC. 2016). If regulations had required the decision not to list to be subject to review by nongovernmental experts, litigation might not have been necessary. Although increasing the number of decisions requiring outside peer review will result in increased time and costs for the agency, these may be offset by more robust conservation outcomes and less litigation. However, previous informal peer reviews of the FWS scientists' conclusion in favor of listing showed that their conclusion was scientifically sound, but these reviews were ignored by agency leadership. When the political and economic stakes are high concerning listing of a species, litigation may be difficult to avoid, at least in the United States.

Even in Canada, where scientific advice is required to inform both positive and negative listing decisions, political actions can constrain the role of scientific advice in the process. Although COSEWIC assessments are based solely on evidence, species receive no formal protection until the relevant minister submits the species-at-risk files to the prime minister's cabinet for final approval and the consultation process concludes (Hutchings et al. 2017). This legislative loophole allows for politically motivated delays. Under the Harper administration, the minister of the environment ceased transmitting COSEWIC advice to the cabinet to delay protection of as many as 198 species, subspecies, and distinct populations in Canada, including the shortnose sturgeon (*Acipenser brevirostrum*) (Noël 2016) (Fig. 1).

Agencies also often seek to narrowly define the scientific questions presented to peer reviewers to insulate controversial scientific determinations from review. For example, the scope of peer review of Klamath Basin (U.S.A.) water policies by the National Academy of Sciences and National Research Council was manipulated by direction from Vice President Cheney (Fein 2011). Another example is the review of the proposed delisting determination for the gray wolf (*Canis lupus*), for which reviewers were directed to focus solely on taxonomic issues, rather than consider the full spectrum of scientific questions on available habitat and other topics relevant to the analysis required under the ESA (FWS 2013).

Ensure a Diversity of Independent Scientific Input with Transparency Regarding Conflicts of Interest

Selection of peer reviewers by agencies and contractors remains vulnerable to political interference. The FWS often specifies in the statement of work for peer review that prior “advocacy” disqualifies scientists from serving as peer reviewers (FWS 2013). This clause has been used to exclude scientists who interpret their science for the broader public or comment during a regulatory comment period. Because scientists who have taken positions supportive of agency policy are typically not considered advocates, this screening process may lend bias to reviews.

Political screening processes may subvert the effectiveness of legislation intended to protect declining species. Prior to 2009, COSEWIC recommendations to the Ministry of the Environment for expert appointments were routinely accepted. Under the Harper administration, there were concerns over potential political interference after scientists who had publicly commented on conservation issues were denied renewal of their COSEWIC appointments (Noël 2016). In 2013, negative coverage of the exclusion of key experts from the peer review of national wolf delisting forced the FWS to suspend the initial contractor-led scientific peer review and commission a more independent review by the National Center for Ecological Analysis and Synthesis (Morell 2014). The review by a panel of experts (which included scientists previously excluded from the review) concluded that the proposal was not based on the best available evidence (Morell 2014).

No-advocate reviewer selection policies, where they still exist, should be reformed to reflect peer review policies that explicitly value a diversity of independent and qualified scientific perspectives. The U.S. Office of Management and Budget has such a policy stating that “[o]n most controversial issues, there exists a range of respected scientific viewpoints regarding interpretation of the available literature. Inviting reviewers with competing views on the science may lead to a sharper, more focused peer review. Indeed, as a final layer of review, some organizations (e.g., the US National Academy of Sciences [NAS]) specifically recruit reviewers with strong opinions to test the scientific strength and balance of their reports” (OMB 2002).

Another problematic aspect of current U.S. agency peer-review policies involves undisclosed conflicts of interest by the large corporate contractors frequently used to manage the peer-review process. Although this approach gives the appearance of providing an arms-length separation between the agency and peer reviewers, the reality is often different. Conflict of interest may result in biased selection of peer reviewers and a biased summary of peer reviews being provided by the contractor. Conflicts of interest may arise when the same corporation also

performs services for entities that have a vested interest in the policy under review (Goldman et al. 2015). For example, a consulting firm that has managed hundreds of government peer reviews for toxicological assessments of chemicals also frequently conducts reviews for the chemical industry and has been criticized for relying on a small circle of experts with industry ties as reviewers (Adams & Song 2014). Although the FWS has recently taken steps to document conflicts of interest by individual peer reviewers (FWS 2016), the new policy does not ensure transparency concerning conflict of interest by the contractors themselves.

A key difference between scientific-journals peer review and scientific review that occurs as part of regulatory decision making is the absence in the latter of an independent editor or arbiter who decides whether the agency has adequately addressed shortcomings identified by reviewers (Greenwald et al. 2012). Agency peer review, especially for highly controversial decisions, could benefit from an additional round in which an arbiter or the peer reviewers themselves evaluate the adequacy of the agency’s response to reviewer concerns. Without this process, the only recourse to address an improper decision is a legal challenge. At a minimum, agencies should be required to produce a detailed statement resembling the response to reviewers required by scientific journals, rather than a general response to public comments as required under current policies.

Strengthening Societal Support for Scientific Integrity

Although the reforms we suggest provide procedural safeguards, the most important factor in protecting scientific integrity may be consistent support from agency leaders and other political appointees. A key lesson from the Canadian experience is that undermining scientific integrity creates a cultural change in public service that is only slowly undone, even after formal policy reform. To institutionalize a culture of scientific integrity, agency leaders should be appointed who have solid track records of supporting determinations made by scientists in the face of political pressure. Policies designed to ensure agency scientists are insulated from political pressure should be compared among agencies and best practices adopted more uniformly across agencies in order to implement a structure and culture that supports independent science (Lowell & Kelly 2016). Agency culture should encourage and reward government scientists when they publish policy-relevant research in peer-reviewed science journals, speak publicly about scientific findings, present at scientific conferences, and participate in professional scientific societies. Finally, those holding key leadership positions in agencies making regulatory policy based in significant part on science should

be required to have a minimum background in a relevant scientific discipline.

Scientific societies can play a valuable public service by performing independent scientific reviews of draft agency decisions. For example, 3 U.S. scientific societies reviewed the recovery plan for the Northern Spotted Owl (*Strix occidentalis caurina*) and identified major deficiencies. Their conclusions led the subsequent administration to substantially revise the recovery plan (SCB 2008) (Fig. 1). Agencies should engage independent nonprofit scientific organizations to oversee the peer review process to increase the independence of the process from political pressure. Such organizations include academic institutes, universities, and scientific societies in the relevant fields. Agencies should invite reviews from scientific societies even in cases where the primary review is done elsewhere, rather than simply passively accepting such input as part of the public-comment process. Agencies should also consider soliciting advice from nongovernmental scientists in cooperation with relevant scientific societies to help strengthen scientific integrity policies.

In turn, scientific societies should work to increase engagement in the policy process by the scientific community. For example, scientific societies should encourage their members to contribute their expertise during public-comment periods required for agency rule making. Such public participation by scientists, if properly framed, does not negatively affect their credibility (Kotcher et al. 2017). There are complementary roles for scientific societies, public-sector unions, and other nongovernmental organizations (e.g., the Union of Concerned Scientists and Evidence for Democracy in the United States and Canada, respectively), and some roles will be more appropriately filled by the latter groups than by scientific societies. Establishing mechanisms through which government scientists can securely share information with NGOs and journalists can help the latter organizations publicize and contest integrity abuses.

Scientific societies can also assist in building public support for the use of evidence in decision making, via coalitions between scientific societies in many disciplines and other nongovernmental organizations. The most prominent recent example is the global March for Science, which involved over 100 scientific organizations in over 600 events designed to defend scientific integrity and increase awareness of positive role of science in society (Wessel 2017). Given recent trends toward politicization of science around issues such as climate change, scientists have a civic responsibility to engage with the wider public to affirm that science is a crucial resource for developing evidence-based policy and regulations that are in the public interest (McCright & Dunlap 2011; Garrard et al. 2016).

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Literature Cited

- Adams R, Song L. 2014. One-stop science shop has become a favorite of industry—and Texas. Inside Climate News 19 December. Available from <https://insideclimatenews.org/news/20141219/one-stop-science-shop-has-become-favorite-industry%E2%80%94and-texas> (accessed May 2017).
- ARC (Australian Research Council). 2015. Research integrity and research misconduct policy. ARC, Canberra. Available from http://www.arc.gov.au/sites/default/files/filedepot/Public/ARC/Feedback%20and%20Complaints/ARC_Research_Integrity_and_Misconduct_Policy_Arp15.pdf (accessed May 2017).
- CSIRO Staff Association. 2012. Integrity test for public sector science. Wavelength: Spring 2012. CSIRO Staff Association, Melbourne. Available from https://csirostaffassociation.files.wordpress.com/2011/07/wavelength_spring2012.pdf (accessed May 2017).
- Doremus H. 2004. The purposes, effects, and future of the Endangered Species Act's best available science mandate. *Environmental Law* 34:397–450.
- Doremus H. 2008. Scientific and political integrity in environmental policy. *Texas Law Review* 86:1601–1653.
- Fein I. 2011. Reassessing the role of the National Research Council: Peer review, political tool, or science court? *California Law Review* 99:465–555.
- FWS (US Fish and Wildlife Service). 2013. Order statement of work peer review of the scientific findings in the proposed rule: removing the gray wolf (*Canis lupus*) from the list of endangered and threatened wildlife and maintaining protections for the Mexican Wolf (*Canis lupus baileyi*) by listing it as endangered. US Fish and Wildlife Service, Washington, D.C.
- FWS (US Fish and Wildlife Service). 2016. Memorandum on peer review process, FWS/AES/DCC/061995. US Fish and Wildlife Service, Washington, D.C. Available from https://www.fws.gov/endangered/improving_ESA/pdf/Final%20peer%20review%20policy%20061995%20Signed.pdf (accessed May 2017).
- Garrard GE, Fidler F, Wintle BC, Chee YE, Bekessy SA. 2016. Beyond advocacy: making space for conservation scientists in public debate. *Conservation Letters* 9:208–212.
- Goldman GT, Berman E, Halpern M, Johnson C, Kothari Y, Reed G, Rosenberg AA. 2017. Ensuring scientific integrity in the Age of Trump. *Science* 355:696–698.
- Goldman GT, Halpern M, Bailin D, Olali A, Johnson C, Donaghy T. 2015. Progress and problems: government scientists report on scientific integrity at four agencies. Union of Concerned Scientists, Cambridge, Massachusetts.
- Government of Canada. 2016. Directive on the management of communications. Available from <http://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=30682> (accessed May 2017).
- Greenwald DN, Suckling KF, Pimm SL. 2012. Critical habitat and the role of peer review in government decisions. *BioScience* 62:686–690.
- Hannam P. 2017. 'Don't rock the boat': Rediscovery of plant kept under wraps as project approved. *Sydney Morning Herald*, January 28. Available from <http://www.smh.com.au/environment/dont-rock-the-boat-rediscovery-of-plant-kept-under-wraps-as-project-approved-20170127-gtzrf3.html> (accessed May 2017).
- Holdren JP. 2010. Memorandum for the heads of executive departments and agencies, 17 December. Office of Science and Technology Policy, Washington, D.C.

- Holthaus E. 2016. Why I'm trying to preserve federal climate data before Trump takes office. Washington Post, 13 December. Available from <https://www.washingtonpost.com/posteverything/wp/2016/12/13/why-im-trying-to-preserve-federal-climate-data-before-trump-takes-office> (accessed May 2017).
- Hutchings JA, Otto SP, Whitton J, Kerr JT, Mooers A, Findlay SF. 2017. Recovering the species at Risk Act. Policy options, February 2017. Institute for Research on Public Policy, Montreal. Available from <http://policyoptions.irpp.org/magazines/february-2017/recovering-the-species-at-risk-act/> (accessed May 2017).
- Khan S. 2017. Why we're marching for science in Australia. The Conversation, 7 March. Available from <http://theconversation.com/why-were-marching-for-science-in-australia-73907> (accessed May 2017).
- Kotcher JE, Myers TA, Vraga EK, Stenhouse N, Maibach EW. 2017. Does engagement in advocacy hurt the credibility of scientists? Results from a randomized National Survey Experiment. *Environmental Communication* 11:1–15.
- Kypri K. 2015. Suppression clauses in university health research: case study of an Australian government contract negotiation. *The Medical Journal of Australia* 203:72–74.
- Lowell N, Kelly RP. 2016. Evaluating agency use of “best available science” under the United States Endangered Species Act. *Biological Conservation* 196:53–59.
- Markham A, Osipova E, Lafrenz-Samuels K, Caldas A. 2016. World heritage and tourism in a changing climate. UN Environment Programme, Nairobi.
- McCright AM, Dunlap RE. 2011. The politicization of climate change and polarization in the American public's views of global warming, 2001–2010. *Sociological Quarterly* 52:155–194.
- Morell V. 2014. Science behind plan to ease wolf protection is flawed, panel says. *Science* 343:719.
- Nicholson E, Regan TJ, Auld TD, Burns EL, Chisholm LA, English V, Harris S, Harrison P, Kingsford RT, Leishman MR. 2015. Towards consistency, rigour and compatibility of risk assessments for ecosystems and ecological communities. *Austral Ecology* 40:347–363.
- Noël B. 2016. How Stephen Harper's government screwed over Canadian wildlife. Vice News, 4 January. Available from https://www.vice.com/en_us/article/there-was-a-dramatic-drop-in-wildlife-protection-under-stephen-harpers-majority-government (accessed May 2017).
- NSW OEH (New South Wales Office of Environment and Heritage). 2016. An open, transparent and accessible OEH. NSW Office of Environment and Heritage, Sydney South. Available from <http://www.environment.nsw.gov.au/resources/whoware/Open-oeh-case-studies-160445.pdf>.
- OMB (Office of Management and Budget). 2002. Guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by federal agencies. *Federal Register* 67:8452–8460.
- Price T. 2009. Scientific freedom of speech: the changing tide. *Optics and Photonics News* 20:12–13. Available from <http://www.osa-opn.org/Content/ViewFile.aspx?id=11162> (accessed May 2017).
- Professional Institute of the Public Service of Canada (PIPSC). 2013. The big chill, silencing public interest science: a survey. PIPSC, Ottawa. Available from <http://www.pipsc.ca/portal/page/portal/website/issues/science/bigchill> (accessed May 2017).
- Ritchie EG, Driscoll DA, Maron M. 2017. Communication: science censorship is a global issue. *Nature* 542:165–165.
- Salleh A, Borschmann G. 2017. CSIRO: leaked emails reveal claims organization ‘missing in action’ on climate advice. ABC Science, 1 May. Available from <http://www.abc.net.au/news/science/2017-05-02/csiro-missing-in-action-on-climate-advice/8479568> (accessed May 2017).
- SCB (Society for Conservation Biology). 2008. Review of the final recovery plan for the Northern Spotted Owl. SCB, Washington, D.C. Available from http://conbio.org/images/content_policy/SCB-AOU_Review_%E2%80%93Northern_Spotted_Owl_Final_Recovery_Plan.pdf (accessed May 2017).
- Sutherland WJ, Pullin AS, Dolman PM, Knight TM. 2004. The need for evidence-based conservation. *Trends in Ecology & Evolution* 19:305–308.
- Wessel L. 2017. From a tweet, a march for science is born. *Science* 355:556–557.



From: [RDAP Google Admin](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Tuesday, July 27, 2021 2:47:59 PM

RDAP (Research Data Access & Preservation) thanks OSTP and the Scientific Integrity Fast-Track Action Committee (SI-FTAC) for the opportunity to provide comments on scientific integrity processes and practices in the US research enterprise.

Appropriate and effective research data management and sharing is an important foundational step for ensuring transparency and integrity in science and scholarship. RDAP's comments focus on policies and practices surrounding the management of and long-term access to research data and other research products (e.g. software, survey instruments, research protocols).

SI-FTAC asked for comments on five specific topics. We list these and our responses below.

1. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science:

No comment on this topic.

2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information:

Making more of the research process transparent, including long-term access to research outputs such as data and software, is an important foundational step towards scientific integrity. **OSTP should continue to enact and strengthen research funding agencies for research data management and public access.** Furthermore, OSTP should advocate that these agencies provide funding for research data infrastructure and services so that researchers can comply with these policies.

A specific action OSTP can take is to **advocate for research funding agencies to ask about researchers' execution of their data management plans submitted with funded research proposals at grant close-out.** Through gathering this information these agencies will learn what gaps exist in infrastructure and services for research data management and public access, and can begin to address these gaps.

Additionally, **OSTP and research funding agencies should continue to engage with and provide support to academic institutions and research organizations in strengthening research data management and public access policies and scientific integrity policies.** Effective enactment of research funder policies can lead to more administrative burden for funded organizations. This burden can unnecessarily slow

research progress across all research organizations and hinder smaller ones from continuing to conduct research.

3. Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce:

The scientific research process should be as transparent as possible but as closed as necessary. RDAP advocates for appropriate public sharing of research outputs. Outputs associated with national security, economic competitiveness and human research participants should not always be publicly accessible. Also, not all research products should be preserved and accessible forever.

Research participants of all genders, races, ethnicities, and backgrounds, whether they are subjects or citizen scientists (or both) should have a say in and should be informed about how their research data is managed, used and publicly shared. RDAP advocates for these principles to be kept in mind while addressing scientific integrity. For data originating from indigenous societies, the CARE principles (<https://www.gida-global.org/care>) provide a useful framework for data management.

OSTP should convene workshops and studies on which research products long-term access should be maintained (and how long 'long-term' is) for the sake of transparency and scientific integrity while accounting for limited research resources.

4. Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices:

Because long-term access to research outputs such as data and software is an important foundational step towards scientific integrity, it is important that researchers be better trained to manage and share these research outputs effectively and appropriately. Many RDAP members have positions that include training researchers in effective research data management and dissemination, and can assist in development of research data policies and practices in their respective organizations. **OSTP and research funding agencies should continue to work with and take advantage of expertise outside of the government in improving research and scientific integrity practices, including expertise within RDAP.**

5. Other important aspects of scientific integrity and effective approaches to improving trust in Federal science:

No comment on this topic.

About RDAP

RDAP (<https://rdapassociation.org/>) supports an engaged community of information professionals committed to creating, maintaining, advancing, and teaching best practices for research data, access, and preservation. The RDAP community brings together a variety of individuals, including data managers and curators, librarians, archivists, researchers, educators, students, technologists, and data scientists from academic institutions, data centers, funding agencies, and industry who represent a wide range of STEM disciplines, social sciences, and humanities.

From: [Phillip Worts](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI - Public Comment
Date: Tuesday, July 27, 2021 4:09:56 PM

Good afternoon,

Evidence-based policy making should be approached the same way evidence-based medicine is approached. Empirical evidence must drive decision making for our legislative bodies. Too often are bills written and laws passed that have little to no evidence in support of the bill. In some cases, the bills are drafted and laws passed directly contradict the best available evidence.

Partisan politics negatively affect the country as a whole and it has only grown more toxic lately as voting rights and female body autonomy are being depleted rapidly.

My suggestion would be to implement a best-practices checklist that outlines required criteria that every bill written should meet in order to be voted on. In medical research checklists for human subject research consent forms utilize this same principal to achieve consistent results that meet the best practices guidelines.

Thank you for your time.

Phillip Worts

From: [Schultz, Lori Ann Mcallester - \(lschultz\)](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FATC RFI: Response University of Arizona
Date: Tuesday, July 27, 2021 5:10:14 PM

Submitted for the University of Arizona, on behalf of:

Elizabeth R. Cantwell, PhD, MBA
Sr. Vice President for Research & Innovation

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The University of Arizona stands for the insatiable curiosity of exploration and the power of inclusion and values the goals of Federally funded research and development (R&D): maintaining economic competitiveness, strengthening national security, improving health care, and protecting the environment as matching what matters most to our institution.

The University of Arizona appreciates the opportunity to provide information and feedback on the White House Office of Science and Technology Policy (OSTP) Federal Register notice “Request for Information to Improve Federal Scientific Integrity Policies (Federal Register Nol. 86, No. 121). Comments on specific items from the Federal Register notice are listed below.

Policy and Definitions: There is no uniform or consistent definition of scientific integrity across federal agencies or how it is related to research misconduct. Only a framework for the policies and procedures that might fall under the integrity umbrella exists. Implementation of such policies is made more challenging when scientific integrity issues intersect more than one federal funding agency. Meaningful policies, and those that are easiest to follow, must be consistent and provide clear guidance to both agencies and recipients.

Review of Processes and Inclusion of Stakeholders: While clear policies are important, review of the systems and constructs supported by existing policies is critical. A new policy will fail if systems and processes are not updated to remove obstacles and incentivize desired behavior. Some examples:

- *Merit-based peer review:* Longstanding processes for the review of grant applications create the conditions for non-disclosure of possible conflicts of interest/commitment or variable reporting of interests with the goal of putting one’s best foot forward from application to application. Aside from clear and consistent reporting requirements, this information is best captured as “Just-In-Time” prior to award, to encourage complete and accurate reporting.
- *Include Higher Education in Policy Discussions and Rulemaking:* Issues

surrounding foreign influence and the resulting policy clarifications have shown us that changing one side of the equation without systems approaches only creates confusion and more opportunities for non-compliance. Federal agencies should continue to engage the grantee community in these conversations so that everyone has the tools to make these policies effective.

- *Evidence-Based Policies and Sharing of Information:* As the evolving foreign influence situation shows, policy decisions cannot be made in a vacuum. Grantees have a difficult time creating effective compliance when there isn't enough information to provide support and assistance to researchers.

Invest in Open Access: The sharing of materials, data, and knowledge creates accountability, honesty, and the ability to own and correct errors. Infrastructure and resources are needed to ensure data replication, management, and storage.

Integrity is a collaborative practice. Effective policies must be developed using accurate scientific information that is supported by consistent and transparent integrity policies. When these policies have clear roles and responsibilities, all parties are able to contribute to outcomes that strengthen the U.S. R&D enterprise.

From: [Greg Guthrie \(Fed\)](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Cc: SI-FTAC-RFI
Subject: Tuesday, July 27, 2021 5:49:29 PM
Date:

Hello,

I submit this suggestion to the White House Office of Science and Technology Policy as an interested individual who works for the Federal Government, and is a Union member.

I work for the National Technical Information Service (NTIS) of the Commerce Department, and am a member of the National Federation of Federal Employees (NFFE) local 1627.

I believe that scientific integrity and faith in science could be enhanced by instituting a “Science Court”

This idea is not new – in fact I read about it in a report that I found here in the NTIS’s National Technical Reports Library (NTRL) database.

Proceedings of the Colloquium on the Science Court, Held at Leesburg, Virginia, on September 19-21, 1976.

[>https://ntrl.ntis.gov/NTRL/dashboard/searchResults/titleDetail/PB261305.xhtml<](https://ntrl.ntis.gov/NTRL/dashboard/searchResults/titleDetail/PB261305.xhtml)

There are numerous articles on this idea on the internet as well. See

[>https://pubmed.ncbi.nlm.nih.gov/17759241/](https://pubmed.ncbi.nlm.nih.gov/17759241/)
<

I believe that such an interdisciplinary approach – a “Science Court” –consisting of leaders and members from Government, Industry, Law, Science, Labor Union members from science Agencies , News media, and others – could provide a venue that would foster scientific integrity.

Thank you.

Greg Guthrie

Gregory G. Guthrie
Management Analyst
Office of Program Management
National Technical Information Service (NTIS) US Department of Commerce

July 27, 2021

Ryan Donohue
Scientific Integrity Fast-Track Action Committee
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

Dear Mr. Donohue,

In response to the White House Office of Science and Technology Policy's (OSTP's) Request for Information on efforts to promote and protect scientific integrity to enhance public trust in science, I am writing to highlight several relevant activities within the National Academies of Sciences, Engineering, and Medicine (the Academies) and to offer the Academies' significant knowledge and leadership in this area as assistance for this effort.

The Academies has recently announced the formation of the Strategic Council for Research Excellence, Integrity, and Trust (the Strategic Council), created in response to several key reports recommendations that an independent body be created to review, improve, and promote scientific policies and procedures across the scientific enterprise (including researchers, funders, research institutions, journals, and organizations that apply science to sound policy).¹ Key goals are to insure that policies across the different stakeholders in the research enterprise are not in conflict and that they result in efficiency, transparency, integrity, and trust.

Additionally, a recent editorial in *Issues in Science and Technology*² outlined a plan to publish a series of articles in 2022 to advance ideas and spur discussion on how the scientific enterprise must evolve over the next 75 years to adjust to a world of accelerated change and, among other things, to improve the connection between science and the public (and its trust). The US government and OSTP have a role to play in this:

“The challenge for national governments is to develop and implement policies that enable countries to benefit from the assimilation of new knowledge to enhance productivity, national well-being, and new ways of doing things.”

¹ <https://www.nationalacademies.org/news/2021/07/new-strategic-council-for-research-excellence-integrity-and-trust-established-by-national-academy-of-sciences-to-support-the-health-of-the-research-enterprise>

² <https://issues.org/the-next-75-years-of-us-science-and-innovation-policy-an-introduction/>

Research integrity is a core component in the development of trust in science and policies that depend on excellent scientific research. I would like to offer the Strategic Council and its membership of leaders across the scientific enterprise as an important partner in OSTP's efforts to assess the effectiveness of current policies and to improve scientific integrity across the Federal government. For example, the Strategic Council could be a sounding board for possible ramifications across the research enterprise of actions being considered by OSTP. Our inaugural meeting, held virtually, is October 21 and 25 and I welcome OSTP's participation.

Yours sincerely,

A handwritten signature in black ink that reads "Marcia McNutt". The signature is written in a cursive style with a long horizontal line extending from the end of the name.

Marcia McNutt
President
National Academy of Sciences

July 27, 2021

Dear Members of the White House Office of Science and Technology Policy:

I am writing to you as a concerned researcher at the University of Illinois at Urbana-Champaign in response to the “Request for Information to Improve Federal Scientific Integrity Policies” (86 FR 34064, Document Number 2021-13640). I represent a working group for Reducing the Inadvertent Spread of Retracted Science (RISRS), which brings together diverse stakeholders in the academic publishing ecosystem to address the problems created by the continued citation of retracted research (see <https://infoqualitylab.org/projects/risrs2020/>). Retracted research is research that is withdrawn from the scientific record for reasons of error, misconduct, or fraud.

We welcome the White House Office of Science and Technology Policy (OSTP) initiative to improve the effectiveness of Federal scientific integrity policies to enhance public trust in science.

We encourage the OSTP to

- 1) develop mechanisms for assessing the integrity of reported research, when concerns are raised, that are distinct from processes to determine whether individual researchers have committed misconduct;¹ (Wager et al. 2021)**
- 2) codify best practices for federally funded databases and repositories in handling retracted research; and**
- 3) promote awareness of retraction issues as part of Responsible Conduct of Research (RCR) Education.**

We provide background on these three priorities below.

Current Problem: Retracted research continues to circulate without information about its invalidation. This threatens public trust in science and limits the utility of public data for innovators.

- Research circulates widely beyond expert communities due to electronic and networked research communication and data sharing and public access.
 - Since 2013, federal agencies with more than \$100 million in annual research and development expenditures have been directed to develop and implement plans for increasing public access to the results of the research they support.
- Increased public access includes a risk of exposure to retracted research that is not clearly marked as retracted.

¹ As recommended by the Working group on Cooperation & Liaison between Universities & Editors CLUE Report:

Wager, E., Kleinert, S., on behalf of the CLUE Working Group. et al. Cooperation & Liaison between Universities & Editors (CLUE): recommendations on best practice. Res Integr Peer Rev 6, 6 (2021). <https://doi.org/10.1186/s41073-021-00109-3>

- Professional scientists continue to cite retracted research (1) intentionally, to study it or comment on it; and (2) inadvertently, to use it without mention of retraction, which continues to spread retracted items. Since retracted items are derived from instances in which the scientific process or the integrity of scientific and technological information was compromised, their use may threaten the validity of new work.
- It is imperative that new forms of access to the results of research be accompanied by federal guidance and guidelines on best practices regarding retracted research and associated data.
- This has particular importance for data impacting human health studies and for federal agencies charged with promoting cost-effective evidence and science-based policy.
- There is a growing awareness of retracted research in the public, amongst the scientific community, and in the scientific publishing industry. Further guidance is needed on retractions in federally-funded and federally-disseminated scientific information.

Statement of Need: Access to publicly funded scientific information and data helps to leverage federal investments in research, innovation, and entrepreneurship. However, flawed research undermines the use of and confidence in this information and data. Policies designed to ensure the public's ability to search, retrieve and utilize research and data lack clear guidance on how to identify, withdraw, or retract erroneous or outdated findings.

- As noted by the 2021 Cooperation & Liaison between Universities & Editors (CLUE) Report¹, “develop mechanisms for assessing the integrity of reported research (if concerns are raised) that are distinct from processes to determine whether individual researchers have committed misconduct”.
- Provide guidance and exemplar protocols indicating how agency repositories should mark items as retracted or withdrawn, with the reasons for retraction where possible.
 - Codify best practices for federally funded databases to facilitate the public and unrestricted access to and dissemination of retraction notices. Build off of existing databases that do this. At minimum, databases should feature APIs to track and disseminate retraction statuses.
 - Example: PubMed is a federally funded public database with an API that allows for unrestricted access to and dissemination of retraction notices, but only covers biomedicine.
- Promote awareness of retraction issues as part of Responsible Conduct of Research (RCR) Education topics in federal funding agency guidance. Provide guidance for understanding and working with the evolving landscape of post-publication amendments (e.g. editorial notes, corrections, and expressions of concern).
 - Encourage institutions to develop authorship guidance which emphasizes the need to correct publications (including retraction, if necessary), published

data sets, and other research products as an expectation of responsible research.

My RISRS colleagues and I would welcome further conversations on these priority areas.

Sincerely yours,

Jodi Schneider

Assistant Professor of Information Sciences

University of Illinois at Urbana-Champaign

PI of Reducing the Inadvertent Spread of Retracted Science: Shaping a Research and Implementation Agenda, funded by the Alfred P. Sloan Foundation,
<https://infoqualitylab.org/projects/risrs2020/>

Response to Request for Information To Improve Federal Scientific Integrity Policies

Submitted by: Virginia Zaunbrecher, JD, as an individual

Respondent type: Academic

The U.S. Government can better facilitate scientific integrity by making it easier for U.S. researchers to fund foreign collaborators with federal grant funding in limited circumstances.

This issue is directly relevant to the following charges of the Scientific Integrity Fast-Track Action Committee (SI-FTAC):

- 1) “Support scientists and researchers of all genders, races, ethnicities, and backgrounds,” and “advance the equitable delivery of the Federal Government's programs.”
- 3) “[I]dentify effective practices for implementing scientific integrity policies in specific areas of particular interest, including . . . addressing . . . evolving scientific practices.”

Funding of international science is critical to addressing global problems

The U.S. Government funds a broad range of research that includes work on global challenges that are crucial to our long term national security and prosperity, including climate change, pandemics, and food security. Some of this work by necessity takes place in foreign countries that offer habitats, species, research infrastructure, and field locations that cannot be accessed in the U.S., and enhance the research conducted by American scientists. It is critical for American scientists to retain access to these foreign research environments if they are to continue vital work on global and interconnected challenges. This work also opens opportunities for science diplomacy, building global scientific capacity and generating good will for the U.S.

Collaboration with local scientists enhances American research

Collaborating with foreign counterparts enriches American research and researchers. This is particularly true in instances where local knowledge, cultural literacy, and local connections to communities and decision makers make it easier to conduct research with respect and integrity for host populations. Local researchers can contribute insights that improve experimental design, for instance pointing out how a survey protocol could be modified to better reach target populations. Local researchers also help connect research teams to decision and policy makers, increasing the potential impact of American science. International research experience can expose American scientists to new skills, cultures, and techniques. Conducting collaborative research with local scientists is an important aspect of scientific integrity.

The norms and laws that govern international research are evolving

American scientists are undertaking international research as the world reckons with the colonialism, exploitation, and interference that historically have pervaded international scientific practice. This is particularly true for research conducted in countries in the global south and

those that are former colonies of western powers. It is no longer acceptable for American scientists to take data, biological samples, or other scientific materials back to the U.S. from a foreign country without some collaboration and benefit sharing with the host country.

This historically exploitative approach to research increasingly raises legal issues for U.S. scientists conducting research in foreign countries, in addition to moral ones. The Nagoya Protocol sets standards for visiting scientists to share benefits with the countries where they source genetic materials. For instance, an American scientist who travels to Cameroon to sample a species for molecular genetics research needs to demonstrate benefit sharing with Cameroon to legally export the samples, even though the U.S. is not a party to the Nagoya Protocol. Many countries also require local collaborators to be listed in the applications for permits required to conduct research abroad. These requirements apply to not-for-profit researchers, including many funded by the U.S. Government, and can often be met by forming substantive collaborations with local researchers. This can include co-advising a graduate student, paying for the costs of field work for foreign collaborators, or supporting the salary or laboratory costs of local scientists. This work often takes place in countries that lack domestic research funding, leaving local scientists without access to resources to support their research. Expecting local scientists who have limited access to research funding to participate in research activities as required by national law without financial support is unrealistic and unfair. Conducting research in these host countries without substantive collaboration is unethical, and, increasingly, illegal.

Federal research funding agencies increasingly limit or ban funding for foreign collaborators

At the same time this global push for equity and benefit sharing is occurring, U.S. scientific funding agencies are becoming more restrictive in their ability to fund foreign collaborators. For example:

NASA: “If the foreign investigator does not have a position at a US institution, then NASA funds cannot be used to support them, not even for travel.” (NASA)

NSF: “Foreign organizations - NSF rarely provides direct funding support to foreign organizations. NSF will consider proposals for cooperative projects involving U.S. and foreign organizations, provided support is requested only for the U.S. portion of the collaborative effort. In cases however, where the proposer considers the foreign organization’s involvement to be essential to the project (e.g., through subawards or consultant arrangements), the proposer must explain why local support is not feasible and why the foreign organization can carry out the activity more effectively. In addition, the proposed activity must demonstrate how one or more of the following conditions have been met:

- The foreign organization contributes a unique organization, facilities, geographic location and/or access to unique data resources not generally available to U.S. investigators (or which would require significant effort or time to duplicate) or other resources that are essential to the success of the proposed project; and/or

- The foreign organization to be supported offers significant science and engineering education, training or research opportunities to the U.S.” (NSF)¹

These restrictions severely limit U.S. scientists’ ability to support local collaborators, particularly those from countries that lack domestic scientific funding streams. While agencies sometimes offer work arounds, such as treating foreign collaborators’ work as “services” that are contracted for, these work arounds are imperfect, often ineffective, and relegate foreign scientists to roles as service providers rather than true collaborators. Such classifications degrade the integrity of scientific partnership.

Increased flexibility in federal funding for foreign collaborators is necessary for scientific integrity

American scientists need resources for some foreign collaborators to practice science ethically, legally, and with integrity. Funding to support foreign collaborators should be available for projects that must work internationally in countries that have limited domestic scientific funding, and where American researchers are gaining access to samples, local knowledge, unique habitats, or other scientific resources. This funding can be used to pay research costs for local collaborators, support local graduate students, or reimburse for time local researchers spend on projects.

It is possible to distinguish circumstances where U.S. funding for foreign collaborators is critical to maintain scientific integrity from circumstances where collaboration and financial support imperils national security or competitiveness. Concerns over the latter have driven increasing restrictions on U.S. funding of foreign research collaborators at the expense of the former. To maintain integrity among American scientists who work internationally to address complex, critical problems, U.S. scientific funding agencies should implement a balanced and nuanced approach that is more permissive of funding foreign collaborators who lack access to domestic funding sources, while limiting funding in circumstances that implicate national security concerns.

For example, the Cuvette Centrale in Central Africa is the world’s largest tropical peatland complex and stores an estimated 30 billion metric tons of carbon (Dargie et al 2017), making it a critical protection priority to prevent further climate change. The participation of Congolese researchers could enhance American-funded research on the Cuvette Centrale by increasing access to remote field sites, providing access to local knowledge about forest dynamics and land use, and connecting researchers directly to policy makers responsible for land use decisions. Since the Republic of Congo has almost no resources to support basic scientific research, grant funding from American institutions would be critical to support Congolese participation. Treating Congolese collaborators working with Americans to research and protect the world’s largest tropical peat deposit the same as, for example, Chinese government scientists working on super-durable materials for use in space exploration would not make any sense. U.S. research funding can and must distinguish between these vastly different circumstances.

¹ While these are the general guidelines for NSF, many actual calls for proposals specifically bar funding support for foreign collaborators, including collaborators who are required to play a substantive role in the project.

While there are irregular opportunities to apply for funding for foreign collaborators (e.g. the USAID PEER program), the lack of consistently available funding makes it very difficult for American scientists to design and implement research projects that take place in the developing world. While there are some national security and intellectual property concerns around funding foreign scientists, it is entirely possible to design funding rules that allow for the financial support of foreign collaborators under appropriate circumstances. Standards based on per capita research funding, rating on the Nature Index or a similar measure of scientific output, and legal requirements in the country where research is taking place could be used if necessary, although administrative burdens to access such resources should be minimized.

Allowing funding for foreign collaborators in certain instances improves American researchers' ability to follow international laws regarding sample collection, improves their science by incorporating local knowledge, and supports their efforts to operate with integrity under evolving scientific practices regarding international and community-engaged research. Making such support the norm rather than the exception would also send a clear message that U.S. research funding agencies prioritize integrity, inclusion, and fairness in the practice of science.

The comments above are based on my experience designing international research partnerships in my role as the Associate Director of Congo Basin Institute. The Congo Basin Institute develops collaborative research partnerships to find solutions to pressing challenges facing the Congo Basin and the world. I am making this submission as an individual, and not on behalf of any institution.

References

Dargie, GC; Lewis, SL; Lawson, IT; Mitchard, ETA; Page, SE; Bocko, YE; Ifo, SA. 2017. Age, extent and carbon storage of the central Congo Basin peatland complex. *Nature* 542:86-90.

NASA FAQ page, #14: <https://science.nasa.gov/researchers/sara/faqs#14>

NSF Proposal & Award Policies & Procedures Guide (PAPPG), Part I, Chapter I, §E.6: https://www.nsf.gov/pubs/policydocs/pappg20_1/pappg_1.jsp#IE

Science has a great role in society as a process for answering questions and in pursuit of the truth. This essential role requires that scientists are rigorous, dedicated, and focus on the pursuit of the truth. Scientific integrity policies should be designed to help pursue this noble goal. In addition, the unfettered ability to pursue the truth regardless of the ideology of the presidential administration or Congress instills trust in federal science agencies amongst the public.

I am Dr. Adrienne M. Wooten (Ph.D.), a climate scientist at the University of Oklahoma. I am writing representing my own views as an academic regarding scientific integrity and approaches that could be taken to improve public trust in science agencies.

Science is a process for answering questions and a philosophy whose normative principles are grounded in reason and objectivity. The four main normative principles (originally named by Merton 1942, [discussed in depth here](#)) are communality, universalism, dis-interestedness, and organized skepticism. Policies surrounding scientific integrity and public trust in federal science agencies should be entirely based on these four principles as they on their own provide the basis for many of the institutional practices of science. In addition, policies around scientific integrity and public trust should not incorporate anything based on critical theory, critical race theory, or critical social justice. Let me start first with the principles.

The first normative principle, communality, states that scientific knowledge belongs to all. It is the basis from which the practice of publishing and the push for more open access publications comes. The opposite of communality is secrecy. Multiple polls show that the public trust scientists more if the data and methods are publicly accessible ([example here](#)). Therefore, I recommend requiring that all publications and data be made more accessible. The current situation has multiple avenues depending on the agency for hosting data, publications, and final reports for projects depending on the funding agency. It appears that it is being more hidden when the publications and data from federal scientists are in obscure places on government websites and not easily accessible. In addition, a commitment to transparency and the common ownership of scientific data necessitates a two way dialogue. Therefore, it should be encouraged and required that scientists in the federal government answer all questions in a timely manner when a question is asked by the public. I recommend that the administration establish a process to facilitate open communication between federal scientists and the public to communicate and build trust.

The second normative principle, universalism, is simply that the work of a scientist should be judged only on the basis of impersonal criteria. That is, the work of all scientists should not be judged based on race, sex, gender, professional affiliation, or any other aspect that irrelevant to the work. The work of a scientist should only be judged on whether the work is conducted in an unbiased manner and answers the question posed. As such, scientific integrity policies should strictly enforce the principle of universalism. That is, scientific integrity policies should strictly mandate that any discrimination on the basis of any immutable characteristics is impermissible. This includes forbidding discrimination against white people, men, and Christian and Jewish people, which is also supported and required of the federal government by the Fourteenth

Amendment and the Civil Rights Act. These rules should be publicly accessible also. Treating people as the unique individuals and brilliant scientists that they are is an excellent way to ensure scientific integrity and promote trust.

The third normative principle is dis-interestedness. Dis-interestedness is quite simply that a scientist's research should remain uncorrupted by self-interested motivations. Taken to its full extent, dis-interestedness is that a scientist should do research only to pursue the truth not to satisfy any ideology. It was concerning to see in the RFI that the administration is interested in preventing "improper political interference." This statement implies that there is a "proper political interference." All political interference is improper, degrades scientific integrity, and damages public trust. My recommendation is to develop a system to allow scientists to report and have alleged instances of political interference reported and investigated. In addition, conflict of interest reporting should also be required and enforced.

The final normative principle is organized skepticism. Under this principle, dialogue and debate on topics is encouraged focusing on the work and arguments presented. It is improper to judge the motives and intentions of a scientist when discussing and debating work. In this vein, bullying and harassment among scientists is unacceptable. In addition, federal scientists should not be disrespectful and answer public criticisms with respect. The policies of the federal government with regards to scientific integrity should incentivize cooperative discussion and debate and encourage scientists to engage respectfully with the public (especially those who are critical and disagree).

Scientific integrity should center around supporting these four normative principles of science. These also, in part, will help improve the public trust in federal science agencies. In addition, it should be recognized that a significant percentage of the population doesn't trust science as an institution. An important reason for this was neatly articulated in a [recent piece in the Wall Street Journal](#). In short, there is a hubris among established scientists and federal agencies that if people only listened to them things would be great. This is a patently untrue belief, but it is one that I (as an early-career scientist) have observed many times. Trust is destroyed if you treat the public that funds you with disrespect. Move in a way to change the culture of federal agencies and academia to understand and respect the public as equal human beings. One recommendation I suggest is requiring a service component to some early career grants and graduate school grants to serve in the community.

Finally, I strongly encourage and recommend that no material from Critical Theory, Critical Race Theory, or Critical Social Justice (hereafter referring to all as CT) be incorporated into any scientific integrity policies. [CT, with its roots in postmodern thought, is often either indifferent or openly hostile to science, viewing it as often a "white way of knowing." CT in practice also forces conformity of thought around all issues, encourages groupthink, and \(because it views everything as political\) encourages political interference in everything including science.](#) CT also:

- Holds that only those people with "lived experiences" have [knowledge of certain things](#) (in violation of communality)

- teaches that people should be treated differently on the basis of immutable characteristics ([as shown by oppression matrices for example](#) and in violation of universalism).
- Has a political activism component to serve its own self interests ([James Lindsay showing text from Critical Race Theory: An Introduction](#)), which will encourage political interference in violation of dis-interestedness.
- Regularly assumes that a person's motives are suspect if one disagrees with its premises ([Cynical Theories](#), pg 198-207). This is shown in prominent examples such as Being White, Being Good (by Barbara Applebaum) and White Fragility (by Robin DiAngelo) and is a direct violation of organized skepticism.

Experience only provides so much information and it does not alone determine thought. [Many people who have the same experiences have very different thoughts about that experience](#). In addition, much of critical theory in practice has prompted multiple lawsuits alleging violations of the Civil Right Act, including one such example of the [employees of the California Department of Fish and Wildlife against the leadership of the department](#). I personally have heard from many members of the public who would not trust federal agencies and scientists if the federal government incorporates CT into scientific integrity policies. Respect for diverse viewpoints and the free debate of ideas is critical to finding the truth to inform policy. The rigorous nature of science with debate will also increase public trust if it is supported. I strongly encourage you to craft scientific integrity policies based on normative principles and philosophy of science and leave those policies themselves free from any political or ideological interference.

The unfettered pursuit of the truth via the scientific process is incredibly important to inform policy on many issues, including climate change. I sincerely hope the administration pursues scientific integrity policies which enforce and support the four normative principles of science. If I can answer any questions regarding my comments, please feel free to contact me.

From: [kfoxhall](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Cc:
Subject: [EXTERNAL] Testimony for OSTP Listening Session : SI-FTAC RFI
Date: Thursday, July 29, 2021 1:36:19 PM

Mean, Ugly Censorship

To the Work Group:

I testified at the hearing 7/28/2021

Below is the written version of my testimony.

Over the last two to three decades agencies in the federal government, like entities elsewhere, have implemented rules that ban employees from speaking to journalists without notifying authorities, often by going through public information officers.

This means in essence that no word can pass without people in power controlling it.

President Biden has been in Washington long enough to have known the days before this was the case and to have seen the transition in the agencies and Congress.

It is mean, ugly censorship. It is pervasive, it is human rights abuse and it is successful. Control of information by people in power has been one of the most debilitating, deadly things in all human history.

You should have the letter that 25 journalism and other groups have signed opposing these restrictions.

I have worked with the Society of Professional Journalists on this, but this statement is mine alone.

Please understand in many agencies reporters can't go into the building. They cannot get credentials to do so even though thousands of employees do. Everyone in the agency is forbidden to speak to them without going to the public information officers, who have been made into our censors. When the reporter goes through the permission-to-speak process, from everything we

hear, most of the time they are not allowed to speak to the person requested. In HHS the request has to go up three levels in the hierarchy. People in agencies have hidden discussions on whether to allow the contact and on what can be discussed. People in high positions block any contact they don't want to happen.

As a 40-year reporter, if there is one thing I can get you to focus on it is that after journalists get the story through official avenues, there is always, routinely, more to the story. And we, the entire public, are walking in mine fields with all the hazards people are silenced about.

I was editor of the American Public Health Association's newspaper during the very dark early days of AIDS. That was years before the agencies began the censorship. No one necessarily knew which reporter talked to which employee. In just one example, a fairly-highly placed official at CDC educated me about some basics, on the condition that his name not be used. That could have been worth a million lives eventually, given that we were still early in the infection spread and I was writing for public health professionals.

In contrast, the official story I would otherwise have written was interesting, accurate and insidiously curated, devoid of even basic facts that tended not to support the administration's policies.

Thankfully, sometimes staff members today defy the rules and speak to reporters outside official avenues. However, it happens much less often because most contacts are banned and there are the censors on conversations.

Officials say they need to coordinate the information and that it is dangerous to let people just talk: they might say the wrong thing.

Coordinating the official story may be a legitimate function for agencies and offices.

However, despite all our divisions in this country, nobody wants to be allowed to hear only the story officials coordinate for them.

Free speech can be problematic, sloppy and dangerous. It has never been as dangerous as mechanisms people in power can use to control information according to their own inclinations.

Questions for the workgroup and OSTP:

---Why is it necessary to have such controls on staff members when it was not in the past?

---Why should people in official positions be allowed to implement such blockages on contacts?

---How do you know enough about the workings and character of agencies like CDC, NIH, FDA or EPA? How does anyone have a sufficient overview when the agencies control public scrutiny of themselves? Are there any independent persons watching for any of us, since the press is not there?

---Why would an agency with so little oversight not develop serious corrosion? What do we know about that? Why are we taking the risk?

---Since we know about these restrictions what responsibility do we have to the human lives that depend on these agencies?

Kathryn Foxhall

Hello, and thank you for soliciting public comment. I am a physician who practiced family medicine, including obstetrics and pediatrics, for 25 years in Washington State. I believe that the science of medicine can provide a blueprint for scientific integrity across government agencies. The science of medicine is for human health; the art of medicine is based on the doctor-patient relationship. I believe that restoration of this relationship, and the return of physicians to the helm of healthcare in this country, is imperative.

I took an oath to First, Do No Harm. The Precautionary Principle guides physicians with the premise that the public should not be exposed to any item whose safety has not been proven. Exposure to thousands of dangerous products has caused catastrophic outcomes for the health of our nation. The issue of integrity is not about the science, but rather about the application of science to protect the public.

Physicians for Human Rights (PHR) was founded on the conviction that health workers can be uniquely powerful voices for human rights, which are a bedrock necessity for human health. PHR believes that *through evidence, change is possible*; this has been proven around the globe in their consistent use of science as a means of accountability.

The FDA seemingly ignored the science when it recently approved Biogen's new Alzheimers drug despite overwhelming dissent by the FDA Advisory Panel and others. Studies show a complete lack of clinical efficacy as well as significant side-effects, yet Biogen immediately launched an aggressive direct-to-consumer advertising campaign.

The U.S. and New Zealand are the only countries that allow this type of advertising. In America, it contributed to the demise of the doctor-patient relationship. Pharmaceutical advertising to physicians is also deleterious because it usually involves misinformation. A particularly devastating example is the opioid epidemic, intentionally perpetrated by the Sackler family. Interestingly, the same family also launched the Valium epidemic in the 50s, by similarly ignoring the science and misrepresenting the drug to the FDA.

Physicians should be the arbiters of health in America. We must be allowed to apply rigorous science for the welfare of each patient in the context of their family and/or current living situation. Instead, our present system allows private corporations to insure their own profit at the expense not only of public health but also of our democracy.

Another devastating example of the lack of public protection despite the availability of good science is documented in the movie *Dark Waters*. It exposes the undue influence of chemical companies, in this case DuPont, over the EPA. The specific example highlighted in this movie is Teflon; the chemicals are PFAS, Per- or PolyFluoroAlkyl Substances, long known to both industry and to the EPA for their toxicity.

Earlier this month Physicians for Social Responsibility (PSR) released its epic report *Fracking with Forever Chemicals*, revealing what scientists have known for years: that

PFAS and other toxic chemicals are in fracking fluid. They are endocrine disruptors and carcinogens, causing preterm labor, birth defects, childhood leukemias, thyroid problems, testicular and kidney cancer, and more. The Halliburton Loophole allows for use of these known toxins by proclaiming fracking fluid "proprietary." The EPA has failed to regulate PFAS since the chemical companies are always one step ahead in creating new ones.

The recent and horrifying discovery of benzene in spray-on sunscreen products belies the vulnerability of the public to the ubiquity of carcinogens and other toxins in our air, water, food, soil and cosmetics. They are also in our bloodstreams because of unrestrained usage over the past several decades. Policy adherence to the Precautionary Principle would avoid these and myriad other harms to the public. Other examples of known toxins from which the public has not been protected, presumably due to persuasion by unproven science, include

- pesticides, which also cause poisoning and death to farmworkers' children
- bisphenol A (BPA) in plastics and food packaging (which have in some cases been replaced by more toxic bisphenols)
- numerous cosmetic ingredients including fragrances (banned in other countries)
- recombinant bovine growth hormones (rBGH, or rBST), which are banned in Europe, Canada and several other countries. They are in fact promoted on the milk label: "There is no significant difference between milk from rBST-treated and non-rBST-treated cows"
- high fructose corn syrup. Its role in childhood obesity and diabetes, as well as metabolic syndrome in adults, is well-proven but is not reflected in food labeling

In addition to protecting the public from known toxins, peer-reviewed science should be used in our justice system. Such medical issues as hospice care and pregnancy, which belong in the intimacy between patient and physician, are now debated in a legislative context or in a courtroom. According to Christopher Greeley, a pediatrician and expert on Shaken Baby Syndrome (SBS), some lawyers defend their child-abusing clients by arguing in court that SBS is a hoax. Dr. Greeley explains, "This is not a medical argument, but a legal argument in a white coat." White coats belong on scientists and physicians. Child abusers need mental healthcare, not incarceration.

The lack of availability of mental healthcare explains the alarming drop in life expectancy from 1998-2013 for white Americans aged 45-54. This was in contrast to other races in America and to whites in other developed countries. It was because of deaths by suicide, drug overdose, and alcoholic liver disease. These have been termed "deaths of despair" and are prevented by the safety net that is provided in many other countries. The bedrock of this safety net is healthcare for all Americans based on the reliable science that is available but often ignored.

Sadly, deaths of despair are usually related to past physical and/or psychological trauma in the life of the deceased. Trauma and its lasting deleterious effects on the human brain are well-documented. The ever-evolving and expensive pharmaceuticals used to treat mental disorders are unproven, yet the FDA continues to approve them. In

addition, the science supports the diagnosis of Childhood Developmental Disorder (CDC) since it includes all of the behaviors exhibited by traumatized children, but the American Psychiatric Association refused to include it in the Diagnostic and Statistical Manual in 2013 (DSM V). Furthermore, pharmaceuticals are not the best treatment for CDC.

One final example illustrates the necessity of science-based protections is in medical education, which is imperative to the doctor-patient relationship. I spent the pandemic teaching medical school in the Caribbean. The Department of Education loans freely to students despite the often very-low chance of their success. Many predictably fail and are left with huge debt and no prospects. The school pockets the tuition as profit and boasts of wildly-inflated United States Medical Licensing Exam (USMLE) pass rates. When I reported my concerns about the school's misuse of Financial Aid funds to the Department of Education, I asked to see the standards that allow an unaccredited, offshore school to receive these U.S. taxpayer funds. The answer: "We don't make those determinations; that's another department." Medical school faculty and curriculum standards are well-researched, well-documented, and ever-improving; they simply have to be enforced.

The most recent rating of *Americas Most & Least Trusted Professions* as reported by Forbes in 2018 is telling. Nurses, as usual, are #1, followed by physicians and pharmacists. Car salespeople are second from the bottom. Who is below them? Members of Congress. Corporations and special interest groups (who's more special than the American people?) have influenced our elected officials to the point where they no longer represent us. Instead, they have allowed our health, and our very democracy, to become a political football. Returning physicians to the helm and restoring the doctor-patient relationship would be transformative for our country.

I applied to work for the Biden Administration in January, hoping to help Build Back Better. At the time I was unaware of OSTP; It would be an honor to serve with you if that opportunity is available.

Thank you for your commitment to maintaining the integrity of science across government agencies!

Phoebe Woodworth-Jefcoats, Ph.D.
Donald Kobayashi, Ph.D.
Pacific Islands Fisheries Science Center, NMFS/NOAA

27 July 2021

White House Office of Science and Technology Policy
Re: Request for Input to Improve Federal Scientific Integrity Policies

Dear Office of Science and Technology Policy,

We submit the below recommendations to improve the effectiveness of Federal scientific integrity policies to enhance public trust in science. Current Federal scientific integrity policies prohibit interference which impedes the timely release of scientific or technological findings.¹ Yet, current internal review practices can often result in the publication of research results being delayed by several months. In our role as Federal research scientists, we have extensive firsthand experience with the application of internal review policies meant to “ensure that manuscripts intended for external peer-reviewed literature meet basic standards of clarity and scientific integrity.”² While successful in advancing agency goals of ensuring that leadership is kept apprised of forthcoming publications and that no policy misstatements are made, such internal review policies lack efficiency. This lack of efficiency diminishes scientists’ trust in the agencies vetting their research and slows the free flow of scientific and technological information. Furthermore, lengthy internal reviews have a deadening effect on collaboration with non-Federal scientists to whom the protracted process rings of censorship, even when none is taking place. Thus, we recommend the following practices be adopted by Federal agencies:

- All parties should be held accountable to strict internal review timelines – authors, reviewers, and approving officials alike.
- Authors should have a clear path to timely recourse in the event that the internal review process extends beyond stated timelines.
- Manuscripts destined for external peer-reviewed literature (as opposed to agency reports and technical memoranda) should only be subject to Technical and Editorial review if deemed necessary by a supervisor or approving official – not required as a default. Requiring Technical and Editorial reviews is not only redundant to the peer review process, thereby unnecessarily slowing the release of scientific information, it also sends Federal researchers the tacit message that their work is assumed to be flawed unless established to be otherwise.
- Agency internal review policies should take a realistic approach to publications with non-Federal partners as the primary or lead author and agency staff as coauthors. Such an approach should be both expeditious and involve only those steps needed to determine whether a disclaimer is needed.

¹ NOAA Administrative Order on Scientific Integrity (NAO 202-735D-2):

<https://www.noaa.gov/organization/administration/nao-202-735d-2-scientific-integrity>

² NMFS Policy on the Internal Review and Approval of Fundamental Research Communications (National Marine Fisheries Service Instruction 04-113-01): <https://media.fisheries.noaa.gov/dam-migration/04-113-01.pdf>

- In instances when publications are coauthored by staff from multiple Federal agencies, internal review should take place within the lead author's agency. Current practice is for *all* authors' agencies to conduct parallel, non-complementary internal reviews.

Above all, the greatest improvement to enhance Federal researchers' trust in the application of scientific integrity policies and to expedite the free flow of scientific and technological information would be to enhance the timeliness of internal review procedures. Finally, we emphasize that we submit this input as individuals. We do not speak for the US Federal Government, the National Marine Fisheries Service, or the Pacific Islands Fisheries Science Center.

Thank you for considering our input,

Phoebe Woodworth-Jefcoats, Ph.D.
Research Oceanographer

Donald Kobayashi, Ph.D.
Research Fishery Biologist



July 27, 2021

White House Office of Science and Technology Policy

Dear Dr. Lander and OSTP Staff Members:

Thank you for your work on improving Federal Scientific Integrity Policies. My comments, given below, are based on my experience of more than 20 years in academic research, as a graduate student researcher, post-doctoral associate, and Assistant and Associate Professor. In addition to publishing more than 70 research papers and a leading research methods textbook, I have been deeply involved in training, having mentored four successful PhD students (3 others currently in progress, and, since 2017, having served as Director of the University of Pittsburgh Biomedical Informatics Training Program.

As scientific integrity is central to all of these efforts, I offer my responses to the questions raised in the request for information.

1. Effectiveness of Federal scientific integrity policies in promoting trust in Federal science As assessing public attitudes regarding scientific integrity is outside of my field of expertise, I cannot make any empirical comments regarding the efficacy of any policies. However, I note that federal scientific integrity policies are almost completely absent from any news coverage of scientific matters. The OSTP and related agencies should consider outreach strategies and campaigns designed to bolster awareness of any policies, ideally in the context of policy changes aimed at bringing meaningful action in support of integrity. My relevant suggestions are given below.

2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information

To improve the communication of scientific information, Federal agencies can take concrete steps to make relevant information clearer and more useful:

- *Provide meaningful conflict of interest information:* questions regarding possible conflicts are key toward communicating integrity. Clearly and explicitly indicating which conflicts might exist, and when, will help the public understand the impacts of conflicts and allay concerns over lack of transparency.
- *Disclose and discuss potential limits of information:* Presentation of scientific information should be included with clear descriptions of limitations, potential biases, and any shortcomings that might limit generalizability.
- *Adopt common formats:* Any information that might be used to assess scientific integrity should be displayed in clear, well-designed common formats. Similar to the now-familiar RDA labels on food products, these labels would provide clear guideposts for interpreting relevant information.

3. Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce

Several appropriate policies should be enacted to bolster the scientific workforce and efforts to promote integrity:

- *A truly diverse workforce*, including not only scientists of different gender and ethnic backgrounds, but also representing different scientific disciplines and methodologies, should be constantly en-

gaged in addressing and considering questions of integrity.

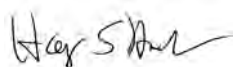
- *External review by outside auditors*, perhaps through a newly-established independent agency, can provide increased confidence in the scientific process.
- *Oversight through career staff, empowered to overrule appointed agency leaders if needed* will be necessary to appropriately act on cases of potentially inappropriate behavior.
- *Meaningful whistleblower protection*: will ensure those that speak out that they will be protected if they raise any concerns.

4. *Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices:*

Integrity and responsible conduct of research training at all levels of the scientific process needst to be improved and integrated into the culture of Federal science activities. When I was a post-doctoral researcher at the National Institute of Aging (2003-2006), the relevant training material was poorly-produced, uninteresting, and treated only as a perfunctory requirement. Better materials are desperately needed, but they are not sufficient. Scientists at all levels should be not only trained, but evaluated, on their adoption of best praictices designed to promote scientific integrity.

These suggestions represent a start. A truly meaningful scientific integrity effort would build upon these and other comments, engaging with the scientific community to build an end-to-end environment and culture in support of transparent, high-quality science.

Sincerely,



Harry Hochheiser , PhD
Associate Professor
Department of Biomedical Informatics
Director Biomedical Informatics Training Program

From: Michael Mummert (member of the public)

Background and Perspective:

The request for information from the White House OSTP encouraged input from members of the public “representing all backgrounds and perspectives.” Here is my background and perspective, mixed in with my comments.

-- Big picture: I have an immune response (specifically, a chemical sensitivity) to chlorine and chloramine (used to kill microbes) in tap water. I have had this immune response for most or all of my life. In my limited interactions with people I personally know, I know of 7 other people who have this immune response or something similar. For a total of eight that I know of, in my very small range of contacts. **Yet, there is approximately no recognition (U.S. Governmental or solid, respectable scientific) that this immune response occurs [in part, because there is no test available. And, there is no test because nobody important will work to have a test developed]. Thesis Statements – (1) Why is that? and (2) How can the government science system change so that this failure (and failures of a similar etiology/cause/origin) ends as soon as possible.**

-- I am a good laboratory chemist with 30 years of industry experience. Although I don't expect to communicate specific information clearly enough to lead to change, I have to try. One of the problems I face (in this communication) is that I don't know how my learnings and insights fit in the larger picture of government use of science. **What I do expect is that the answer to “Thesis Statements (1) and (2)” are a part of what keeps government science from being applied to me and other people in similar or analogous situations, with most of those people being highly vulnerable.**

-- In my job, I have been capable at “knowing approximately where there is something I/we don't know” when working on a technical problem. **Specifically, I don't know what part(s) of my experience as a person who has a “not-government-recognized” immune response (to chlorine/chloramine at the levels that are used to treat all tap water in the U.S.) are useful to “Thesis Statements (1) and (2)”**. I guess that a knowledgeable and perceptive questioner could obtain useful information from me, and I will gladly communicate with someone who wants to ask questions.

-- I have had a set of symptoms, one symptom being persistent, high levels of fatigue, for most of my life. Formally and/or informally, I have been trying to figure out the underlying condition(s) for the last 45 years. Significant medical testing (of me) has yet to explain the fatigue. Notably, several years ago, I asked an allergist to test me for chemical sensitivity to chlorine, chloramine, and/or similar antimicrobials. She said that there was no test(s) available. When I asked her to just place diluted chemical(s) on my skin and make a judgement, she said that would be unethical, with her tone indicating it would be highly unethical. **What lacks consistency with government-funded science on this is that my body itself is a highly sensitive biological indicator of an immune response. So, I am a test, but no test is available?** What is it about an immune response to the two chemicals that are put in possibly every drop of tap water

treated in the U.S. that keeps a test from being available, and thus being able to test/estimate the prevalence of this immune response(s) in a population? **With regard to “Thesis Statements (1) and (2)”, what is it about the science/government combination that keeps this test from being developed, and affected populations estimated?**

-- To recap, I know 7 other people who are similar to me, including two sets of people who are related. Yet, I have not yet found effective communications (and, in my memory, no communications) from government or serious, scientific medicine that study this or publish on it. Tap water is used for drinking, for bathing, for washing hands, for washing dishes, by food companies for rinsing food (along with bleach, which is weird), and by food companies for most beverages. Although my level of chemical sensitivity is not acutely life-threatening, it causes persistent diarrhea, imposes important limits on food choices, and the constant low level immune response appears to target the relative draining of some nutrients (for example, specific amino acids, possibly specific vitamins and minerals) from my body over others. All told, it is too complicated for me to figure out on my own. More generally, members of the public are in a nightmare scenario of no government/scientific/medical support.

-- I believe that tap water needs to be treated to eliminate dangerous microbes, as I am pro-government, pro-science, and pro-public health. I am writing this input in good faith. However, the government needs to research and communicate on the negative health effects of chlorine and chloramine when used to treat tap water, and needs to research and communicate how to mitigate those negative health effects. For example, I have found that using vitamin C to act as a reducing agent for chlorine and chloramine has been effective in my personal use of tap water, as a way to minimize exposure. Drinking reverse-osmosis purified water has also been useful. Government research could find and optimize negative effects and mitigation strategies faster, more broadly, and more ethically than an individual.

-- **When I ask myself the rhetorical question of “Why doesn’t anyone (in government authority and/or solid science authority) research this immune response?,” my current answer, in my words, is that there is a problem in the government culture(s) that actively works against recognizing “wrong” and finding the “range of right”.**

More Background and Perspective

-- I have a B.S. in chemistry, an M.S. in pharmaceutical chemistry, and ~ 30 years experience in industry as a pharmaceutical analytical chemist, as a bench chemist of increasing seniority.

-- I was (and am) a fast learner when functioning well, including being a National Merit Scholar/Finalist in high school.

-- I had (and have) fatigue with no known cause, that increased over time such that by my early 40’s it caused me to sleep an average of 11 hours a day, while still being fatigued the rest of the day.

-- Now in my mid 50's, the fatigue is less, due to some things that I found to work. Because those things are just things that I found to work, I believe it would be unethical to mention them in this public discussion. However, I am willing to appropriately discuss them if contacted.

-- After writing my first good draft, I recognized that there were many dead ends and successes that I did not include. I further recognized that government-funded research and communications amongst a broad set of people could do hundreds of times more than the sum of my experiences, in times as short as 3 to 6 months, compared to the 45 years I have been dealing with it. So, I added this note, but not further experiences.

July 28 2021

Scientific Integrity Fast-Track Action Committee (SI-FTAC)

Office of Science and Technology Policy

Eisenhower Executive Office Building

1650 Pennsylvania Avenue

Washington, DC 20504

Sent by email to: ScientificIntegrityRFI@ostp.eop.gov

To: Members of SI-FTAC

From: Taylor & Francis Group, Priya Madina, Director of External Affairs & Policy
Respondent type: industry (academic publisher)

Ref: Taylor & Francis Group response to [Request for Information To Improve Federal Scientific Integrity Policies](#) (86 FR 34064)

Academic publishers, including Taylor & Francis, are experienced and highly skilled in managing how research is shared, disseminated, and made accessible to all its stakeholders. As a result, we hope that our insights to this OSTP request will be useful. **We would be very happy to follow up on any of the points raised and support the Committee and OSTP with the evolution of policies and practices designed to assure scientific integrity.**

Drawing upon our experience, we offer the following comments and suggestions on the specific items raised:

1. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science

In our experience, trust in science and research blossoms when there is a visible commitment to accountability, transparency, and equity.

Recent public health events highlight that **our definition of ‘science’ must be holistic and encompassing**. This includes research from Arts, Humanities, and Social Sciences (HSS) in resolving world crises, as more holistic evidence-based policies are produced by governments when informed by science from across the disciplinary spectrum. A live example is the Coronavirus pandemic, highlighting the value of all disciplines in generating knowledge and enabling society to act upon that knowledge and progress¹. The recent ISI report on subject

¹ Paraphrasing Will Hutton, the incoming president of the Academy of Social Sciences

<https://www.theguardian.com/commentisfree/2021/apr/15/britain-harness-social-sciences-covid-pandemic-deprivation>

[Accessed 08/07/2021]

diversity also notes “*Diversity of research contributes to stability, resilience and innovation in ecological and economic systems*”².

To support trust in research, it is essential that the origins of research, such as research funding source and institution affiliation, are captured systematically and published alongside outputs. Publishers have been working alongside infrastructure and bibliographic indexing agencies, such as Crossref, to certify and provide structured and transparent information about the provenance and contributions to research. **The OSTP, federal agencies, and publishers could align on doing this more systematically.**

To ensure that all Americans trust in science, research must be carried out and communicated by a research community which reflects the diversity of wider society. Many publishers are working to enable greater diversity across journal editorial boards and introduce ways for researchers and communities from all walks of life to participate in research. **This is a practice that the OSTP could look to emulate, expanding opportunities for all stakeholders to become involved in the process and scrutiny of research.**

Many publishers are also working alongside research advocacy organizations and policy think tanks to ensure that there is an effective bridge between research and policy and practice. This is important – both to support effective messaging and communication of research findings and to ensure that these outputs are framed within the context of the end user. **OSTP could consider how it makes all audiences of research aware of its origins and robustness, to ensure holistic assessments are made about trust and use of the research.**

Several research publishing initiatives already exist to support transparency, trust, and integrity around research. **OSTP could consider how to align any relevant policies, looking to develop working partnerships where appropriate.** For example:

- [Crossmark](#) is used to reassure users that they are viewing the most up to date version of a research outcome, capturing any corrections, and clearly signposting retractions.
- The [Committee on Publication Ethics](#) creates best practice guidance for editors and researchers to address any issues around research integrity and prevent these occurring in future.
- The [Think. Check. Submit.](#) Initiative provides support to researchers looking for credible venues through which to make their research available.
- The [Council of Science Editors](#) offers training, support and guidance to the publishing and researcher communities, and is dedicated to the responsible and effective communication of science.
- The [Hong Kong Principles](#), a series of indicators developed “*with a specific focus on the need to drive research improvement through ensuring that researchers are explicitly recognized and rewarded for behaviors that strengthen research integrity.*”

² Global Research Report, Subject diversity in research portfolios: what it is, how to index it and its role in innovation – Adams et al, Institute of Scientific Information, ISBN 978-1-8382799-3-6. Available via: <https://clarivate.com/blog/time-to-get-even-the-value-of-research-diversity/>.

Finally, there is global movement towards more open and collaborative ways of working across science and research more broadly ('open science'). The aim of open science is to democratize access to knowledge and enable collaboration in ways that accelerate the potential for research to have impact. Open science encourages researchers to share the products and outputs of research; including throughout the research lifecycle e.g. from study design and methodology, and research data and software, in addition to negative and null findings, to support robustness and transparency in the way research is conducted. Open science can play a pivotal role in enabling trust in research. There are many examples of good practice developed by the community in line with the values of open science; for example, the HuMetrics [<https://humetricshss.org/>] values framework. **OSTP would be strongly placed to use its influence to support and incentivize Open Science activities.**

In summary:

- (i) having **safeguards in the system to ensure trust in knowledge** that is being created at an expanding pace is critical, supported by **structured and transparent information about the provenance and contributions to research**.
- (ii) ensuring that **scientific integrity policies apply to all areas of science and research** is essential.
- (iii) support for **a wide range of research disciplines** including HSS as well as STEM research fields is valuable to i) build bridges between hard science and public engagement, ii) ensure that agencies benefit from a range of expertise and insights and iii) foster broader public trust at the interface of policy and research.
- (iv) ensuring appropriate, **diverse, and transparent governance** of scientific funding and processes will foster trust.
- (v) making sure that **all policies and commitments are made simply and openly available** is key, alongside any performance-related indicators on how those policies are being implemented in practice.
- (vi) **aligning with existing initiatives designed to support transparency, and research ethics and integrity** is likely to be highly effective, and a route to help bring further consistency in policy and practice across the whole research ecosystem.
- (vii) **considering how incentivizing open access publishing and open science approaches more generally can facilitate greater trust in research.**

2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information

For communication to be effective, communicators must be mindful of context – particularly the audience that they are engaging with, their level of understanding, and their characteristics. In our experience, building social infrastructure is key to achieve this aim – with a focus on training researchers and staff around science communication and public engagement, based on the need for communication to be contextual, consistent, and credible.

Our suggestions to the Committee focus on two elements – firstly, investment in training programs, and secondly, support for a wider range of research outcomes.

Training

We suggest that OSTP continues to invest in training programs for researchers at all career stages. Publishers, such as Taylor & Francis, are well placed to support this activity. We have developed advanced programs to support the academic community to share the published outcomes of their research and enhance the potential to deliver impact. As examples, publishers:

- provide researchers with training and advice on maximize the opportunities for public engagement in research (for example via the Taylor & Francis Author Services site: <https://authorservices.taylorandfrancis.com/research-impact/>).
- partner with bodies like *Sense about Science* to connect researchers with policymakers and the broader public.
- work with research offices at institutions to promote key pieces of research.
- develop discoverability platforms to ensure that research outputs are not only certified and validated (through peer review) but are also trustable, findable, and curated.

Research dissemination strategies

Technology platforms and publishers now present many more exciting opportunities for researchers to share their work in formats beyond the traditional written article, as well as outputs from throughout their research process. As well as making outcomes available more rapidly than the written narrative, this encourages transparency, and fosters trust. **OSTP could consider incentivizing researchers to present the outcomes of their research in formats beyond the traditional written article**, for example:

- policy summaries (distilling key elements of an article to support legislators with policy making).
- [Plain language summaries](#) – communicating the significance of scientific research evidence to a broad audience, including patients and professionals in nearby disciplines, in jargon-free and clear language. Some examples <https://www.tandfonline.com/doi/full/10.1080/14787210.2020.1792290> and <https://doi.org/10.6084/m9.figshare.9772256>.
- posters, slides, impact reports, and other formats (see for example the range of outputs openly available at <https://gatesopenresearch.org/browse/documents>).
- video abstracts, with researchers presenting the outcomes of their research using accessible language (<https://authorservices.taylorandfrancis.com/research-impact/creating-a-video-abstract-for-your-research/>).

3. Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce

The Reproducibility Crisis³ in research has led stakeholders across the research and scholarly communications ecosystem to review their policies and practices. This crisis has led to a

³ <https://www.nature.com/collections/prbfkwmwvz/>

number of initiatives, all designed to improve the integrity and reproducibility / replicability of research. Initiatives include standards and guidelines; principles around data creation, hosting, and reuse; and industry bodies such as the Committee on Publication Ethics (COPE). **Many of these initiatives could be endorsed by OSTP and the Federal government and adopted to help address scientific issues.** This would build on federal policies that are already in place to address research misconduct.

OSTP could also consider how it can use its influence to support a shift to an academic research culture that works to the best effects of research. A growing number of funding agencies, academic publishers, and institutions are signatories to the San Francisco Declaration on Research Assessment (DORA)⁴. DORA's mission is to shift the basis upon which research and researchers are evaluated, from a system focused on the publication of research in high impact journals and quantitative indicators of 'success', to a system where good research conduct and practice are equally valued⁵.

We encourage OSTP to review and reward the invisible work carried out by many researchers in the service of their communities – for example peer review, mentoring, training colleagues, taking up advocacy roles within their institutions. This work is fundamental to ensuring diversity and good practice in the research ecosystem, but often disproportionately falls to certain groups – such as minority ethnic researchers, women, and early career researchers, impacting career progression in many cases.

To summarize, we suggest that the Committee considers:

- (i) Reviewing assessment mechanisms to reward grantees and researchers who work collaboratively and provide support to their communities;
- (ii) How to better reward those who carry out sound science (including negative or null outcomes); and
- (iii) Endorsement of existing best practice guidance and cross stakeholder initiatives that promote the responsible conduct of research (RCR).

4. Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices

We commend the NSF's mandate for students and postdoctoral researchers to undergo training around the responsible conduct of research (RCR): <https://www.nsf.gov/bfa/dias/policy/rcr.jsp>. **There would be great benefits if such training became commonplace and was even mandated by funding and research agencies.**

The scholarly communication and research communities have developed a significant body of guidelines and best practices that apply to general research practice and communication, as well as to specific fields. These resources have been created to foster quality, reliability, and rigor in research and the outcomes of the research process. Many of the guidelines developed have gained significant support within the community as they outline common and

⁴ <https://sfdora.org/>

⁵ <http://www.leidenmanifesto.org/>

interoperable standards, promote transparency, outline common methodologies and checklists, and provide tried and tested examples of best practice that are valued by researchers. These have typically been developed with the input of key stakeholders including researchers, learned societies, funders, institutions, and publishers, and are often regarded as being essential to the creation and dissemination of trusted research outcomes.

We suggest that the OSTP and federal agencies review this body of best practice, and, where appropriate, endorse and align with these goals, and partner with stakeholders, including publishers, in advocating for adherence to these practices. Some examples include:

- The International Council of Medical Journal Editors Recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals: <http://www.icmje.org/recommendations/>
- The EQUATOR Network (Enhancing the QUALity and Transparency Of Health Research): <https://www.equator-network.org/>. This brings together reporting guidelines for a range of study types, such as the ARRIVE guidelines (Animal Research: Reporting of In Vivo Experiments): <https://arriveguidelines.org/>
- The Transparency and Openness Promotion Guidelines (TOP) guidelines <https://www.cos.io/initiatives/top-guidelines>
- The FAIR data principles (ensuring that research data is Findable, Accessible, Interoperable, Reusable): <https://www.go-fair.org/fair-principles/>

We recommend that OSTP considers outreach and training programs for the purposes of improving popular media reporting on scientific research. Although many news outlets have acted commendably during the course of the pandemic, there have also been some instances of sensationalist reporting on the results of clinical trials; especially around negative results and conclusions found only within academic preprints that have not yet undergone peer review. Wider advocacy around the nature of academic publications and the scientific method, as well as greater emphasis on the translation of results into communications suitable for wider audiences within the media, may help improve public trust in the scientific method and prove as further justification for spending on scientific investigation.

5. Other important aspects of scientific integrity and effective approaches to improving trust in Federal science

Research is a global endeavor, carried out through innumerable formal and informal networks and connections across regional and disciplinary boundaries. We believe that ensuring integrity in the research and scientific communication processes requires inputs from the whole community. **We encourage OSTP to collaborate with the many willing stakeholders in this ecosystem to improve on trust building initiatives.**

Supporting and fostering research integrity is a priority for many academic publishers, including Taylor & Francis. We have been actively engaged in developing standards and best practice that support the responsible conduct of research across the disciplinary spectrum. Publishers play an important role in the scholarly communication ecosystem by acting as

independent bodies, separated from any political agenda or motivation. It is in our interest to publish quality, reliable research outcomes in support of the research community.

We believe that together we can facilitate the creation and dissemination of reliable and trusted information. This will accelerate the potential for research to have value and impact and reach the communities it is designed to serve and, in the words of the President, ensure that the fruits of science and technology are fully shared across America and among all Americans.

END

I am writing in my capacity as a scientist and professor working for the University of Wisconsin-Madison and advising dozens of civil-society groups and foreign governments on endangered species and wildlife science. I received my PhD from Harvard University in 1997, double bachelor's from Rice University in 1990, post-doc at UW-Madison from 1997-2000, and research fellow for three non-profit conservation organizations. From 2007-present, independently and with U.S. government co-authors, I have investigated ecology, conservation, and management of wildlife in the USA and abroad. I have published >133 scientific papers on these topics. I draw here from my research on scientific integrity [1-15].

My comments relate to the completeness of the science and the scientific integrity used by several federal agencies, but focused on the U.S. Fish & Wildlife Service (USFWS, Department of Interior) decisions under the Endangered Species Act and about National Wildlife Refuges.

In 2019, I served as an official peer reviewer for the USFWS proposed rule removing Endangered Species Act (ESA) protections from gray wolves *Canis lupus* nationwide. All five peer reviewers identified shortcomings in the biological report produced by the USFWS https://www.fws.gov/endangered/esa-library/pdf/Final%20Gray%20Wolf%20Peer%20Review%20Summary%20Report_053119.pdf. Those shortcomings ranged from internally contradictory conclusions, dozens of missed scientific articles including in top journals such as *Science*, *Scientific Reports*, and *Nature*, and flawed analyses based on non-peer-reviewed data. Yet, the final rule did not substantively improve and the biological report remains largely uncorrected if at all. When I learned the USFWS and White House were proceeding with a scientifically flawed biological report in Fall 2020, I met with the Office of Management and Budget and seven officials from DOI in September 2020 to explain some of the basis for judging the final rule did not follow the best available sciences mandated by the ESA. As late as December 14, 2020, I found the assistant director of USFWS citing obsolete and inaccurate science that I had been at pains to explain to his staff since 2014 and specifically in the two communications I referenced above. Note INT? his case, the USFWS was siding with some state interests against other state interests and using bad science to do so. In December 2020, Gary Frazer Assistant Director of USFWS sent a letter to the California Fish & Game Commission to try to reassure them that California's fledgling wolf population would not be harmed by federal delisting of gray wolves. Dr. Treves responded, correcting poor science and inaccuracies in the USFWS letter. For the California FGC letter that started the discussion [click here](#), then see the [USFWS response to CA FGC](#) and [Treves reply](#).

In my opinion, the above examples reflects the USFWS choosing a predetermined outcome and trying to force the science to fit the prejudged issue. When the science flatly contradicts the USFWS, leadership ignored and cherry-picked results they liked better, even when the cherry-picked results were inaccurate, obsolete, or fabricated. A review of federal court cases on Grizzly bears, wolverines, and wolves will show that I am not alone in this opinion.

However, even more pernicious than the above specific failures to follow best science, two federal agencies with whom I have interacted have tried to damage my research team's efforts. In 2012, the USFWS regional office in my region withdrew a grant which had been offered to my lab in an email shortly before the contracts officer signed the paperwork. The basis for that withdrawal was believing a lie by a state wildlife agency staffer and a lie by a colleague with a competing financial interest to lie about me. Yet the USFWS regional office believed them. Why? Please see the public comment by David Parsons, M.S. submitted to your team for an explanation of the unhealthy and illogical affiliations between USFWS and state wildlife agencies. It seems relevant to point out that I have been sending in public comments to the USFWS since 2014, often addressed directly to leadership in their regions or centrally in D.C. (<http://faculty.nelson.wisc.edu/treves/CCC.php>). Never once in the ensuing 7 years has

the USFWS reached out for a conversation or meeting, until colleagues and I brought in the Union of Concerned Scientists in 2014. They worked with us then to improve peer review practices. Thereafter, silence reigned again – despite multiple invitations to dialogue and sharing of information. Of course no one likes to be criticized but the best available science demands that we separate our egos and preferences from results, expect to be found to be wrong, and open one's mind to results that are not favorable to our own interests. The best way to do that is to listen closely to critics and learn from the criticisms.

I do have a clear example of USFWS learning from its past errors. From 2014-2015, I led 968 colleagues to send a petition to the USFWS to fortify its use of best available science by strengthening the process of seeking independent peer review. Following the petition launch, the FWS issued a new and improved peer review policy for the agency. The new policy is a step forward in safeguarding the science that informs endangered species listing; it provides a clear and consistent, agency-wide framework that improves the separation between scientific status assessments and policy decisions, provides more clarity around agency procedures when decisions are controversial, and increases transparency ([Goldman et al. 2016](#)). While the provisions could be stronger in a few areas, the new policy takes strong steps toward more robust and transparent peer-review at the agency. Sadly, the Trump administration did not live up to that new policy. After I participated in a scientific peer review for nationwide delisting of the gray wolf in 2019, I found the process had improved by (a) preventing the USFWS from cherry-picking its external scientists to get the results it wanted politically and (b) creating a transparent document without editing or outside modification of the peer reviewers' writing in a format easily obtained by the public. However, the USFWS still ignored the science despite all 5 external peer reviewers finding shortcomings in the biological summary and the conclusions drawn from it. Four out of five found major shortcomings and few if any of the suggestions led to improving the proposed delisting. Therefore, in my opinion, the decision to delist in 2020 was politically motivated and prejudged, while the science was ignored. That pitfall is not unique to the Trump administration given the Obama administration tried to delist gray wolves in 2013 and fell afoul in a botched peer review process (<https://www.twincities.com/2013/08/13/feds-delay-review-of-plan-to-drop-wolf-protections-2/>) and then fell faced unanimous condemnation of the science of gray wolf genetics by the second peer review process in 2014 [16]. So I hypothesize the USFWS scientists face undue political pressure.

The second federal agency that I feel has breached scientific integrity as a result, is a subdivision of U.S. Department of Agriculture Animal & Plant Health Inspection Services called Wildlife Services (USDA-WS). The USDA-WS has a well-documented history of ignoring the best available science and instead promoting its own deeply flawed research [17, 18]. Observe how many times that agency has been sued by civil society. Then look at the briefs to see how in the course of those proceedings, the federal agency treats the work of independent scientists who dare to question their findings or publish contrary results. I was involved in one such demoralizing encounter with that agency in “Western Watersheds Project et al. v USDA-WS” 2018, U.S. District Court for the District of Idaho. Such intimidation must stop and that rogue agency must be held to higher standards of scientific integrity.

The problem of federal agencies avoiding use of better science to push through minority interest group uses of our federal lands is epitomized by the recent proposed rule on National Wildlife Refuges (NWR). Please see our 6 July 2021: Petition to USFWS to retract proposed rule 50 CFR Parts 32 and 71 2021–2022 "Station-Specific Hunting and Sport Fishing Regulations" across the National Wildlife Refuge system. [Full text here](#). Here the USFWS treats all NWRs as identical, ignores the absent or outdated environmental assessments across the system, and ignores the scientific evidence showing that public hunting, trapping, hounding, and fishing can threaten species listed under the ESA with accidental take

(by-catch, non-target off-take, etc.) and illegal killing. Please see work on poaching since 2011 by colleagues and I published in peer-reviewed scientific journals ranked in the top ten worldwide and freely available here: <http://faculty.nelson.wisc.edu/treves/publications.php>. (Note we pay for open access fees in virtually all of our work to eliminate any possible obstacle for government agency staff.) Finally, in the context of hunt management and scientific integrity, I'd like your team to be aware of a recent review published in Scientific Reports that analyzed 667 hunt management plans across North America and found the vast majority lacked the hallmarks of science and so did not deserve the adjective 'science-based' alongside their plans. Therefore, federal land managers from USFWS to BLM to USDA should not rely on state management of wildlife to be science-based [10, 11]. Even the one peer-reviewed comment on the latter paper could only point to a federal waterfowl management system as science-based [19], which is a credit to USFWS in that case, but scant justification for opening NWRs to more hounding, trapping, baiting and mammal shooting ostensibly regulated by states and tribes.

Synthesis

The examples above evoke three core principles of scientific integrity. First, transparency, which is probably the single most important principle because it permits the others to occur in an authentic manner; second, independent review by scientific peers; third, reproducibility of results.

Transparency demands that a biological review or regulatory action that is legally mandated to consider all the scientific data should not omit a single peer-reviewed scientific article on the species in question. In 2019, I pointed out at least a dozen articles the USFWS had ignored. When the USFWS is non-transparent in this way, they mislead the public and disadvantage scientists who are not their favorites.

Second, the USFWS in 2019 and 2020 appears to have paid lip service or gone through the motions of an independent peer review in which I participated. Without modifying its preconceived notions of the science, nor changing its biological report in the critically important ways identified by the peer reviewers, the USFWS made a parody of independent review, which is supposed to improve science by gaining a plurality of scientific views and verifying the quality of data.

Third, the principle of reproducibility ensures that a finding can be replicated by a peer scientific team working independently by the same methods. Federal land management agencies and wildlife agencies make liberal use — even depended upon — non-peer-reviewed data (which are often not made public and therefore are probably irreproducible). Because the federal agencies rely on data collected by lower jurisdictions [20] and because lower jurisdictions are held to lower standards of science typically or ignore the higher standards they do face, federal wildlife and land management agencies may be trapped in irreproducible, non-transparent data that has not been subjected to independent peer review.

In short, all the data used by the federal science agencies should have been subjected at a minimum to transparent, complete description of methods, assumptions, or validated measurements. The elements of authentic independent review include a lack of competing interests (financial or non-financial) among reviewers [21], and complete access to all data, methods, and assumptions used for data collection or analysis. At present, serious scientists from outside the agencies cannot access much of the data used by USFWS because government bodies have claimed exclusive access to those data. My students and I have placed 7 requests for data relating to wolves and grizzly bears and been denied access by federal agencies. In the few cases we went so far as to FOIA the data, we found the USFWS had made errors in reporting on the data to the public [22] and [15] for a case where USFWS deferred to the state that denied the data and the state made the errors [23, 24]. These breaches of scientific integrity by federal

agencies engaged in wildlife and endangered species science are unfortunately common. The federal government can and should lead the way in this regard and thereby model the scientific integrity needed in states, tribes, and lower jurisdictions also.

I also have a recommendation about conflicting results in the scientific literature. When two or more scientific studies come to opposite conclusions or approaching scientific questions from different angles (e.g., does regulated hunting conserve wildlife or does regulation of hunting conserve wildlife?), the federal agency should be obligated to report on the existence of both sets of studies not cherry-pick their favored one. Moreover, the federal agency should be obligated to weigh the evidence in light of the quality of the science using internationally recognized standards of inference and the National Academies of Science (NAS) 2017 guidelines on fostering research integrity. The NAS 2017 guidelines make clear why one should prefer science with higher transparency, higher and clearer standards of review, established ethical standards backed by accountable institutions, or replicated with equal or higher standards. The last element of NAS 2017 demands that reproducibility be used as a standard on evaluating research [25-28]

A start would be to maintain a list of scientific journals that meet published, minimum criteria for editorial policies (e.g., signatory to the international Committee on Publication Ethics), avoid predatory journals which have been exposed [29], and require data publication in full with the article. A common practice by federal agencies engaged in wildlife science is not to Share raw data (or claiming the states or tribes own those data even when the federal agency has paid for the research). Such excuses are simply a way to dodge legal duties to the public — a least when discussing environmental science and not national security.

My final recommendation is that the tone from the top or standard set by leadership is crucial to scientific integrity. One may not need to promulgate new policy if the directors of federal science agencies are sending the right message. An important step in that direction would be to fill the post of director of USFWS swiftly with a scientist trusted by the independent research community (and do the same for USDA-WS). Another important step would be to require federal agency staff training at all levels using the NAS 2017 guidelines. Only by strict adherence to the principles of comprehensive and thoroughgoing transparency, authentic independent review, and stringent reproducibility can federal science regain the trust of the public.

Thank you for considering my comments,

References cited

- Articles with Treves can be found here: <http://faculty.nelson.wisc.edu/treves/publications.php>
1. Treves, A., F. Santiago-Ávila, and W.S. Lynn, *Just Preservation*. Biological Conservation, 2018. **229**:134-141. 10.1016/j.biocon.2018.11.018. <https://www.sciencedirect.com/science/article/pii/S0006320718310139?via%3Dihub>.
 2. Treves, A., *Standards of evidence in wild animal research*. 2019, The Brooks Institute for Animal Rights Policy & Law. <http://faculty.nelson.wisc.edu/treves/CCC.php/standards>.
 3. Treves, A., *Scientific ethics and the illusion of naïve objectivity*. Frontiers in Ecology and the Environment, 2019. **7**:361. doi:10.1002/fee.2091.
 4. Treves, A. and F.J. Santiago-Ávila, *Myths and assumptions about human-wildlife conflict and coexistence*. Conservation Biology, 2020. **34**(4):811–818. 10.1111/cobi.13472.
 5. Treves, A., N.X. Louchouart, and F. Santiago-Ávila, *Modelling concerns confound evaluations of legal wolf-killing*. Biological Conservation, 2020.

- <https://doi.org/10.1016/j.biocon.2020.108643>:108643. 10.1016/j.biocon.2020.108643.
<https://doi.org/10.1016/j.biocon.2020.108643>.
6. Treves, A., P.C. Paquet, K.A. Artelle, A.M. Cornman, M. Krofel, and C.T. Darimont, *Transparency about values and assertions of fact in natural resource management*. Frontiers in Conservation Science: Human-Wildlife Dynamics, 2021. **2**:e631998. 10.3389/fcosc.2021.631998.
 7. Treves, A., F.J. Santiago-Ávila, and K. Putrevu, *Quantifying the effects of delisting wolves after the first state began lethal management*. PeerJ, 2021. **9**:e11666. 10.7717/peerj.11666.
 8. Carroll, C., B. Hartl, G.T. Goldman, D.J. Rohlf, A. Treves, J.T. Kerr, E.G. Ritchie, R.T. Kingsford, K.E. Gibbs, M. Maron, and J.E.M. Watson, *Defending scientific integrity in conservation policy processes: Lessons from Canada, Australia, and the United States*. Conservation Biology, 2017. **31**(5):967–975.
 9. Carroll, C., D.J. Rohlf, B.M. von Holdt, A. Treves, and S.A. Hendricks, *Wolf Delisting Challenges Demonstrate Need for an Improved Framework for Conserving Intraspecific Variation under the Endangered Species Act*. Bioscience, 2021. **71**(1):73–84. doi:10.1093/biosci/biaa125.
<https://doi.org/10.1093/biosci/biaa125>.
 10. Artelle, K.A., J.D. Reynolds, T. A., J.C. Walsh, P.P. C., and C.T. Darimont, *Hallmarks of science missing from North American wildlife management*. Science Advances 2018. **4**(3):eaao0167.
 11. Artelle, K.A., J.D. Reynolds, T. A., J.C. Walsh, P.P. C., and C.T. Darimont, *Distinguishing science from “fact by assertion” in natural resource management*. Science Advances (eLetter), 2018. **4**(3):eaao0167.
 12. Darimont, C.T., P.C. Paquet, A. Treves, K.A. Artelle, and G. Chapron, *Political populations of large carnivores*. Conservation Biology, 2018. **32**(3):747–749. 10.1111/cobi.13065.
 13. Santiago-Avila, F.J., W.S. Lynn, and A. Treves, *Inappropriate consideration of animal interests in predator management: Towards a comprehensive moral code*, in *Large Carnivore Conservation and Management: Human Dimensions and Governance*, T. Hovardos, Editor. 2018, Taylor & Francis: New York.227-251.
 14. Santiago-Ávila, F.J., A. Treves, and W.S.e.c.-a. Lynn, *Just preservation, trusteeship and multispecies justice*. Animal Sentience: Response to Commentary on Treves et al. on Just Preservation, 2020. **27**(27):393-409. 10.51291/2377-7478.1665.
https://www.wellbeingintlstudiesrepository.org/cgi/viewcontent.cgi?article=1665&context=animal_sent.
 15. Santiago-Ávila, F.J., R.J. Chappell, and A. Treves, *Liberalizing the killing of endangered wolves was associated with more disappearances of collared individuals in Wisconsin, USA*. Scientific Reports, 2020. **10**:13881. /10.1038. | <https://doi.org/10.1038/s41598-020-70837-x>.
 16. NCEAS, *Review of Proposed Rule Regarding Status of the Wolf Under the Endangered Species Act*. 2014, National Center for Ecological Analysis and Synthesis.
 17. Treves, A., M. Krofel, and J. McManus, *Predator control should not be a shot in the dark*. Frontiers in Ecology and the Environment, 2016. **14**:380-388.
 18. Mitchell, B.R., M.M. Jaeger, and R.H. Barrett, *Coyote depredation management: current methods and research needs*. Wildlife Society Bulletin, 2004. **32**(4):1209-1218.
 19. Nichols, J.D., F.A. Johnson, B.K. Williams, and G.S. Boomer, *Science Alive and Well in North American Wildlife Management*. Science Advances (eLetter 3 April 2018), 2018. **4**(3):eaao0167. 10.1126/sciadv.aao0167.
 20. Nie, M., C. Barns, J. Haber, J. Joly, K. Pitt, and S. Zellmer, *Fish and wildlife management on federal lands: Debunking state supremacy*. Environmental Law, 2017. **47**:797-932.
 21. Treves, A. and C. Batavia, *Improved disclosures of non-financial competing interests would promote independent review*. Academia Letters, 2021. **Article 514**:1-9.

22. Louchouart, N.X., F.J. Santiago-Ávila, D.R. Parsons, and A. Treves, *Evaluating how lethal management affects poaching of Mexican wolves* Open Science, 2021. **8** (registered report):200330. <https://doi.org/10.1098/rsos.200330>.
23. Treves, A., J.A. Langenberg, J.V. López-Bao, and M.F. Rabenhorst, *Gray wolf mortality patterns in Wisconsin from 1979 to 2012*. Journal of Mammalogy, 2017. **98**(1):17-32. DOI:10.1093/jmammal/gyw145.
24. Treves, A., K.A. Artelle, C.T. Darimont, and D.R. Parsons, *Mismeasured mortality: correcting estimates of wolf poaching in the United States*. Journal of Mammalogy, 2017. **98**(5):1256–1264. DOI:10.1093/jmammal/gyx052 <https://doi.org/10.1093/jmammal/gyx052>.
25. Allison, D.B., A.W. Brown, B.J. George, and K.A. Kaiser, *Reproducibility: A tragedy of errors*. Nature, 2016. **530**:27-29. doi:10.1038/530027a. https://www-nature-com.ezproxy.library.wisc.edu/news/polopoly_fs/1.19264!/menu/main/topColumns/topLeftColumn/pdf/530027a.pdf.
26. Baker, M. and K. Brandon, *1,500 scientists lift the lid on reproducibility*. Nature, 2016. **533**:452-454.
27. Clark, A. and G. Alvino, *Building research evidence towards reproducibility of animal research*, in PLoS ONE blog. 2018. <https://everyone.plos.org/2018/08/06/arrive-rct/>.
28. Goodman, S., D. Fanelli, and J. Ioannidis, *What does research reproducibility mean?* Science Translational Medicine, 2016. **8**(341):341ps12 DOI: 10.1126/scitranslmed.aaf5027.
29. Bohannon, J., *Who's Afraid of Peer Review?* Science, 2014. **342**(6154):60-65.

President Biden's January memorandum on scientific integrity reaffirmed President Obama's 2009 memorandum. This 2009 memorandum was issued after nine FDA device whistleblowers complained to him of issues with scientific integrity at the FDA, a GAO report, and revelations of criminal investigations of these whistleblowers. Yet despite this memorandum calling for whistleblower protection and that existing laws be followed which include those regarding whistleblower protection. Six of these whistleblowers were fired in mid-2010, and in 2012 it came out that these whistleblowers had also been spied upon.

President Obama's memorandum followed on the heels of a number of other instances of violations of scientific integrity and whistleblower retaliation at the FDA including Leo Lutwak and fen-phen, Robert Misbin and Rezulin[®], Lotronex[®] and Paul Stolley, David Graham and Vioxx[®], Andy Mosholder and antidepressant induced suicidality in adolescents, David Ross and Ketek[®], Rosemary Johann-Liang and Avandia[®], Susan Wood and Plan B[®], FDA pressure on Health Canada not to withdraw Adderall XR[®] from the market, Victoria Hampshire and ProHeart 6[®], and Renee Dufault and mercury in high fructose corn syrup. Plus, Commissioner von Eschenbach's internal statements to reviewers that those who fought corrupt practices would be fired, and his public statements that whistleblowers would not be tolerated. These of course were not all the major violations of scientific integrity that had occurred. Plus, I personally know of dozens and dozens of smaller violations. As well as other major violations that did not get into the mainstream press. Although a series of some particularly egregious violations that occurred during this time were recently reported in an open petition to President Biden in the Washington Post.

There was also the Institute of Medicine FDA culture report and the Union of Concerned Scientists survey of FDA employees.

Yet despite outrage by these and other public interest groups, the AP asking in 2009 if the FDA was a broken agency with Representative Dingle saying you can expect an FDA scandal at least once a month, and multiple Congressional hearings, no one was held accountable. In fact, David Graham said to me *"Twenty times as many people were killed by Vioxx[®] as were killed in the World Trade Towers. We went to war over the World Trade Towers but not one person was held accountable for Vioxx[®]."* Meanwhile I heard FDA managers who were involved in suppressing the Vioxx[®] safety issue say it would all blow over, and then saw them help Pharma executives write the 2007 FDA Amendments Act with Senator Kennedy that actually helped protect the pharmaceutical industry and further diminished scientific integrity.

Despite the FDA issuing a scientific integrity policy in 2012 (SMG 9001.1) and discontinuing policies that opened staff to firing if they spoke to the press and said anything that the FDA did not like (MaPP 4641.3). Revised policies (SMG 2126.3) and government wide regulations (5 CFR §2635.807) still require preapproval for any public discussion of FDA policies or practices, including the revelation of practices that result in the violation of scientific integrity, except in the course of uncompensated teaching. Which of course will only be approved for those they trust not to reveal what truly occurs. Plus, there have been multiple laws that have been passed since the Bush administration that further weaken FDA scientific integrity.

In addition, in the past few years in addition to the fall-out from opioid crisis which is due in part to the FDA's unlawful 1995 OxyContin labeling approval, there was the 2016 approval of Exondys 51[®] by Janet Woodcock the Director of the Center for Drugs, because of the financial implications to the company, despite the science being clear that the change in the surrogate marker was too small to have any effect. With her decision to approve the drug based on this surrogate being made before reviews were even completed and despite a near unanimous vote by the advisory committee against approval due to a lack of clinical effect.

According to a 2020 report by the Union of Concerned Scientists the FDA appears to be better than other agencies with respect to the resolution of scientific disputes.¹ However, the revised scientific dispute policy issued in October 2010 (MaPP 4151.1 Rev.1) only allows filing of scientific disputes if the reviewer does not have other work. Plus, it includes an iterative process up through the chain of command, all of whom may be involved in scientific dishonesty as integrity issues often come from the top down. Plus, as shown by the Exondys[®] 51 approval, just because there's a dispute process, in the end it is often simply a way to claim a process was followed when the decision was already preordained despite the science.

Since the most important disputes are likely to occur at the end of the review cycle for a New Drug Application, FDA management is likely to pile on work to make it difficult for the reviewer to document their concerns even in their regular review, and is then likely to hold off on issuing the review memos on which to base a dispute until the last minute when it's too late to respond and file a dispute. In addition, the very same day this revised policy was issued the FDA issued the Equal Voice Policy (MaPP 4151.8). This Equal Voice policy states that all reviewers from a discipline area including consult groups will issue a joint review that everyone is responsible for and it's signed by the division director. Which had not been the previous practice. While this policy allows scientific dispute memos, as stated above filing a scientific dispute is not feasible in practice, as the reviewer may not even know what the consult groups are going to say until the final review is handed to the reviewer who is then told to file it on the very last day when the approval decision is issued. Consequently, this policy makes it appear that the primary reviewer agrees with things that they don't. In addition, this policy really only applies to clinical pharmacology, where consult groups include pharmacometrics and pharmacogenomics. Groups that are known to work closely with industry and the Reagan Udall Institute and that demand that primary reviewers simply copy and paste what they say even when biologically impossible.

In addition to the above, there are numerous FDA policy and procedures (172 publicly available), staff manual guides (~ 1000 total), and scientific and regulatory guidances (2622), as well as statutes and regulations that are constantly changing and difficult to search. While most will not be applicable to everyone, reviewers typically don't even know that MaPPs and SMGs exist, and in particular those that are applicable to scientific integrity, as they are not informed. In addition, statutes, regulations and especially guidances are typically full of loopholes that favor the pharmaceutical industry as are often written by or with the industry, and regulations, policies and procedures, and staff manuals are often rewritten when reviewers try to take advantage of them for purposes of scientific integrity.

¹ Center for Science and Democracy at the Union of Concerned Scientists. Roadmap for Science in Decision making. Strengthening Scientific Integrity at Federal Agencies. Recommendations for 2021 and Beyond. August 2020. Available at: www.ucsusa.org/resources/roadmap-science-decisionmaking/. Accessed: November 8, 2020.

Although FDA guidances state that they are not legally enforceable standards. This only applies to the pharmaceutical industry as good guidance practice regulations require that reviewers follow them unless justified and with supervisory concurrence. (21 CFR §10. 115) However, when reviewers ask that they be followed by the FDA and justify that they need to be followed in order to fulfill Food Drug and Cosmetics Act requirements (even when the science says they are still inadequate to truly fulfill these requirements), they are dismissed and statutes are violated.

Currently, there is outrage over the FDA's approval of Aduhelm for Alzheimer's, with the press (e.g., Bloomberg, Washington Monthly) once more asking is the FDA is broken. Three advisory committee members quit, there are planned Congressional hearings, and one of the advisory committee members called for Congress to broaden the investigation into other scientific integrity issues at the FDA days after I spoke to him about evidence of integrity issues and major violations of laws and regulations, I found in the Aduhelm approval documents that have not been reported on and two days after I sent him information on other major scientific integrity issues at the FDA.²

I worked in the approving division in the group whose work is being used to justify the Aduhelm approval and can see how it is due to policies, practices, and people who were put in place during the Bush administration, when I was told to *"be careful because Lilly has people in the White House."* In fact, I recently found evidence of political influence during the Bush administration with the first drug approved under the animal rule, which allows approvals when it's unethical to do studies in humans, that involved the same people that helped with the Aduhelm approval. Where this approval under the animal rule is clearly in violation of other Food Drug and Cosmetic Act requirements and is expected to result in deaths. A lack of scientific integrity that still has repercussions and if widely known could have significant national security and foreign relation implications.

While there are many specific laws and regulations that involve scientific integrity that were violated in the Aduhelm approval, I will not discuss them here. However, I do suggest that the Food Drug and Cosmetics Act be amended to require that the objectives of studies be clearly stated and that the regulatory pathway for approval must be specified in the application. Where the prespecified objective and primary endpoints are the mandated basis for determination of efficacy. In addition, that all communications with sponsors include witnesses and be documented, and that they shall be released as part of the approval package in order to minimize issues with backdoor communications that are too often inappropriate and where recent statutes override regulations regarding documentation where even the regulations had huge loopholes. Plus, that information requests and approvability decisions by specific review disciplines shall only come from the primary review discipline involved (e.g., pharmacology/toxicology, clinical pharmacology, chemistry, statistics) and that the primary reviewer's recommendation shall not be inferred with or overridden, and that everyone on the primary review team (i.e., reviewers and team leaders for medical efficacy and safety, pharm/tox, clinical pharmacology, statistics, and chemistry) has to agree with the decision. That communications regarding the progress of the

² Steenhuisen J and Beasley D. Former FDA adviser calls for wider probe into Biogen Alzheimer's drug approval. Available at: <https://www.reuters.com/legal/litigation/former-fda-adviser-calls-wider-probe-into-biogen-alzheimers-drug-approval-2021-07-20/>. Accessed July 20, 2020.

review be eliminated. That PDUFA due dates may not be extended in order to facilitate drug approvals including by major amendments, and that protocols and data shall be released, including for drugs that were not approved.

As for engagement with the press. Prior to the Bush administration staff could easily talk to trade journals or make comments at scientific conferences and there were never issues as everyone knows what's confidential information and can't be discussed. Since, then such communications have been limited to senior officials and there are public relations people monitoring everything those who are given permission to speak say. Comments at scientific meetings also brings harassment even when in agreement with FDA management, as FDA management wants to control messaging and so will not tolerate any unapproved communications.

All review information needs to be posted on the FDA website in a manner that's searchable and facilitates independent review. Including for supplemental applications.

There are many good policies on the books, however they are not followed or have loop holes that are too easy to get around. For example, merit system principles are nice but they are only recommendations. They need to be required. Another example is FDA scientific advisory committees. Despite numerous qualified individuals being available people are screened in or out, and asked to return or not based upon whether they are seen as friendly to industry. Plus, even though the First Amendment and regulations both state that the public has the "right" to address advisory committees and other hearings, there are multiple cases where individuals were denied this right when it was known the presentation would reveal issues with scientific integrity, even though presentations met published criteria and/or there were no other requestors

There needs to be reassessment of various laws that have been passed over the last 30 years that have progressively lowered FDA standards, integrity, and credibility. For example, supplemental applications for additional indications no longer need the submission of full reports, rather only a summary document where the contents are often at odds with the data in the full reports is now needed.

President Biden's January 27, 2021 "Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking" reaffirmed President Obama's Presidential Memorandum of March 9, 2009 on "Scientific Integrity" which stated "The selection of scientists and technology professionals for positions in the executive branch should be based on their scientific and technological knowledge, credentials, experience, and integrity."

On April 12, 2021 Janet Woodcock appointed Patricia Cavazonni as Director of the FDA Center for Drugs. Dr. Cavazonni is a psychiatrist. Documents filed in a lawsuit and readily available by googling her name³ indicate that in 2002 Dr. Cavazonni, was involved in purposefully misleading the FDA about the antipsychotic Zyprexa® causing diabetes. Legal documents also reveal that before this Dr. Cavazonni dismissed findings by Dr. Elizabeth Koller, an FDA endocrinologist who reported on the link between Zyprexa® and elevated blood sugars. In addition, according to a June 23 2020 article, during a lawsuit over Zyprexa® induced diabetes,

³ Sergeants Benevolent Association Health and Welfare Fund v. Eli Lilly. Available at: <https://www.communitycatalyst.org/pal-docs/zyprexacomplaint.pdf>. Accessed: April 13, 2021.

hyperglycemia, and associated metabolic disorders, Lilly lawyers described Cavazzoni as “*the chief detective at Lilly when it comes to understanding the safety of Zyprexa.*”⁴ As such she would have known that Zyprexa® and related drugs were killing elderly dementia patients when Lilly was pushing their off-label use prior to this becoming public knowledge especially as the FDA approval package for Zyprexa® shows Lilly knew as far back as 1995 based on randomized controlled trials in this population, and that Zyprexa® was killing babies when taken during pregnancy or while breast feeding which was documented in the FDA adverse event reporting system. Yet this latter thalidomide like safety issue is still being covered up.

Janet Woodcock herself has well known integrity issues, yet President Biden appointed her as Acting FDA Commissioner. Despite repeated calls by members of Congress, members of the public, and NGOs to have her removed from service. Where since then she has made statements to the press indicating that it's the FDA's standard practice to violate the Food Drug and Cosmetics Act.⁵ Practices that are known in some cases to result in massive financial fraud and deaths, e.g., opioids. Consequently, it must be mandated that executive branch officials in decision making capacities, i.e., even non-political appointees) be vetted for scientific integrity with accountability mechanisms.

How can we have confidence in any scientific integrity policy if President Biden won't even follow his own policies.

With regards to training and informing staff about scientific integrity even though the FD&CA requires training regarding bias there is none. Even when bias is discussed only certain types of bias are even considered, i.e., those in study designs. Even standard workplace signs, such as regarding discrimination that were posted in every division were eliminated when the FDA moved to the White Oak Campus. So, in addition to mandatory annual training, I would recommend that there be required postings of these workplace signs along with new signs/posters regarding scientific integrity policies and who to report to. Especially as people are unaware of the existence of the IG or OSC, and going to Congress or the press is considered professional suicide.

Staff also need to feel secure. I was one of the 5% of review staff who are native born. Yet I know of a foreign national who was forced to return home because documentation to renew her visa was not submitted, and the foreign national who replaced her who was threatened with the same thing for making a reasonable request for assistance with new scientific methods because this might take someone away from helping drug companies. And another native born citizen who got a PhD with the most clinical pharmacologist whose work the industry is modeling wholesale changes around was forced to leave and work overseas.

Mechanisms to interfere with scientific integrity include overwork, , reassigning reviewers and team leaders, resubmission of materials with assignment of the same resubmitted materials to

⁴ Florko N. STAT - The new Janet: The FDA turns to a quiet problem-solver who brings expertise — and a little controversy. June 23, 2020. Available at: <https://friendsofcancerresearch.org/news/stat-new-janet-fda-turns-quiet-problem-solver-who-brings-expertise-and-little-controversy>. Accessed July 20, 2021.

⁵ Karlin-Smith, S. And Then There Were Three: Woodcock Offers Another Explanation For Aduhelm's Labeling Fiasco. 14 Jul 2021. Available at: <https://pink.pharmaintelligence.informa.com/PS144644/And-Then-There-Were-Three-Woodcock-Offers-Another-Explanation-For-Aduhelms-Labeling-Fiasco>. Accessed July 23, 2021.

others, overriding scientific analyses using patently absurd justifications and pseudoscience, delaying approvals and then finding new ways to obtain approval while at the same time forcing reviewers out either through intimidation or firing. Plus, false complaints against reviewers by drug companies and/or FDA management is common. All of which are virtually impossible to stop no matter what new integrity policies are put in place.

Interference in FDA scientific reviews may even constitute witness tampering under 18 USC §§1512(b), (c), (d) and (k), and if there were mandatory prosecution it would go a long way to help minimize problems.

This leads to issues with respect to whistleblowing regarding violations of scientific integrity that constitute abuses of authority and criminal behavior. The HHS Inspector General uses any excuse possible not to investigate. They should be required to investigate and actually talk to the scientist. Plus, they need to be required to protect anyone who makes a complaint, and there needs to be a zero tolerance policy for retaliation. Currently, policies require 2 separate findings and it's virtually impossible to get even one. Retaliation should also be criminally prosecuted, with prosecution mandated by law. IG offices need to include scientists because science is often treated by lawyers as a he said she said issue, where FDA management and companies are well aware of Daubert and can control the narrative. IG offices also need to be out from under the Agency's they cover. Currently they are dependent upon the agency for their budget so they are simply unwilling to investigate corruption because of possible retaliation and defunding. Plus, they can only hold people accountable for corruption when there are actual bribes involved. Thus, it needs to be stated in law that bribery is not required for prosecuting certain crimes such as conspiracy to defraud the government of honest services.

Whistleblowers, who are fired also need financial support if they are able to make a prima facie case initially. Plus, complaints to OSC that are upheld must require reinstatement and making the person whole and not simply allow reinstatement to be up to the agency head. Because whistleblowers are openly held up as examples to other staff, and so when someone is vindicated but still has their life destroyed, it sends the message to others you better not even try because no matter what you will be destroyed.

Jury trials are must for whistleblowers in all circumstances, MSPB and the Court of Appeals are viewed as simply kangaroo courts. Jury trials only for delays because of a lack of a quorum or other reasons will not fix this. For as Thomas Jefferson wrote in defending the need for jury trials *"I consider trial by jury as the only anchor ever yet imagined by man, by which a government can be held to the principles of its constitution."* Yet, whistleblowers have no access to jury trials by which to hold government to these principles much less scientific integrity. For example, in the FDA reviewers may see abuses that endanger their own lives or their families. Yet have no access to jury trials for retaliation for petitioning Congress or OSC to protect their own lives, or members of their families, for issues involving scientific integrity even when they involve substantial and specific dangers to the public health. In addition, regulatory prohibitions against government employees using information they learned of during their employment in court cases must be eliminated. It not only prevents the ability to defend yourself from retaliation for scientific integrity. It's less than that afforded to similarly private sector individuals who can demand such documents on discovery, and it can result in substantial numbers of deaths or other

serious harms to the public. Similarly, nondisclosure agreements that result in harm to others must be eliminated and made unenforceable in all cases.

As for supporting scientists of all backgrounds and advancing areas of governmental concerns. The FDA has a history of being one of the worse agencies in all of government in regards to hiring and retention of people with targeted psychiatric disabilities. In fact, it's common practice at the FDA to harass reviewers with these disabilities who raise scientific integrity issues in order to either cause a constructive discharge, or to justify removal. Despite knowing such tactics can result in death. Yet investigations of such harassment take too long and are rigged, where in the interim constructive discharge or termination often takes place. One such example of harassment of a government scientist that resulted in suicide, albeit not for reporting issues involving scientific integrity, is that of Bruce Ivins an Army biologist at Fort Detrick who committed suicide due to harassment over being suspected of being involved in an anthrax scare. For scientists with targeted severe psychiatric disabilities, it's hard enough as it is to obtain the qualifications needed to be an FDA reviewer but then to have it be common practice so that per NTEU multiple such reviewers have had their careers and lives destroyed because they were committed to scientific integrity is outrageous. I personally know of at least 4 such reviewers in the psychiatry division who were harassed because of their concerns that scientific integrity issues endangered the lives of psychiatric patients.

Similarly, there were clear indications of discrimination of blacks in the area I worked in, with most of the reviewers employed by the FDA the longest being black, yet underrepresented as team leaders with new reviewers being rapidly promoted, with only a single token "*black team leader position.*" Whereas in other disciplines Orientals were held back with Indians being promoted preferentially while both groups were lumped together as Asians for statistical purposes which hid what was occurring.

Training is another area that is in dire need of improvement at the FDA for training in new methodology or areas of deficiencies is often only offered to those managers like or who are planning to return to their home countries where the pharmaceutical industry is moving. While others are then sidelined. Instead training needs to be mandatory with FDA management openly identifying new areas that will affect review disciplines and document areas of deficiencies by staff. With training and documentation of mastery required. In addition, there needs to be online reference material of original literature including of developing areas and not just guidances.

As for improving trust in Federal science people know that actions speak louder than words. Consequently, holding people accountable including by firing, criminal prosecutions, disgorgement of pay received in violation of the Lloyd-LaFollette anti-gag appropriations rider and making whistleblowers whole and replacing corrupt individuals with people with demonstrated integrity will send the message that dedication to scientific integrity is not simply talk. For as President Obama said "*the American people are tired of politicians who talk the talk but don't walk the walk.*" Where although this was said with respect to fiscal responsibility. Scientific integrity with respect to climate change and drugs such as Aduhelm that has the potential to add as much as \$800 Billion per year in health care costs based on the approved labeling, an amount that is more than the \$550 Billion in total annual drug spending, makes scientific integrity a fiscal issue too.

REQUEST FOR INFORMATION (RFI) RESPONSE SUBMISSION

INFORMATION TO IMPROVE FEDERAL SCIENTIFIC INTEGRITY POLICIES

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INFORMATION TO IMPROVE FEDERAL SCIENTIFIC INTEGRITY POLICIES

The National Academy of Public Administration (the Academy) is pleased to submit to the Office of Science and Technology Policy - Executive Office of the President this RFI submission response on improving federal scientific integrity policies. The Academy has responded to all five (5) topics within its comprehensive and integrated response:

- I. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science
- II. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information
- III. Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce
- IV. Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices
- V. Other important aspects of scientific integrity and effective approaches to improving trust in Federal science

The Academy will respond to any subsequent follow-on strategic agency assessment dialogue, discussion, event, crowdsourcing campaign, or competition.

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The Academy's unique feature is its approximately 950 distinguished Fellows, who guide and lead the institution and its work. Among our Fellows are former cabinet officers; members of Congress; governors, mayors, and state legislators; and distinguished career public administrators, scholars, and business executives. Individually, Fellows represent the absolute best in leadership; collectively, they make the Academy an invaluable national asset.

The Academy team looks forward to responding to any subsequent follow-on strategic agency assessment dialogue, discussion, event, crowdsourcing campaign, or competition that arises from this RFI. Naturally, please let me know if you have any questions or requests.

Teresa Gerton
President and CEO
National Academy of Public Administration

Email:
Telephone:

The following study responds to the Topics I, II, IV, and V.

[INDEPENDENT ASSESSMENT OF ALLEGATIONS OF SCIENTIFIC MISCONDUCT FILED UNDER THE NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION SCIENTIFIC INTEGRITY POLICY](#)

(Click title above for more detailed information)

THE CHALLENGE

In September 2019, the National Oceanic and Atmospheric Administration’s (hereinafter “NOAA”) Scientific Integrity Officer (SIO) received four complaints of alleged violations of scientific integrity filed under the NOAA Scientific Integrity Policy ([NOAA Administrative Order 202-735D: Scientific Integrity](#)). The allegations relate to a specific NOAA public statement issued on September 6, 2019, regarding a tweet previously issued by the National Weather Service (NWS) Weather Forecast Office (WFO) in Birmingham, Alabama, on September 1, 2019.

THE BACKGROUND

NOAA’s SIO engaged the National Academy of Public Administration to conduct an independent assessment of those allegations. The goal of the assessment was to determine by a preponderance of evidence, meaning the standard of proof of making a finding of misconduct under [NOAA’s Scientific Integrity Policy and accompanying Procedural Handbook](#), if the NOAA personnel involved with the development and issuance of the September 6 Statement violated NOAA’s Scientific Integrity Policy and engaged in the misconduct intentionally, knowingly, or in reckless disregard of the Scientific Integrity Policy. Pursuant to the Scope of Work, the National Academy of Public Administration (hereinafter referred to as “The Academy”) was tasked to:

- Determine if scientific misconduct or loss of scientific integrity has not occurred and the allegation be dismissed; or
- Determine if scientific misconduct or loss of scientific integrity has occurred and recommend any specific action by NOAA to restore scientific integrity.

The inquiry into the alleged scientific misconduct and loss of scientific integrity associated with the September 6 Statement and the September 1 Birmingham Tweet presented a challenge for the Integrity Review Panel. The facts and circumstances surrounding these allegations of misconduct are not a perfect fit with the existing NOAA policies regarding scientific integrity and scientific communication and the Department of Commerce guidance on public communications. The Academy Team, therefore, created a process to assess the facts developed against existing policy and to determine whether personnel and actions were covered under NOAA and Commerce policies. This process also allowed the development of recommendations as to how policies might be improved.

THE RECOMMENDATIONS

- Develop formal policy guidelines for the issuance of media guidance to NOAA staff. Specifically, these guidelines should clarify roles and responsibilities, institutionalize the process, and identify the circumstances under which the agency should issue media guidance.
- Develop an interagency framework (that includes other federal agencies and the White House) for the sharing of scientific data and materials concerning severe weather- related events. The framework would include protocols for the timely update of information to reflect changing weather conditions and the release of the information to the general public.

- Develop a written policy statement on the right of NOAA scientists to review, comment, and amend any Official Communication that relies on their scientific analysis. This policy statement will complement NOAA's Scientific Integrity Policy.
- Revise NOAA's Scientific Integrity Policy's accompanying Procedural Handbook to include criteria and supporting examples to assist with the determination of scientific misconduct and a loss of scientific integrity. For example, NOAA could cite this case as an example of a violation of NOAA's Scientific Integrity Policy and scientific misconduct with regards to several criteria.
- Establish a formal intra-agency agreement to guide the interactions between Commerce and NOAA officials in the drafting of NOAA communications.
- Establish an intra-agency policy to articulate the role of Commerce political appointees in the communication of scientific findings. Develop supporting procedures and identify examples of political interference.
- Incorporate key principles of scientific integrity, including NOAA's Codes of Ethics for Science Supervision and Management, into NOAA's annual ethics training.
- Require NOAA staff and NOAA political officials to take scientific integrity training that includes the Code of Ethics for Science Supervision and Management, Once a staff member has completed the training, he/she will sign a statement confirming they will abide by these principles.
- Establish protocols with the Commerce Office of Inspector General (OIG) and/or other agencies to investigate alleged violations of scientific integrity involving senior NOAA and Commerce political leadership.

These findings and recommendations were developed as constructive and action-oriented next steps to ensure greater trust in the information that federal agencies (alongside with local partners) share to keep the American public safe and healthy. This report also highlights the rapidly-changing nature of communication mechanisms and the impact this has on maintaining scientific integrity principles.

The following study responds to the Topics I, II, III, IV, and V.

AGRICULTURAL RESEARCH SERVICE: OFFICE OF NATIONAL PROGRAMS REVITALIZATION

(Click title above for more detailed information)

THE CHALLENGE

The Agricultural Research Service (ARS) is the United States Department of Agriculture's chief scientific in-house research agency, conducting approximately 690 research projects across the country. ARS reorganized its approach to research project and program management in 1996 by breaking down disciplinary silos and taking a problem-centered approach to designing the research agenda. The resulting Office of National Programs has aligned and coordinated research projects across the country toward problems of high national or regional priority, making each project more effective, and leveraging the agency's resources for greater impact.

THE BACKGROUND

For decades, the Agricultural Research Service (ARS) has been deemed a world leader in plant and animal research. With a broad national network of research locations, and around 2,000 scientists, the Agency has about 690 on-going research projects. Its work has enormous impact not only in the United States, but all over the world.

ARS contracted with the National Academy of Public Administration (the Academy) to conduct an independent assessment during nine months of its national program structure and research and development (R&D) management processes. Impetus for this work stems from a recognition that its approach to managing its R&D work has not been extensively reviewed for almost two decades. Given the rapid and profound changes in agricultural science and use of technology to enhance research, ARS leaders determined it best to refresh its approach and identify areas to improve the impact of its vital work.

THE RECOMMENDATIONS

The final study report contains eighteen recommendations, organized into three categories, that target opportunities to improve ARS' mission impact. These three categories are:

1. Developing and communicating an overall strategy for R&D management initiatives;
2. Optimizing the organization to promote more innovative research and build enterprise-level research capabilities; and,
3. Building support for enterprise-level, strategic research investments.

These recommendations focus on building and maintaining the organizational infrastructure to support key drivers for scientific integrity, such as transparency, effective communication, training, and workforce development within a science agency focused on research and development to drive better outcomes for the American public.

The report's [eighteen recommendations](#) are organized under six findings from the assessment of the ARS research organization:

Finding 1. There is a need to develop and communicate an overall R&D management strategy.

- a) Develop a strategy that clearly communicates to the entire organization the objectives of its various R&D management initiatives and how they fit together as part of an overall enterprise strategy for achieving greater mission impact.
- b) The R&D management strategy should include a balanced portfolio for achieving impact with a focus on high-risk/high-return research.

Finding 2. There are opportunities at ARS to mitigate insularity within the intramural research organization.

- a) Adopt a system of regular rotation for National Program Leads that includes a mix of external and internal personnel.
- b) Institute a regular process for prospective external expert review of its National Program 5-year plans that focuses on identifying potential synergies across National Programs, especially National Programs in different National Program Areas.
- c) Scientists and National Program Leaders should regularly confer with the Office of International Research Programs when planning projects to help ensure that possible opportunities for cross-national research cooperation are identified and exploited.

Finding 3. There are opportunities to improve ARS' ability to undertake crossprogram research.

- a) Increase the number and training of program analysts who support National Program Leaders (NPLs). These program analysts should be assigned to specific groups of NPLs to enable them to specialize in the issues related to the programs covered.
- b) Take advantage of the forthcoming reorganization of office space at ARS headquarters to co-locate National Program Leaders from different National Program Areas operating in related scientific domains to facilitate interaction and information sharing.
- c) Provide competitive funding for travel to support the building of scientific teams seeking to undertake cross-program, cross-location projects.

Finding 4. There are opportunities to support high-risk, high-return research at ARS.

- a) Augment the design of the ARSX initiative to include a multi-stage process that allows for progressively reducing the risks associated with ARSX projects
- b) Add a provision to the administration of the scientist performance evaluation system that credits participation in high-risk/high-return research initiatives, such as ARSX.
- c) Create a mentoring program for early career ARS scientists interested in pursuing high-risk/high-return research.

Finding 5. ARS' funding process and National Program structure can impede efforts to build and coordinate enterprise R&D capabilities

- a) Strengthen efforts to build enterprise capabilities.
- b) Take advantage of the current hiring surge to pilot an enterprise approach to hiring and talent management.
- c) Take advantage of the end of the USDA hiring freeze and the higher number of retirements expected in the near future to increase the diversity of the ARS scientific workforce
- d) Take greater advantage of term appointments in order to be responsive to new research developments while retaining flexibility to change direction as needed in a rapidly changing research environment.

Finding 6. There are opportunities to enhance ARS' flexibility to make strategic research investments.

- a) Develop a strategy to build USDA, Office of Management and Budget (OMB), and congressional support for dedicated pools of competitive funding to enable HR/HR and cross-cutting research.
- b) Take a more systematic approach to seeking and shaping potential 0500 account funding from Congress to use for strategic investment opportunities.
- c) Develop a strategy to build USDA, Office of Management and Budget, and congressional support for a dedicated pool of funding for investment in enterprise-level capabilities.

The following study responds to the Topics I, II, III, IV, and V.

INTERNATIONAL LIFE SCIENCES INSTITUTE NORTH AMERICA: SCIENTIFIC INTEGRITY REVIEW

(Click title above for more detailed information)

THE CHALLENGE

The International Life Sciences Institute (hereinafter "ILSI") is a nonprofit, worldwide organization whose mission is to provide science that improves human and environmental health. For 40 years, ILSI has addressed problems in food, nutrition, and environmental sciences by engaging experts in academia, government and industry. Since 2007 ILSI's largest branch, ILSI North America has worked extensively with federal agencies and scientific professional societies to develop a framework—the [Guiding Principles for Private Funding of Food Science and Nutrition Research](#) (the Guiding Principles)—to ensure scientific integrity within multi-sector food and nutrition research partnerships. These [Guiding Principles](#) were simultaneously published in six high-impact peer-reviewed journals with the expectation that all of ILSI North America's research activities are conducted in this manner.

THE BACKGROUND

ILSI North America engaged the National Academy of Public Administration (the Academy) to conduct an in-depth analysis of its projects from 2013 to 2017 in comparison to the [Guiding Principles](#). The purpose of the

review was to provide objective, external verification that all research activities conducted at ILSI North America adhered to the Guiding Principles.

In the final published report, the Academy presented detailed analysis of ILSI North America's contracts, publications, and policy guidance and provides recommendations to further improve the clarity and consistency of the organization's contractual and policy requirements, enhance internal control, and strengthen its reputation for scientific integrity. In addition, the Academy identifies a number of structural and process issues that have the potential to significantly enhance the organization's ability to protect the credibility of its research activities.

THE RECOMMENDATIONS

ILSI North America is committed to achieving and maintaining high standards of scientific integrity in their research activities. Industry funding plays a vital role in supporting food science and nutrition research, due to limited research funding from other sources. However, there has been a long-standing debate on the credibility and objectivity of industry funded research. ILSI North America has made significant efforts to reduce funding-based bias or perceived bias in research activities, and as one participating study interviewee said, it requires more vigilance and caution than usual to manage potential conflicts and real/ perceived bias in industry-supported science.

This study reflects the lessons learned by those conducting research beyond the federal agency space. ILSI convenes scientists from academia, as well as the public and private sectors, to collaborate in a neutral forum on scientific topics of mutual interest. This study focused on ensuring credibility of their funded research and explored mechanisms and approaches to strengthening internal controls and governance to facilitate greater trust in the research being conducted. ILSI reached to the Academy due to its reputation as a neutral resource to provide an independent assessment, drawing on public sector experience and lessons learned.

ILSI North America is following, or has recently adopted, promising practices in many areas related to scientific integrity. There are additional internal management practices that would benefit ILSI North America. In this report, the study team identified specific internal control weaknesses and developed recommendations to improve contract management oversight procedures, including:

- Consider further revising its contract/grant agreement provisions and policy guidance to more explicitly reflect the requirements of the 8 Guiding Principles and avoid confusion;
 - ILSI North America should revise its contract/grant agreement provisions to explicitly identify the requirements on specifying the timeframe for publishing research outcomes (Principle 4), COI disclosures (Principle 5 and 6), and research methodology transparency (Principle 7).
 - ILSI North America should revise its policy guidance to clarify requirements on research design (Principle 2) and the accessibility of research methodology (Principle 7).
- Establish effective monitoring and enforcement mechanisms to ensure compliance with contractual and policy requirements;
 - ILSI North America's policy guidance should clearly identify the roles and responsibilities for monitoring compliance.
 - ILSI North America should establish standard compliance review processes and procedures to ensure all parties perform their contractual obligations.
 - The outcomes of compliance reviews should be clearly documented.
- Document operational processes at both the organization level and the committee level.
 - Process documentation should be developed by appropriate officials and formally approved by the ILSI North America's Board of Trustees. Stakeholder input should be solicited, as appropriate, prior to finalizing the documents.

- ILSI North America should ensure all essential operating procedures and processes are appropriately documented and maintained. Process documents should identify the roles and responsibilities of key participants, important procedure/process steps, and key stakeholders who should be involved in the processes.
- ILSI North America should keep process documentation as a living part of its operation and conduct annual reviews of its essential processes to identify what works and what needs attention.
- Process documents should be shared with ILSI North America staff and other relevant stakeholders.

Over the course of this project, the study team identified a number of additional structural and process issues worth further exploration. These issues have the potential to significantly affect ILSI North America's ability to protect the credibility and transparency of its research activities:

- Committee composition—Should ILSI North America require a more balanced representation of academic and government members on their committees? As some participating study interviewees suggested, increasing the number of academic or government representatives may help address the concerns about undue influence from industry members.
- 8 Guiding Principles—Should ILSI North America consider revising the 8 Guiding Principles to reflect the current operating environment? As the authors of the Guiding Principles stated, the paper is “[intended to be a dynamic document, prompting ongoing discussion and refinement of the guidelines it presents.](#)” The 8 Guiding Principles were developed over a decade ago, and it is important to regularly review these principles to determine whether they are still appropriate in a rapidly evolving environment or whether any refinements or updates are required
- Models for enhancing research integrity—There is a variety of tools and practices available to strengthen the objectivity and transparency of research activities. For example, to increase transparency, ILSI North America could establish a permanent public inventory of summaries of funded research.

Upon completion of the research, the summary should be updated to include information on how to access archived data. Subsequently, citations to published work stemming from the research should be listed with the summary. This inventory would increase the transparency of ILSI North America funded research, both to enhance external credibility and to facilitate the assessment of the adequacy of the ongoing monitoring of contract compliance. Another example is addressing research misconduct (e.g., fabrication, falsification, plagiarism, etc.) and other ethical violation. To protect research integrity, it is critical to establish clear policies and procedures for responding to misconduct/ethical violation allegations concerning research supported by ILSI North America. *The roles and responsibilities of ILSI North America and other parties should be clearly defined in the policy guidance. These leading practices provide useful models for ILSI North America to consider as it continues to develop its policy and process to protect the integrity of its research activities.*

These studies illustrate deep understanding of key processes, structure, and accountability mechanisms needed to improve scientific integrity within Federal agencies. Focusing on building trust in the process and outcomes of science and technology research and communications, these exemplars provide relevant perspective to inform the pursuit of improved trust in Federal science.

Sheryan Epperly Chester's public comment for SI-FTAC RFI

First, I unequivocally endorse the recommendations submitted by the Union of Concerned Scientists. I am a retired government scientist and I can demonstrate a need to strengthen scientific integrity, linking to some of the UCS's recommendations.

My example will use the Department of Commerce, NOAA, National Marine Fisheries Services' research and rulemaking pertaining to skimmer trawls in the southeast U.S. and the Gulf of Mexico. NOAA/NMFS often is held up as an example of strong scientific integrity policies, but this example undermines that assertion. I worked as the sea turtle program lead for the Southeast Fisheries Science Center until my retirement at the end of February 2013.

Rulemaking for skimmer trawls, which catch shrimp, began in 2012 and a final rule was advertised in 2019, effective in 2021. The process was rocky. As a result of litigation, SEFSC implemented a mandatory observer program for skimmer trawl vessels in 2012. A proposed rule was published that would require Turtle Excluder Devices (TEDs) in skimmer trawls to allow sea turtles to escape. An analysis of observer data from 2012 indicated that a significant proportion of the turtles were small enough that they could pass through the bars of a TED and likely would be drowned if tow time limitations were lifted and TEDs required in lieu of tow times. That information, along with data showing poor compliance with both the mandatory observer program and with tow time compliance was presented to Southeast Regional Office staff responsible for promulgating the rule. As a result, they published a notice that no rulemaking would follow based on the proposed rule and that further research would be conducted. At the time, all the unpublished reports and most of the internal memos tasking research and conveying research results were posted to the SEFSC's sea turtle website, providing full transparency. Subsequently, the observer reports for 2013 and 2013 were similarly posted, as were several reports and Technical Memoranda resulting from gear research on TEDs with small bar spacing. Detailed data on the 2015 program never was published and posted, but were used in the rulemaking process.

Note, that it was my policy to encourage that everything be posted to our website (I was responsible for starting that website): mission statement, programs descriptions, all publications (peer-reviewed, unpublished reports, contractor reports, supported theses and dissertations, abstracts and presentations, etc.), details about observer programs (including training videos, manuals, forms, etc.), etc. I encouraged our scientists to submit reports that masked confidential data so that the reports could be made public. My goal was to make everything available to everybody: government employees and the public.

In 2016, the agency published a proposed rule to require TEDs with smaller bar-spacing. The rule was based on the observer program findings and the gear research. The proposed rule mirrored the preferred option identified in the Draft Environmental Impact Statement. The final rule and Final Environmental Impact Statement were published in 2019, and differed in significant ways from the proposed rule and DEIS.

The change was based on a very flawed sea turtle take analysis (ignoring all agency policy to take to consider resuscitated turtles as dead – either using 80% or 100% mortality rates) by Babcock et al. (2018), which suggested that mortality in the shrimp fishery (and not just the skimmer trawl fishery) was orders of magnitude less than previously presented and thus such a restrictive rule as the proposed rule was not needed. The final rule also indicated that there were performance and safety issues and significant economic concerns with the TEDs, despite gear research that showed different. It is my understanding (from involved staff) that the agency was forced to change the rule at OMB's direction – clearly an example of political interference, if true. I believe it is not a coincidence that in April 2021, just after the agency was served with a Notice of Intent and soon into the new Biden administration, the agency published an announcement of proposed rulemaking that would modify the existing rule to be consistent with the proposed rule (and DEIS) published years before (2016).

Sometime between when the 2016 proposed rule and 2019 final rule were published, the SEFSC sea turtle website was taken offline. Now, there no longer is an accounting of all the sea turtle publications. One no longer can view a page to see a listing of all publications of all types, but instead one has to know that something exists then search for it at <https://www.fisheries.noaa.gov/resource/publication-database/southeast-fisheries-science-center-publication-database>. This makes it very difficult for the public to follow the process of the research and eliminates much of the transparency in rulemaking since supporting documents are difficult, if possible, to find.

I note that not everything was added to the above website. For example, the Babcock et al. 2018 paper did not appear on this website until recently. This was the unpublished report cited in the final rule for erroneous sea turtle take analysis. Given that it was an important document to the final rule, it is not clear why SERO and SEFSC held the Technical Memorandum so close. Usually, TMs are catalogued and are available online immediately. I was able to find the report much earlier on the GSMFC website <http://gulfcouncil.org/wp-content/uploads/D-5-Shrimp-fishery-turtle-bycatch-Tech-Memo-721-final.pdf>. Also, many of the unpublished reports once available on the SEFSC sea turtle website no longer are available on the Center's search site.

I submitted public comments during the scoping process for both the 2016 and 2021 proposals, repeating much of the above.

The example above demonstrates the need to respond to UCS's recommendations - specifically these:

Ensure that science-based rulemaking is transparent and protected from interference, Prevent conflicts of interests in science-informed decisionmaking, and Create policies that ensure political officials cannot impede the collection or access to federally funded data.

July 28, 2021

Dr. Ryan Donohue
Office of Science and Technology Policy
Executive Office of the President
1650 Pennsylvania Ave NW
Washington, DC 20502

Re: To Improve Federal Scientific Integrity Policies
Federal Register Effective Date: 6-28-2021
Federal Register Page Number: 34064-34066

Dear Dr. Donohue,

Thank you for the opportunity to offer comments to the Executive Office of the President in response to the White House Office of Science and Technology Policy (OSTP) Request for Information to Improve Federal Scientific Integrity Policies.

The American Society of Agronomy (ASA), Crop Science Society of America (CSSA), and Soil Science Society of America (SSSA) represent more than 8,000 scientists from academia, industry, and government, 12,500 Certified Crop Advisers (CCA) and 781 Certified Professional Soil Scientists (CPSS), including many who work in federal agencies. We are the largest coalition of professionals dedicated to the agronomic, crop and soil science disciplines in the United States.

Federal agriculture scientists make discoveries that drive innovation and new technologies – keeping our nation’s farmers, foresters, and ranchers competitive, creating jobs, and developing new industries. Private sector successes depend on the accurate and reliable research performed by federal scientists, and, as publishers of scientific research, we know the value of quality peer review of publications and research proposals, which lies at the heart of scientific integrity.

While federal research is trusted to be accurate and reliable, there is room for improvement in the collection and communication of federal agriculture science data. Scientific integrity is compromised if there are conflicts of interest, or even the appearance of such, and if data is not reliably available or usable, even if it is accurate. For this reason, OSTP is wise to ask questions not only about the policies concerning intentional suppression or distortion of findings, which obviously reduce scientific integrity and transparency, but also about the systemic challenges that undermine integrity, such as the need for automated collection and distribution of scientific information and inclusive research environments.

Work with scientific societies and publishers to reduce conflicts of interest

We in the agriculture research community are concerned about the suppression or distortion of findings that may come when there are conflicts of interest among researchers, publishers, and funders. The

New York Times reported that the e-cigarette company Juul recently “paid \$51,000 to have the entire May/June issue of the American Journal of Health Behavior devoted to publishing 11 studies funded by the company offering evidence that Juul products help smokers quit.”^{1,2} There is a close association between agriculture researchers and agribusiness, with companies that supply fertilizer, seed, agrichemicals, equipment, and software funding a significant and growing portion of agriculture research. This presents potential opportunities for conflicts of interest in research and publications.

To prevent such conflicts of interest, OSTP should work with scientific societies and publishers to standardize publication requirements and best practices that reduce or eliminate conflict of interest issues. For example, researchers could be required to pre-register studies, which would reduce the chances of publishing only cherry-picked results. Additionally, researchers could be required to acknowledge all sources of financial support (e.g., funding, grants, sponsorship, in-kind) prior to submitting a manuscript for peer review, as opposed to only after the manuscript is accepted for publication. All commercial or financial relationships, present and future, that might be viewed as a conflict of interest should also be disclosed. Publishers should agree to disclose any agreement with research sponsors that could bias the results or interpretation of the research in any way.

OSTP could propose a ban on the use of federal funds to pay for publishing in journals that do not adhere to certain standards. For example, journals should make standard use of plagiarism software and have an easily identifiable ombudsperson to handle complaints. Publishers should retract articles with documented fraud or fabrication, and they must post notices that the article is retracted so that it is not cited again.

Open-source data infrastructure promotes scientific integrity.

One systemic challenge is that there is currently no publicly accessible data repository that is equipped to handle the magnitude and complexity of the data produced by modern agriculture research. Access to this data is essential for agriculture scientists to create decision support tools for climate-smart and economically sound agricultural practices, which, in turn, underpins modern efforts to establish carbon markets. It is not enough that scientists have access to the data via, for example, research publications, this data must also be available to Certified Crop Advisers and those who transfer the research outcomes to agricultural practitioners.

The U.S. Department of Agriculture (USDA)’s National Agricultural Library supports a small data repository that contains some of the data produced by USDA scientists, but this effort must expand to include all USDA-produced data, including historic datasets, data from conservation districts and the National Cooperative Soil Survey, and data from USDA-funded researchers and others. Furthermore, as imaging technologies rapidly advance, there will be a need to create infrastructure that can handle these even larger datasets in the near future. Soil survey data and USDA yield estimations are already key enablers of the digital transformation occurring in agriculture and generate value for startups and established businesses alike. A right-sized data repository that can transparently handle current and evolving agricultural data needs will engender trust in the science underpinning agricultural progress.

The RFI asks about “good practices Federal agencies could adopt to improve scientific integrity, including in the communication of scientific information, addressing emerging technologies and evolving scientific

¹ <https://www.nytimes.com/2021/07/05/health/juul-vaping-fda.html>

² <https://www.ingentaconnect.com/content/png/ajhb/2021/00000045/00000003>

practices, supporting professional development of Federal scientists, and promoting transparency in the implementation of agency scientific integrity policies.” Each of these goals is addressed by support for data infrastructure that ascribes to “FAIR” (Findable, Accessible, Interoperable, Reusable) principles.

For example, a modern, searchable database that rivals NIH’s Genbank or the National Oceanic and Atmospheric Administration’s National Climatic Data Center, with a budget that matches the amount and complexity of the data it houses, would vastly improve the communication and utilization of the excellent agriculture data federal scientists are already producing. To address “emerging technologies and evolving scientific practices,” USDA should hire specialists to create data extraction and upload software wizards or templates for automatic extraction, standardized formatting of data and metadata, and depositing of data directly from research and farm equipment, and these data specialists should work with equipment designers and advisers in the field to harmonize standards from the start. This would increase the immediate utilization, and trust, in the data, as it would reduce the opportunity for user-errors in inputting data.

To further reduce the likelihood of errors, USDA should support the training of federal scientists, and scientists whose research or education is supported by USDA grants and fellowships (“professional development”), in the collection, formatting, and uploading of data into the FAIR repository so that new data can begin to populate the repository immediately. To promote and ensure transparency, considerable thought should be put into data management, data provenance, long-term sustainability, preservation and curation practices, and importantly, data privacy, especially where working farms are concerned.

What is needed is a well-supported, open-source, thoughtfully designed data repository that ascribes to FAIR principles and employs automatic uploads of data where possible. Also necessary is funding for adequate training of Certified Crop Advisers, who will work with the primary data collectors, and of end users, including scientists, to engender trust in the data the repository houses. Such a system would reduce unintentional data distortions and make intentional data distortions difficult. Furthermore, the repository would have the additional benefit of enabling researchers to develop new tools and software for searches, analytics, and modeling.

Research integrity is bolstered by the dissemination of non-significant results.

A second systemic issue is the lack of data from experiments that produced negative or non-significant results. Currently, in the absence of a repository for housing such data, these results are rarely published or otherwise available to the research community, leading to multiple researchers wasting resources by attempting similar experiments.

There are journals specifically created to publish negative data as a service to the community. In 2018, the American Society of Agronomy and Crop Science Society of America began publishing the *Agroecosystems, Geosciences & Environment* journal to fill this need. This high-quality, peer-reviewed journal focuses on providing a publishing platform for negative results, time-limited studies, and regional findings. But non-significant data is more difficult to capture. The Societies suggest the creation of study registries, which researchers would be required to use and update if they have received a federal grant. If the research is successfully published, then a link to the publication could be provided, but if the study yielded results too weak to publish, or if the research needed to be taken in a different direction, that crucial information would be available to other researchers considering the same line of study.

Safe and inclusive research environments strengthen scientific integrity.

There is always bias in science. It can come from the questions researchers ask or do not ask, the methods used to collect data, the accessibility of conferences or publications where the research is presented, and the identities of the researchers themselves. Scientific data need not be intentionally distorted for it to be doubted by communities that have traditionally been left out of the scientific process.

For example, there is a stark racial disparity in Covid-19 vaccinations in the United States, with about 47% of white Americans receiving the first dose of the vaccine but only 34% of Black Americans.³ While surveys have shown Black Americans to be considerably more concerned about contracting or spreading the virus, they are significantly less likely to say they will get the Covid-19 vaccine than other groups. According to a Pew survey, “Black adults express less confidence in the coronavirus vaccine research and development process – a judgment closely aligned with intent to get vaccinated.”⁴

Inclusive research environments that support a diversity of scientists and engage in multidimensional and multicultural outreach will engender trust in the scientific community. Such an environment begins when people committed to the idea of fostering such an environment receive the regular training and constant support needed to make it a reality. Federal agencies should encourage universities to provide implicit bias training for faculty, post-doctoral researchers, and students to begin building awareness of what a safe and inclusive environment is.

Additionally, the Federal government should encourage and reward culturally responsive mentorship programs, which can positively engage a more diverse group of students in STEM fields. And because there is a gap between what is known to be effective in mentorship and what is often practiced in academia, programs should include scientifically-based best practices that result in “intentional, inclusive, and effective” mentorship, as reported by the National Academies of Sciences, Engineering and Medicine.⁵ For example, funding agencies could require mentorship education and mentoring plans in grant applications, with required reporting of outcomes and diversity metrics.

Agricultural institutions may confront extra challenges creating inclusive research spaces because so many are located in small, rural communities, which are less diverse than suburban or urban places.⁶ This fact of geography can lead to a smaller number of diverse candidates applying to fill faculty and other research positions and to fewer diverse candidates accepting such positions when offered. New faculty of color can and should be supported despite a less diverse community at large, and universities can use aggressive, active recruitment strategies for minority and women candidates. One such strategy

³ <https://www.kff.org/coronavirus-covid-19/issue-brief/latest-data-on-covid-19-vaccinations-race-ethnicity/>

⁴ <https://www.pewresearch.org/fact-tank/2021/03/09/black-americans-stand-out-for-their-concern-about-covid-19-61-say-they-plan-to-get-vaccinated-or-already-have/>

⁵ National Academies of Sciences, Engineering, and Medicine. 2019. The Science of Effective Mentorship in STEMM. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25568>.

⁶ <https://www.pewsocialtrends.org/2018/05/22/demographic-and-economic-trends-in-urban-suburban-and-rural-communities/>

is dual hiring, since small cities are less able to support two professionals and women are more likely to be in dual career relationships than men⁷.

Thank you for your consideration of these factors that contribute to scientific integrity. Our societies stand ready to work with you to ensure the nation's food and agriculture research enterprise is trusted, reliable, and robust.

⁷ Schiebinger, Londa L., Andrea Davies Henderson, and Shannon K. Gilmartin. *Dual-career academic couples: What universities need to know*. Michelle R. Clayman institute for gender research, Stanford University, 2008.



Basil Hassan, Ph.D.
Director and Deputy Chief Research Officer

7/28/2021

White House Office of Science and Technology Policy (OSTP)
Scientific Integrity Fast-Track Action Committee (SI-FTAC)
ScientificIntegrityRFI@ostp.eop.gov

Dear: Scientific Integrity Fast-Track Action Committee

Subject: ***Request for Information to Improve Federal Scientific Integrity Policies***

The information herein is in response from Sandia National Laboratories to the White House Office of Science and Technology Policy Request for Information (RFI) To Improve Federal Scientific Integrity Policies announced in June 2021. This response addresses all the topics listed in the call, which are included below. In general, consider a policy that promotes excellence in scientific research, is more proactive in openness and transparency to foster scientific integrity, and has a process for periodically reviewing the policy and its effects, and revising the policy based on the effects for continuous improvement. Specifics given herein are developed from recommendations given by the National Academies (2017), OECD (2007), and expectations at Sandia National Laboratories (SNL) and input from SNL's Office of Research and Development Excellence Advisory Committee.

Topics of interest from the RFI:

1. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science.
2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information.
3. Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce.
4. Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices.
5. Other important aspects of scientific integrity and effective approaches to improving trust in Federal science.

Policy improvements to promote trust

Recommendations to include in the Federal policy to promote trust in Federal science are to:

- Encourage and value publication of negative results and fund replication of research for verification. This will help prevent costly duplication of unpublished efforts that will increase

learning and knowledge and promote transparency in the research process. Federal funding, research institutions and journals should support these efforts.

- Obtaining effective peer review, ensuring Differences of Professional Opinions are adequately addressed, clearly defining roles and responsibilities for each collaborator, and analyzing errors are other enduring approaches that are applicable to any new and emerging technologies.
- Additionally, consider using unbiased and diverse committees made up of people with appropriate scientific backgrounds to select topics of research and choose projects to fund and base decisions on specific criteria that is laid out in advance.
- Consider developing a process to report and address instances of inappropriate interference in scientific research, funding biases, and hostile research environments to include in the Federal policy and the resources needed to support effort. A lack of reporting mechanism and corrective measures results in no accountability for those acting inappropriately.
- Monitoring the integrity of R&D environment is needed and should be accomplished through peer review. Ensure enough information is included to reproduce the results and open access to experimental methods used, research data and code, and possibly unique equipment or facilities when applicable should be provided.
- Funding to develop infrastructure to archive research records and datasets and allow public access can be substantial and may be best addressed at the Federal level to avoid duplication of efforts and incompatibilities among agencies, research institutions, and publishers. Questions such as how long data records should be archived and what format to use remain unanswered.

Another recommendation to build public trust is to foster scientific integrity and monitor the research environment through the establishment of an independent Advisory Committee as proposed in NAP (2017). The committee would look after the interests of and help hold stakeholders across the research enterprise such as Federal scientific agencies, research institutions, and scientific publishers accountable. The committee would require broad expertise across relevant scientific fields. It could help develop approaches to increase scientific integrity and the impact of research output through improved processes and expectations and assist with scientific integrity in international collaborations when needed. The Advisory Committee at SNL consists of some of the most prestigious researchers at SNL, has been integral in helping establish an effective scientific integrity policy, training members of the workforce about expectations, and developing tools to help researchers practice higher standards.

Federal Level Policy Improvements

As an FFRDC, SNL operates under DOE and funding for research may come from many different Federal agencies. Inconsistencies among agencies can make it difficult to be compliant with all policies governing research at SNL. Establishing a framework at the Federal level to provide guidance for complex situations involving multiple agencies could be helpful while allowing specific agencies to have requirements tailored for their needs. Specifically, policies need Federal level definitions and procedures. An area of particular concern is with inconsistent management of plagiarism. Allegations of plagiarism often center around intellectual theft “without giving appropriate credit” from collaborators or students/supervisors, which can also be viewed as “authorship disputes” or in line with “accepted practices of the relevant R&D community” rather than plagiarism. A clear, unified definition of “authorship disputes” and explicit and consistent policies around these instances of possible plagiarism are needed. Consistent procedures for handling allegations, and application of inquiries, investigations, and appeals are also needed. Additionally, there is a need for guidance around authors on publications.

Journals need to articulate criteria and expectations around authorship to ensure appropriate credit is given and only to those who truly made contributions to the work.

Professional Development

Guidance around professional development at the Federal level would be useful to ensure equity and cultivate high quality researchers to address the needs of the nation. Consider better reporting on scientific workforce professional development as an integral part of the federal policies for transparency and accountability. Funding decisions for research, scientific awards, and hiring should include broad assessment of options and documentation supporting decisions. Recognize that a perceived lack of history of accomplishments and awards may be due to bias and therefore additional metrics should be used to assess value and potential.

Consider developing training curricula and/or videos that agencies could utilize with examples of good and bad scientific practices, and interagency and international collaborations. This would better align inconsistencies among agencies and prevent duplication of effort, which has huge cost savings. Public communication about substantiated violations of scientific integrity should be consistent with how the false information was communicated. For example, if false information was published in a journal article, a retraction and necessary information should be published in the journal. If false information was communicated from the media, corrections should be made from the media source.

Federal policies to encourage development of leadership in the scientific workforce are needed for not only technical scientific leadership but also soft skills leadership for scientists and engineers. Policies should be developed to encourage voluntary professional certification for scientists. As an example, professional engineers obtain a license where their work impacts public safety. In the United Kingdom (UK), these are "chartered engineers" and the UK has a voluntary license for scientists such as Chartered Chemists and Chartered Physicists. Chartered Scientists, like many professions, are required to meet standards and continue professional development training to maintain their status. Voluntary certification would qualify scientists in practicing research at high standards.

Improvements in communication of scientific and technical information to the public

Principles for conveying scientific and technological information to the public need to be established. The information conveyed must be accurate and unbiased. Allow the scientists to review, make edits, and approve of media communications before release. If an answer is unknown, state that fact rather than speculate or provide an unsubstantiated answer. Recognize that science is a process and results may be preliminary and may change based on new information and understanding but may be the best information at the time. Due diligence in journalism is needed when reporting on scientific results to ensure reporting good scientific results. Get input from other unbiased, qualified scientists on the results before releasing it to the public. Report on all aspects of the research including unanswered questions, verification of results, and differing opinions. Give enough information to tell the whole story.

Acknowledgements:

We would like to thank the following members of SNL's Office of Research and Development Excellence Advisory Committee for their insightful contributions: Carla Busick, Cynthia Phillips, Katherine Simonson, and Hy Tran.

References:

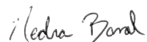
National Academies of Sciences, Engineering, and Medicine. 2017. *Fostering Integrity in Research*. Washington, DC: The National Academies Press. doi: <https://doi.org/10.17226/21896>.

Organization for the economic co-operation and development (OECD) Global Science Forum. 2007. *Best Practices for Ensuring Scientific Integrity and Preventing Misconduct*, Chairs: Makoto Asashima and Nigel Lloyd, Tokyo workshop, Nov. 28, 2007. (<https://www.oecd.org/science/inno/40188303.pdf>)

Sincerely,



Basil Hassan, Ph.D.
Director and Deputy Chief Research Officer



Nedra Bonal, Ph.D.
Manager, R&D Integrity Officer

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July 28, 2021

The White House

Office of Science and Technology Policy

1600 Pennsylvania NW

Washington, DC 20500

Sent via email to: ScientificIntegrityRFI@ostp.eop.gov

To whom it may concern,

On behalf of the members of the organizations we lead, the Population Association of America and Association of Population Centers, we are pleased to submit comments in response to a Request for Information (RFI) issued by the Office of Science and Technology (OSTP), "To Improve Federal Scientific Integrity Policies."

The PAA and APC are two affiliated organizations that together represent more than 3,000 scientists working in the population sciences, an interdisciplinary field that includes demographers, sociologists, economists, and statisticians. Population scientists study the causes and consequences of population change. The APC is comprised of the over 40 federally supported population research centers based nationwide at universities and private research institutions. Population scientists have made groundbreaking and meaningful contributions on a wide array of topics relevant to society, including the social determinants of health and mortality, child and adolescent development, aging, migration, fertility, economic well-being, education, retirement, and post-disaster resiliency. Our members rely on competitive funding from the National Institutes of Health (NIH) and National Science Foundation (NSF) and data produced and disseminated by the federal statistical agencies to conduct their scientific and applied research and research training activities.

The RFI seeks input to "help improve the effectiveness of Federal scientific integrity policies to enhance public trust in science" in support of the President's Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. We appreciate OSTP's leadership and the initiative that the Biden Administration is taking to: promote public trust in Federal scientific agencies; improve the communication of scientific and technological information; encourage adoption of effective policies and practices; and enhance support for the scientific workforce. We hope that our comments inform the important work that OSTP and National Science and Technology Council interagency working group will be conducting to meet the objectives of the President's Executive Order.

Politization of Scientific Agencies

In recent years, our organizations have strongly opposed efforts to install partisan appointees at scientific and statistical agencies. For example, when the Trump Administration appointed three political appointees in the office of the Census Bureau Director, our organizations [expressed](#) strong concern. Scientific and statistical agencies should be led by objective, qualified experts. We urge the working group to reiterate the need for Federal scientific and statistical agencies to be led by individuals who have the appropriate credentials to advance their agencies' missions. Having trustworthy, nonpartisan leadership at the helm of these agencies is essential for securing the public's trust and maintaining their credibility.

Affirm Principles of Scientific Peer Review

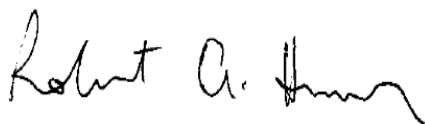
We encourage the working group to use this exercise as an opportunity to reaffirm the Administration's support of the NIH and NSF peer review processes. The peer review processes that the NIH and NSF employ for selecting the most meritorious research applications are recognized as the "gold standard" for determining the allocation of precious Federal research dollars. The peer review processes that these agencies use to rank and award research funding should be identified as "best practices" and reaffirmed as a model framework for ensuring that only the very best, innovative science is supported.

Embrace Principles and Practices of Federal Statistical Agencies

In March 2021, the National Academies Press of the National Academy of Sciences, Engineering, and Medicine (NASEM) published the [7th edition](#) of the "Principles and Practices for a Federal Statistical Agency." This consensus study report "offers five refined and updated principles for statistical agencies, such as public trust, credibility, independence from undue influence, and innovation — as well as 10 practices to help agencies fulfill the principles." The report, which was written by objective NASEM experts, and reviewed by outside stakeholders, provides numerous recommendations regarding how Federal statistical agencies should be managed to deliver accurate, timely, and relevant information for public and policy use. We think the recommendations in this report are very useful and hope that the members of the working group will identify them as "best practices."

Once again, thank you for seeking input from the scientific community. We appreciate your consideration of our views and hope you will contact us if our organizations can be a resource to you during the working group's deliberations.

Sincerely,



Dr. Robert Hummer
President
Population Association of America



Dr. Sara R. Curran
President
Association of Population Centers



July 28, 2021

White House Office of Science and Technology Policy
725 17th Street NW
Washington, DC 20500

Submitted electronically to ScientificIntegrityRFI@ostp.eop.gov.

RE: SI-FTAC RFI (86 FR 34064)

The Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA) appreciate the opportunity to provide written comments to the White House Office of Science and Technology Policy in response to its Request for Information regarding the current state of scientific integrity processes and practices.

IDSA and HIVMA represent a community of over 12,000 physicians, scientists, public health experts, and other health professionals who specialize in infectious diseases and HIV medicine. Our members work across a variety of healthcare settings, including hospitals, academic medical centers, long-term care facilities, public health departments, publicly funded clinics, and private practice. We support the six principles outlined in the 2009 Presidential Memorandum on Scientific Integrity and urge the Task Force to use these principles as foundation for their work. We are pleased to offer recommendations to the interagency task force of the National Science and Technology Council that we believe will help promote trust in Federal science and strengthen evidence-based policymaking.

1. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science:

- Ensuring transparency should be at the forefront of efforts to promote trust in federal science. This includes the regular and accessible release of data and scientific findings and a commitment to meaningful public input and engagement in the development of regulatory processes.
- Limit political interference in federal research, which can undermine public health experts and compromise transparency and trust. IDSA has previously [commented](#) on proposed Federal COVID-19 data reporting protocols that would have removed the

Centers for Disease Control and Prevention (CDC) as a recipient of data on patients hospitalized with COVID-19.

- Promote the integrity of scientific research by ensuring review boards are composed of subject matter experts committed to transparent and equitable review. Lack of appropriate expertise on Federal advisory boards can undermine trust in federal research processes.
- In cases of Emergency Use Authorizations (EUA) in a public health emergency, regulatory authorities should establish and publicly communicate benchmarks for the receipt of diagnostic, therapeutic, and vaccine EUAs, as well as requirements for receiving licensure after an EUA is granted. Agencies should require the public release of clinical trial data both before a therapy receives an EUA and before it receives subsequent license approval.
- Require clinical trial sponsors to include plans for recruiting Black, Indigenous and other people of color, Latinx communities, children, individuals who are pregnant and breastfeeding, and others who are immunocompromised, including people with HIV, as applicable. Ensure inclusion of individuals living in rural areas and outside of large academic medical centers to ensure more representative trial populations.

2. *Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information:*

- Increase and cultivate collaboration and engagement with Federal scientists and contractors working on scientific matters with researchers and physicians from public and private universities and medical schools to facilitate the accurate dissemination of evidence-based scientific data on news and social media. Examples include Dr. Anthony Fauci from the National Institute of Allergy and Infectious Diseases communicating data from peer-reviewed publications in “layman’s terms” on news outlets to provide scientific rationale for Federal health policies during the COVID-19 pandemic. Other examples include physicians who have testified to the United States Congress on the COVID-19 pandemic and on vaccine policy in general. Accuracy and implementation of safe public policy requires the protection of scientific independence during clearance and review processes and the avoidance of political or other improper interference in research or data collection.
- Provide scientific communication training through federally funded grants, which could require explanations for how investigators will ensure the dissemination of data are available in an accessible way to both peers, impacted communities and populations and other constituents.
- Fund and develop mechanisms to enhance accurate scientific communication through social media and other digital platforms to allow for transparent scientific communication and dissemination of important messaging.
- Federal agencies should prioritize the rapid development and release of evidence-based guidance, even in the settings of incomplete science. During the COVID-19 pandemic Federal agency guidelines were often delayed weeks or months, which

resulted in the need for state and local public health agencies to create their own recommendations.

- Support collaborations between the Food and Drug Administration, National Institutes of Health, CDC, and the clinical research community to strengthen and improve clinical trial infrastructure, expand funding mechanisms, and develop better analytical and predictive tools. Federally supported infrastructure should provide an integrated framework to link patients with appropriate trials and encourage large-scale collaboration across many different types of facilities. Expanding clinical trial participation beyond major academic medical centers will also allow studies to reach more diverse patient populations.
- Provide resources within agencies to help researchers and personnel understand effective strategies in communicating science. Resources like the NIH [Science, Health, and Public Trust](#) should be supported in working to increase effective communication of scientific research.
- Promote equitable clinical trial design and strategies informed by input from the impacted communities to ensure access to clinical trials for Black, Indigenous and other people of color; Latinx communities; immigrants; and others who are underserved or live on low incomes.

3. *Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce:*

- Increase funding support for diversity initiatives that supplement and build on existing programs like the [NIH UNITE Initiative](#), which aims to address structural inequity in the scientific workforce and emphasizes transparent communication with internal and external stakeholders.
- Provide guidance on authorship and settling of authorship debates.
- Provide guidance on commercialization and addressing scientific integrity across the continuum of academia and industry.
- Re-enforce protections for career civil service employees and create an independent body to review candidates for science and technology appointments, including for advisory board appointments, to ensure appointees have the appropriate scientific credentials and expertise.
- Ensure that study section participants include individuals from underrepresented backgrounds and clinician scientists who understand the unique challenges encountered by trainees.
- Provide more funding opportunities for early-stage investigators from underrepresented groups. NIH does this at the predoctoral level with the [F31](#) NRSA Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research mechanism
- Foster increased collaboration among federal agencies, research institutions and community-based organizations with expertise in health disparities to develop and

inform strategies to improve mentorship programs and career support for underrepresented minorities during training.

4. *Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices:*

- Allocate funding to support educational modules on Responsible Conduct of Research and Rigor and Reproducibility; these teaching obligations are often taxed on research faculty and could benefit from federal support. Develop modules for the training of these topics and host a federal data sharing platform to enable public access to data on a supported server.

5. *Other important aspects of scientific integrity and effective approaches to improving trust in Federal science:*


- Promote and prioritize the uptake of implementation science, particularly in the development of Federal guidelines and recommendations. By using implementation science, researchers can help bridge the divide between research and practice and bring programs that work to communities in need.

We thank you for the opportunity to help improve the effectiveness of Federal scientific integrity policies and enhance public trust in science. For any questions about our comments, please contact Jaclyn Levy, IDSA Director of Public Policy, at jlevy@idsociety.org or Andrea Weddle, HIVMA Executive Director, at aweddle@hivma.org.

Sincerely,



Barbara D. Alexander, MD, MHS, FIDSA
President, IDSA



Rajesh T. Gandhi, M.D., FIDSA
Chair, HIVMA

Scientific Integrity Fast-Track Action Committee (SI-FTAC)

ScientificIntegrityRFI@ostp.eop.gov

Responder: Springer Nature

Responder Type: industry

We are proud of the role Springer Nature plays in supporting and enabling the integrity of US research. It is an honour and privilege to be responsible for managing quality assessment (QA) of large numbers of US research contributions, and to be the curators, custodians and maintainers of the scientific record in the form of published papers. As such we strongly support the goals articulated in the Jan 27 Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking.

1. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science:

We are a strong supporter of open science as a major contributor to promoting transparency and trust in science. To achieve all the benefits of open science for public trust in federal science the federal government needs to strongly support the pre-existing mechanisms for quality assessment, including the peer-review and improvement processes that editors and publishers manage, while developing new more open ways of working that complement and enhance those mechanisms.

Publications, data, code and detailed protocols all have the potential to be made publicly accessible at point of publication and, indeed, much earlier in many cases. We are committed to building on our own existing work in this area, for example our innovative [preprint](#) and [protocol](#) sharing initiatives. Research assessment processes need to recognize and reward researchers for adopting open research practices. Ultimately, we need to ensure that outputs like data, code etc that underpin specific research findings are certified in peer review at journals and made openly available. In this way the pre-existing certification checkpoint that journals provide can be leveraged to allow a faster and more effective transition to open science informed by community expectations. The federal government can play an important role in helping develop shared expectations that can be iterated across the research lifecycle at respective stakeholders - institutions, funders and publishers. There are already good examples of the benefits of coordination among these key stakeholder groups such as the [flexible consensus framework for transparent reproducible research and open research practices](#) which we contributed to. When done in a way that maintains the quality and integrity of all of these outputs, trust in research will be massively enhanced.

To ensure this happens as rapidly as possible and without unintended consequences federal government engagement with research publishers is crucial. For example the present pandemic has starkly illustrated both [the value of increased sharing through preprints](#) but also [the pitfalls](#) in blurring the lines between these and the peer-reviewed and curated Version of Record. There are ways of dealing with these pitfalls. Preprint platforms that are well-managed can enable rapid withdrawal of worrisome papers and we have contributed to early community efforts on [responsible communication of preprints to a broad audience](#). However more work is needed and the federal government can help. In particular the government could lead in developing a framework in collaboration with all stakeholders to ensure support for the early sharing benefits that preprints enable while minimising, ideally eliminating, misuse of early research contributions that have not been certified and improved through the processes that publishers manage.

Better sharing of federally funded research data is a key improvement needed to promote trust in science. Supporting researchers to overcome [data sharing challenges](#) is vital to achieve this improvement and there are [numerous areas](#) we and other publishers can work with OSTP and funding agencies on: persistent digital identifiers, mandates and policies, data management planning and stewardship, appropriate data sharing infrastructure, training, accreditation and aligning incentives are some of the most important.

Similarly: continued strong federal programmatic support for collecting data relevant to diversity, equity and inclusion (DEI) outcomes in research and DEI strategy development is needed in order to assess the extent of systemic inequity and monitor the impact of policies and initiatives to redress the balance. Publications are a key measure of research productivity and as such working in a coordinated fashion with publishers on DEI is needed to maximise positive change in this area.

Detection of misconduct and deterrence of potential violations of scientific integrity policies before they occur is a [major focus for us](#) in the context of the quality assessment and improvement processes we manage for research publications. As such we already work with institutions and funders on these issues. However a co-produced federal framework for expectations on institutions, funders and publishers in this area, with input from all these stakeholder groups, would be useful, as would more federal funding and other support for training and accreditation of researchers in relevant areas.

2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information:

As the publisher of *Scientific American* and *Nature's* journalism and multimedia we are well-versed in the issues around communicating science to a broad US audience. Training and support (including guidelines etc) for federal scientists that engage with media and social media is important, as is ensuring that the mediators of their scientific message, whether they be professional journalists or social media influencers, have the tools available to them to help pass on and contextualise this information for their audiences. Clear federal guidelines for distinguishing between communication of science based on sources that vary in their credibility (including, but not limited to, raw data, press releases, non-peer reviewed preprints, peer-reviewed versions of record and systematic synthesis of evidence based on a large body of literature) would be extremely helpful. Again co-production of these with all relevant stakeholder groups including publishers would be the best approach. Another idea worth considering is defining an easy to understand scale that summarises the standards of scientific evidence for a specific broadly communicated research finding, analogous to that [previously suggested](#) to help provide context for policy makers in making decisions.

With respect to scientific independence of research communication: the primary QA mechanisms for research contributions at present are the processes that publishers manage. As such these represent a robust, healthy mechanism of third party certification that helps maintain trust in the system. Similarly the broader communication of scientific results by scientists needs to maintain its independence from potential political influence, and the policy framework under which scientists are funded or employed by federal agencies needs to support that independence.

So we support all reasonable measures to ensure that scientific independence of federally-funded scientists in communicating their research is maintained. In particular the line between peer reviewed published research, that has been through the QA and improvement processes independently managed by editors and publishers, and science based policy statements needs to be clearly delineated and communicated as such. The latter will draw on many different areas of research, in addition to other policy considerations. However, version-of-record-backed peer reviewed findings are the bedrock of research and it should be up to credible and independent scientists to assess and present the balance of the evidence from the scientific record on matters of science which inform the science-based policy.

3. Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce:

Scientific disagreements are a normal part of the scientific process. Science progresses based on the free exchange of evidence but also opinion. So the federal government needs to support the scholarly communication structure that enables robust discourse and debate around key scientific issues at dispute. However the government and policymakers need a policy structure and culture in place that minimises the politicisation of scientific disagreements. In areas of disagreement the federal government needs robust and independent expert advice that is able to distill all pertinent information to reach a considered consensus position on a given issue upon which policy, taking into account non-scientific factors, can be based. Understanding the strength of evidence for any given issue at dispute is vital and, again, a system of classification of evidential strength for specific conclusions that can be shared with policy makers and the general public (as per [the example](#) mentioned above) would be very useful in this context.

Emerging areas of research importance like artificial intelligence pose particular challenges in terms of research integrity due to the rapid pace of progress in a highly competitive environment, within a regulatory framework that is challenged by an evolving set of broader societal implications. To address gaps in this area requires a co-creation approach: researchers within and beyond the relevant fields, ethical and regulatory experts and the broader community all need to be engaged in finding the best solutions. We (and other publishers) have developed [field-specific reporting checklists](#), [innovative approaches for methodology dissemination](#), [pre-registration of research studies](#) and [other initiatives relevant to robustness and reproducibility](#). So we are well placed to contribute to plans for addressing gaps in emerging fields and helping implement them effectively.

Supporting and enhancing continuing professional development (CPD) for researchers should be a key area of focus in future to support research integrity. The federal government needs to dedicate funding in this area and look at setting up a framework that encourages robust training and accreditation from diverse and reputable organizations (public and private) for practices that are vital to research integrity, many linked to the transition to open science. Of course early career researchers are a vital group to focus training/CPD on in order to support research integrity and good research practice but, with rapid developments in the way research is conducted in most areas (increasing involvement of AI, team science and data management just three of many relevant trends), senior scientists also need regular training and updates.

A considered approach to CPD could also address endemic issues that researchers face in their career pathway: providing structured support for researchers transitioning to vital roles outside of academia. An academic career path still is the predominant cultural focus within universities, despite it being a minority end point for those early career researchers that generate the bulk of the data that underpins scientific progress: a structured and funded approach to continuing professional development could change that.

Supporting diverse and equitable delivery of federal programs needs special attention based on real-world data. A coordinated approach to the collection of relevant data, among funders, institutions and publishers (properly controlled to respect individual freedoms and rights) would be of enormous benefit in this area. Similarly coordination and consultation on data-informed DEI-policy instruments, targets and compliance monitoring with these key stakeholders is the path to faster and more effective change. The federal government should consider measures that prioritise support and action to address historical inequities. These could include dedicated funds to provide particular support for underrepresented groups in research and funding programs that address research questions and areas of study with impact for underserved populations. Minimal representation requirements for research on human populations should also be strongly considered.

Finally we strongly support the development of effective, enforceable and transparent mechanisms to maintain the independence and effectiveness of scientific integrity officials and chief science officers. Such mechanisms should ideally eliminate, but at least minimise, direct and indirect political interference in the work of such officials.

4. Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices:

As previously mentioned, dedicated funding for training and education in research integrity relevant areas of those involved in federally funded research development is an important requirement. Setting a framework / expected standards / guidelines for the development of resources for training and education by appropriate organisations (public and private) may also be helpful in this area. Similarly frameworks / mechanisms that ensure institutions provide necessary infrastructure for management of research data and fully support mandates focussed on appropriate management and curation of data would be an important step forward. Explicitly supporting and/or endorsing pre-existing community and publishing industry standards and initiatives (for example

[COPE core practices](#) and the “[Think. Check. Submit. Initiative](#)” to address predatory journals) would also be useful.

The compliance burden for institutions will likely increase considerably as they are required to better ensure agency research integrity policies are met and demonstrate that they have done so. There are different potential ways of ensuring institutions have the support to deliver on these requirements and perhaps the simplest and best way to ensure progress is for funding agencies to sequester money for this purpose as a block grant to an institution set as a percentage of the total grant funds the institution has received from that agency. Regardless of the implementation details, publishing clear and actionable policies in this area, which - where possible - should be aligned across federal funding agencies, would be a useful contribution. As mentioned above, a co-created framework for the roles of agencies, institutions and publishers in dealing with potential research misconduct, perhaps reflected in an established code of practice for coordination among these stakeholders, would be useful with an aim of maximising transparency, speed and trust. Such a comprehensive framework for federally-funded US research could build on [pre-existing efforts](#) to [coordinate between institutions and publishers](#).

5. Other important aspects of scientific integrity and effective approaches to improving trust in Federal science:

As mentioned multiple times above, we believe that a co-creation approach to addressing improved research integrity is vital. The transition to open science is central to establishing public trust in research and its independence from political influence. So it is in this area that all stakeholders need to work together to ensure rapid progress without unintended consequences. Specifically this means federal agencies developing plans in collaboration with institutions/researchers that produce the research and editors and publishers that curate, improve and maintain the publications that communicate it. Establishing a commission or working committee that has representatives from these and other stakeholder groups to chart a realistic and effective open science transition for US research would be a major contribution to improving research integrity within and beyond the US borders.

via email: ScientificIntegrityRFI@ostp.eop.gov

Subject: **SI-FTAC RFI from API**

The American Petroleum Institute is pleased to provide you with a response to the White House's Office of Science and Technology Policy (OSTP) Request for Information to Improve Federal Scientific Integrity Policies (June 28, 2021; 86 FR 34064; Document No.: 2021-13640).

1. OSTP is requesting information about, "*The effectiveness of Federal scientific integrity policies in promoting trust in Federal science by protecting against ... before they occur.*"

We outline below some effective mechanisms for detecting and/or deterring potential violations of scientific integrity policies. We present several effective practices for improving scientific integrity, particularly related to transparency, reproducibility, and the minimization of potential bias:

A. OSTP should ensure that federal agencies promote a culture of scientific integrity

Perhaps the most important mechanism for deterring potential violations of scientific integrity is promoting a workplace culture of scientific integrity.¹ OSTP should recommend that federal agencies adopt principles discussed by NAS,² which include best practices for individual researchers, research institutions, publishers of research (e.g., journals), research sponsors, and users of research.

B. OSTP should have federal agencies identify barriers to voicing scientific integrity concerns

OSTP should require federal agencies to identify whether scientific workplaces contain barriers to voicing concerns related to scientific integrity. This can be done with anonymous surveys to glean information on potential barriers to voicing concerns in the workplace or organization in question.

- **Internal Factors:** This refers to factors that occur within (or are unique to) the scientific workplace or organization in question. Though not exhaustive, internal factors that may be potential barriers to voicing concerns related to scientific integrity may include:
 - A culture of fear or disempowerment. For example, employees may feel afraid to voice concerns regarding social rejection and/or threats to career advancement or job security from peers or superiors.
 - Unclear or complex chains of command. For example, employees may not know to whom concerns should be communicated or may not want to circumvent superiors.
 - Lack of knowledge. For example, employees may lack basic training in scientific integrity and/or cannot identify potential violations of scientific integrity because they lack the ability to recognize them.

¹ National Academies of Sciences, Engineering, and Medicine (NAS). 2017. "Fostering Integrity in Research." doi: 10.17226/21896. National Academies Press, Washington, DC. 274p.
Mebane, CA, *et al.*. 2018. "Scientific integrity issues in environmental toxicology and chemistry: Improving research reproducibility, credibility, and transparency." *Integr. Environ. Assess. Manag.* doi: 10.1002/ieam.4119.

² National Academies of Sciences, Engineering, and Medicine (NAS). 2017. "Fostering Integrity in Research." doi: 10.17226/21896. National Academies Press, Washington, DC. 274p.

- External Factors: This refers to factors that occur outside the scientific workplace or organization in question that may be potential barriers to voicing concerns. These may include:
 - Result-oriented pressures. For example, employees may experience push-back to complete tasks in a certain manner.
 - Budget or time constraints. For example, appropriate quality-control or peer review may be abridged by limits in budgets or time.
 - Societal perceptions. For example, employees may not voice concerns due to the potential of negative press coverage, reputational risk for the organization (or self), or the confirmation of pre-existing prejudices against the organization.

C. OSTP should recommend that federal agencies utilize technology that detects plagiarized or falsified scientific work

The prevention of violations of scientific integrity *via* the promotion of a culture of scientific integrity within workplaces would be ideal. However, lapses in scientific integrity still occur and thus must be detected such that adequate corrections and consequences can be applied. OSTP should recommend that federal agencies rely on pre-existing technology for detecting potential violations of scientific integrity.³ Some ways in which technology and statistical techniques have been utilized to detect plagiarism and data falsification in science are:

- Detection of plagiarized text. Several technologies exist for the rapid and effective comparison of texts to determine sources of overlap. For example, scientific publishers who have utilized plagiarism detection software to screen submissions found that between 6-23% of submissions had to be rejected due to the presence of plagiarized text.⁴
- Detection of manipulated images. Technology also exists for the manipulation of images in scientific work products.⁵
- Detection of fabricated datasets. Statistical methods can be used for determining whether large datasets were generated by experimental studies or were fabricated. These tools have also been applied to clinical data to detect data fabrication and/or statistical inconsistencies within the dataset.⁶ This is particularly important to ensure datasets are robust and reproducible in the context of open-source online databases (see comment below).

D. OSTP should require the use of publicly-available datasets in data repositories

³ National Academies of Sciences, Engineering, and Medicine (NAS). 2017. "Fostering Integrity in Research." doi: 10.17226/21896. National Academies Press, Washington, DC. 274p.

⁴ Butler, D. 2010. "Journals step up plagiarism policing." *Nature* 466(7303):167. doi: 10.1038/466167a.

⁵ Rossner, M. 2006. "How to guard against image fraud." *The Scientist* 20(3):24-25.

⁶ Shea, C. 2012. "The data vigilante." *Atlantic*, December. Accessed on July 16, 2021 at <https://www.theatlantic.com/magazine/archive/2012/12/the-data-vigilante/309172/>

Simonsohn, U. 2013. "Just post it: The lesson from two cases of fabricated data detected by statistics alone." *Psychol. Sci.* 24(10):1875-1788. doi: 10.1177/0956797613480366. Evans, S. 2001. "Statistical aspects of the detection of fraud." In *Fraud and Misconduct in Biomedical Research (Third Edition)*. (Eds.: Lock, S; Wells, F; Farthing, M), BMJ Books, London, UK. p186-203.

Epskamp, S; Nuijten, MB. 2018. "Package 'statcheck': Extract Statistics from Articles and Recompute p Values (R Package Version 1.3.0)." 19p., May 4. Accessed at <https://cran.r-project.org/web/packages/statcheck/statcheck.pdf>.

Al-Marzouki, S, *et al.* 2005. "Are these data real? Statistical methods for the detection of data fabrication in clinical trials." *BMJ* 331(7511):267-270. doi: 10.1136/bmj.331.7511.267.

A number of peer-reviewed scientific journals strive to promote data transparency and research reproducibility by requiring or encouraging authors to make underlying analytical datasets available at online data repositories. OSTP should consider requiring federal agencies to adopt, adapt or set up new online data repositories dedicated to the storage and access of the analytical datasets relied on in setting regulatory standards. The protection of privacy and confidentiality of study participants, proprietary data, and confidential business information (and other compelling interests) is essential in the formation of online data repositories. Therefore, OSTP should clearly define data processing/scrambling/analytical measures that are deemed sufficient for this protection. Further, OSTP should require that federal agencies utilize technologies that effectively screen potential datasets for fabrication or falsification (see comment above).

Various government agencies, such as the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), the U.S. Census Bureau, and the U.S. Environmental Protection Agency (EPA) maintain online databases and data repositories to allow public data access or restricted access to identifiable data. For example, the U.S. Census Bureau maintains American FactFinder,⁷ an interactive online data tool, to allow public access to statistics data from the Economic Census, the American Community Survey, and the 2010 Census. CDC and CMS both provide restricted and secured access to health data that contain potentially identifiable and privacy information, such as name, residential address, vital status, birth date, and disease diagnosis.⁸ EPA also maintains various online databases to allow public access to data that do not contain identifiable or confidential information. For example, the Air Quality System (AQS) at EPA contains nationwide monitoring data on ambient air pollutants.⁹

OSTP should recommend that federal agencies adopt, adapt, or set up new online data repositories, similar to those that already exist, that allow public access to data on which agency actions rely on, that do not contain personal or confidential information. OSTP could also recommend that federal agencies implement additional background screening processes and security measures for access to data that may contain identifiable or proprietary information, similar to those employed by CDC and CMS for access to research identifiable data.

OSTP should solicit input from EPA Offices (such as the Office of Pesticide Programs) or other federal agencies (such as the U.S. Food and Drug Administration [FDA]) that rely heavily on copyrighted information, proprietary studies, and confidential business information (CBI) for strategies to balance these concerns with transparency. For example, EPA Offices (*e.g.*, Pesticides) that rely heavily on proprietary studies and CBI have apparently already devised mechanisms that balance protection with transparency of pivotal regulatory science. One mechanism is the use of data evaluation records (DERs) that summarize proprietary studies. Another is human health risk assessments that integrate findings in DERs, such that stakeholders can assess the impact of a particular endpoint (*e.g.*, health effect) in a particular study (pivotal regulatory science) on the overall risk assessment. Both DERs and risk assessments have been made available in the docket or by other means. While not as transparent as making the underlying data and models fully available, sufficiently detailed DERs and risk assessments are arguably as detailed and transparent as many health studies and risk assessments published in the peer-reviewed scientific literature. Regarding copyright protection, a potential alternative for copyrighted works that use data that are federally funded may be to solicit from the authors the raw data (which often is not copyrighted) that were used to produce the copyrighted work. These raw data, along with analyses of these raw data, could then be made publicly available.

⁷ <https://factfinder.census.gov>

⁸ <https://www.cdc.gov/rdc/>

<https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/AccessstoDataApplication/index.html>

⁹ <https://www.epa.gov/aqs>

E. OSTP should require that federal agencies ensure scientific analyses are reproducible through requiring proper documentation

Reproducibility is an indicator of reliable scientific work and is integral to scientific integrity.¹⁰ There are many factors that contribute to reproducible scientific work, one of which includes the proper documentation of methods and analyses. Indeed, this includes both documentation of the original studies and analyses based on these studies (and associated underlying data). For example, information that should be documented for epidemiology and experimental studies include objectives and study plans, study design, exposure characterization (if applicable), outcome assessment methods, study results, and discussion.¹¹

We provide dose-response models (DRM) as an example of statistical analyses that are routinely conducted by government agencies (e.g., EPA) and require proper documentation to be reproducible by stakeholders. DRMs are mathematical expressions fitted to scientific data that characterize the relationship between dose and response:

- Documentation: OSTP should require documentation of the choices made at each step of the process and to include a scientific rationale for the selected approach. Key steps requiring this documentation and rationale include:
 - Data selection: determine the response to be modelled and select appropriate data;
 - Model selection: choose the type of model to be applied to the data;
 - Statistical linkage: state the assumptions about the distributions that describe the response; and
 - Parameter estimation: estimate of the model parameters using the above statistics.
- Implementation: use the estimated model parameters and the model formula to predict response/dose as needed and may be used to:
 - Define levels of exposure at which the response measurement is assumed to be virtually unchanged relative to the control measurement;
 - Identify a dose with a known level of response at or slightly below the observable range; and
 - The model(s) may be used to find the dose associated with a negligible (e.g., 1 in a million) response over control.
- Evaluation: OSTP should examine the sensitivity of the resulting predictions to the assumptions used in the analysis (e.g., model comparison, uncertainty).
 - The dose-response relationship can be linear or nonlinear in shape. A linear dose-response relationship suggests that the toxicity or adverse effect being evaluated does not have a threshold, while a nonlinear dose response relationship holds that a range of exposures from zero to some finite value can be tolerated.¹²
- Extrapolation Considerations: OSTP should require the documentation of the methods used and scientific justification for those methods, as well as a need to document potential alternative

¹⁰ Mebane, CA, *et al.* 2018. "Scientific integrity issues in environmental toxicology and chemistry: Improving research reproducibility, credibility, and transparency." *Integr. Environ. Assess. Manag.* doi: 10.1002/ieam.4119.

National Academies of Sciences, Engineering, and Medicine (NAS). 2017. "Fostering Integrity in Research." doi: 10.17226/21896. National Academies Press, Washington, DC. 274p.

¹¹ Goodman, JE, *et al.* 2020. "'Good Epidemiology Practice' guidelines for pesticide exposure assessment." *Int. J. Environ. Res. Public Health* 17(14):E5114. doi: 10.3390/ijerph17145114.

¹² See EPA's Risk Characterization Handbook. <https://www.epa.gov/risk/conducting-human-health-risk-assessment#tab-3>

interpretations of extrapolations and nature of the dose-response curve (*e.g.*, threshold, no-threshold, supralinear, etc.).

- **Epidemiological Data Considerations:** OSTP should require that any assumptions, uncertainties, and scientific rationales be documented. Examples of these uncertainties and assumptions include, but are not limited to:
 - The lack of valid semi-quantitative or quantitative estimates of exposure (as a surrogate for dose, as dose is rarely available in observational studies) for each individual studied;
 - Systematic errors or study bias may result in spurious associations between an estimated exposure and the occurrence of disease;
 - Historical exposure estimates may be incorrectly extrapolated back in time. Depending on the direction and degree of all study biases, an observed dose-response may not reflect the true underlying dose-response relationship;
 - Epidemiological studies often suffer from low statistical power due to limited numbers of observed events for relatively rare diseases such as specific cancers. Effects at the lowest estimated doses, where risks are anticipated to be low as well, may be impossible to distinguish from background incidence. This may also preclude differentiating a linear dose-response from a threshold dose-response function; and
 - Statistical/analytical challenges, including the impact of that random error in the exposure measurement can have on the assessment of the shape of the dose-response curve, assumptions on the shape of the dose-response curve and the use of parametric statistics, and problems elucidating possible non-linearity of exposure-response in epidemiological studies.
- **For Reporting Dose-Response:** OSTP should require documentation of any dose or concentration-response assessment for those health effects where the evidence is sufficient to conclude that a causal relationship exists or where the evidence is sufficient to conclude that a causal relationship is at least as likely as not, but not sufficient to conclude that a causal relationship exists:
 - A sensitivity analysis should be conducted to determine the robustness of the concentration-curves; and
 - It is recommended to include a discussion of all models that fit the data equally well (*i.e.*, where there is no statistically significant difference in quality of fit), including threshold and non-threshold models, when there are alternative procedures having significant biological plausibility, the assessments using these alternative procedures should be document any information on the uncertainties in the assessment.

2. OSTP is requesting information regarding, "Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information ..."

Openness in science and related findings underpinning laws, regulations, standards, and guidance documents is particularly important; this is especially true for government-funded research, as well as all policy-relevant scientific studies. As such, OSTP should require that federal agencies include all stakeholders in the process of conducting, evaluating, and making policy decisions based on scientific studies. For example, OSTP should require that federal agencies have representatives from academic, governmental, and non-governmental organizations and industry participate on scientific panels/boards (*e.g.*, Science Advisory Boards) so that all stakeholders have equal opportunity to provide comment.

Importantly, the existence of potential conflicts of interest should not alone cast doubt on individuals' abilities to provide objective and critical opinions regarding scientific studies.¹³

OSTP should also require that federal agencies ensure that all stakeholders have the opportunity to review (or have access to data by the reviewers) scientific information used as the basis for policy decisions, as this would ensure transparency in the process. For example, OSTP should require that EPA (among other federal agencies) update and utilize its own peer-review policy in addition to that provided in the peer-reviewed scientific literature.¹⁴ For proprietary data and CBI that are submitted to EPA to support new chemical registrations and other regulatory actions, EPA has full data access from which to conduct its own peer reviews in accordance with its own policy. However, OSTP should require that all data used in regulatory decision making be made available such that EPA can comply with its own peer review policy.

OSTP should ensure full public engagement in science-based policy decisions to prevent the perception that any certain voice was given disproportionate time. This would allow for the simultaneous engagement of various opinions in potential policy decisions. OSTP should ensure that federal agencies engage stakeholders as early as possible in the decision-making process to ensure application of data transparency principles for studies to be included in policy decisions, and to address how studies that have not been reproduced or that are non-reproducible will be considered in the process. Further, engaging stakeholders early in the decision-making process ensures that studies that are included in policy decisions are interpreted sufficiently and accurately and allow all relevant parties to determine how to apply them to potential policy decisions.

3. OSTP is requesting information regarding, "*Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce.... practices related but not limited to: Handling scientific disagreements about research methods and conclusions.*"

Having protocols in place ahead of discussions related to methodology, results interpretation, and conclusions should prevent many disagreements that might occur were these protocols not in place. The presence of pre-specified protocols also enhances transparency related to the decision-making process, such that when disagreements occur, they can be brought forward in a public forum. OSTP should identify and implement scientific practices that rely on pre-specified protocols for their implementation. For example, OSTP should adopt protocols for the implementation of systematic reviews.¹⁵

OSTP should ensure that federal agencies adopt practices for evaluating the weight of scientific evidence. There are a number of recommendations for evaluating scientific evidence in a systematic manner.¹⁶ OSTP should require that federal agencies consider the available relevant studies, their relative quality and representativeness, the consistency of findings across studies, the strength of any reported results, and the

¹³ Mebane, CA, *et al.* 2018. "Scientific integrity issues in environmental toxicology and chemistry: Improving research reproducibility, credibility, and transparency." *Integr. Environ. Assess. Manag.* doi: 10.1002/ieam.4119.

¹⁴ EPA. 2015. "EPA Peer Review Handbook, 4th 14 Edition." Science and Technology Policy Council. October. EPA/100/B-15/001.

¹⁵ <https://www.equator-network.org/reporting-guidelines/prisma/>

Goodman, JE, *et al.* 2020. "Systematically evaluating and integrating evidence in National Ambient Air Quality Standards (NAAQS) reviews." *Glob. Epidemiol.* 2:1000019. doi: 10.1016/j.gloepi.2020.100019.

¹⁶ Federal Judicial Center. 2011. "Reference Manual on Scientific Evidence (Third Edition)." Committee on the Development of the Third Edition of the Reference Manual on Scientific Evidence; National Research Council, Committee on Science, Technology, and Law. doi: 10.17226/13163. National Academies Press, Washington, DC. 1034p.

Goodman, JE, *et al.* 2020. "Systematically evaluating and integrating evidence in National Ambient Air Quality Standards (NAAQS) reviews." *Glob. Epidemiol.* 2:1000019. doi: 10.1016/j.gloepi.2020.100019.

logic of the available evidence considered as a whole. It is only by considering all of the available evidence that an informed conclusion regarding health-effect causation can be made. There are a number of methods for evaluating scientific evidence all of which emphasize a systematic and transparent approach to the analysis.¹⁷ For example, they all require the following:

- **Rationale and Objectives:** Describe clearly the context of existing knowledge and how the review fits in with this existing knowledge. State explicitly the purpose or research questions of the review.
- **Methods:** Describe the information sources, search strategy, and selection process. Ensure information is presented related to the data collection process, relevant variables, and reviewer strategies.
- **Results:** Ensure that adequate information is presented related to the number of studies gathered, study characteristics, and associated study information to ensure reviewers and stakeholders can review underlying data and the quality of the data. Explicitly address and highlight uncertainties in data, models and analyses when utilizing those studies in decision-making. Explicitly address the certainty of the evidence as it relates to uncertainties in the underlying data.
- **Discussion:** Provide a general interpretation of the results, particularly in the context of individual study quality and prior research. Discuss limitations of the evidence and review processes (or other methods) included in the review.

If two individuals draw differing or opposing conclusions after following pre-specified protocols, then an objective third party can attempt to settle the discrepancy by implementing the protocols themselves or present both conclusions to stakeholders. Further, the disagreement should be documented as well as all uncertainties related to the analysis or conclusion under disagreement to ensure transparency in the process. By adopting recommendations for determining the quality and robustness of a scientific study, OSTP can prevent scenarios in which individuals rely on low-quality studies (or cherry pick findings) to draw conclusions.

The following is offered in response to the general objective detailed in the Summary,

- *Scientific integrity can be improved by embracing policies that clearly distinguish between well-conducted studies and their results.* Political pressure on researchers can be overt or come from pressures that are not openly acknowledged. These pressures include the pressure to produce “positive” results that may increase the likelihood of being published and/or the likelihood of obtaining additional research grants. In addition, researchers may also feel pressure to obtain results that both affirm and extend the mission of the agency. In this climate, non-positive results can be dismissed or regarded as less important and informative. To improve the scientific integrity of federal research, each agency should be encouraged to advance policies that rectify and push back against these powerful incentives. Suggestions may include: (1) Clearly articulate and affirm the value and role of non-positive results in agency scientific integrity policies, evaluation of research proposals and in hiring; and (2) Separate the need and value of objective scientific results from policy decisions that may reflect the mission of the agency.

¹⁷ Rhomberg, LR, *et al.* 2011. "Is exposure to formaldehyde in air causally associated with leukemia? - A hypothesis-based weight-of-evidence analysis." *Crit. Rev. Toxicol.* 41(7):555-621. doi: 10.3109/10408444.2011.560140.

Adami, HO, *et al.* 2011. "Toxicology and epidemiology: Improving the science with a framework for combining toxicological and epidemiological evidence to establish causal inference." *Toxicol. Sci.* 122(2):223-234.

Goodman, JE, *et al.* 2020. "Systematically evaluating and integrating evidence in National Ambient Air Quality Standards (NAAQS) reviews." *Glob. Epidemiol.* 2:1000019. doi: 10.1016/j.gloepi.2020.100019.

Response from Cochrane and the Cochrane US Network to the White House Office of Science and Technology Policy’s Request for Information To Improve Federal Scientific Integrity Policies

July 27, 2021

Thank you for the opportunity to share information relevant to the call to improve federal scientific integrity policies in the United States.

As an organization that has been committed to independence and transparency in healthcare research for over 20 years, Cochrane is supportive of the Federal Government’s intention to bolster evidence-based policymaking and promote scientific integrity. In addition to presenting a significant challenge to the US, the need to ensure research integrity is an issue of global concern. Global efforts are underway and can be drawn on to inform the US’s response; in turn, action taken by the Federal Government and agencies have great potential to be influential on the global stage.

One of the reasons Cochrane has developed a reputation as a trusted source of healthcare information is having our rigorous, evidence-based research integrity policies, which are designed to protect against interference in our work and promote data sharing. In this submission, we will share information on these policies and some of the activities carried out by our international community which may serve as useful resources and examples of good practice for the Task Force as you evaluate and update federal scientific integrity policies. Our responses are organized in line with the different points listed in your Request for Information.

About Cochrane and the Cochrane US Network

Cochrane contributors and groups produce high-quality systematic reviews which summarize the best available evidence on the effects of interventions to inform decisions about health.

[Systematic reviews are a uniquely valuable form of evidence](#): they assess all research on a topic and include checks on the integrity of the included studies, thus can be more trustworthy than a single study. Cochrane Reviews are recognized internationally as representing a gold standard for high-quality, trusted information. Cochrane does not accept commercial or conflicted funding. This is vital for us to generate authoritative and reliable information, working freely, unconstrained by commercial and financial interests.

Cochrane has had an active base of contributors and groups in the US since the organization was founded. In 2019, [the Cochrane US Network](#) was established to further promote evidence-based health decision making in the US. The Cochrane US Network produces systematic reviews; builds capacity among review authors and trains users of Cochrane Reviews; forges partnerships for policy and guidance; and encourages knowledge translation and the dissemination and use of Cochrane evidence.

About Cochrane's Research Integrity Team

Cochrane has worked to identify opportunities for improving research practice and has set methodological standards that are also used outside Cochrane. We are a leader in conducting 'meta-research', in the form of methodological reviews, which can serve to identify research integrity problems and inform improvements in policies and processes. Building on our strong history in research integrity, Cochrane formed a dedicated team – led by our Senior Research Integrity Editor, Professor Lisa Bero, based in Colorado – that is working to strengthen our commitment to research integrity through research; advocacy; policy development and implementation; and community outreach. We are expanding our emphasis to develop and test empirically-based solutions and conduct advocacy to improve the integrity of the research record and research behaviors.

Working with interested researchers from across Cochrane's global community and externally, the Cochrane Research Integrity Editors are developing [Cochrane's Research Integrity Agenda](#) to bring together and prioritize research projects aimed at improving research integrity.

Responses to the request for information

Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices

Minimizing conflicts of interest in Federal science and research misconduct

Cochrane has always strived to develop and implement quality-improving interventions, governance, and policies. A key component is our rigorous Conflict of Interest Policy. First published in 2004, [Cochrane's Conflict of Interest Policy](#) has undergone several rounds of revision; it was last updated in 2020. The policy is based on [empirical evidence on bias in relation to conflicts of interest](#) and consensus on the issue. It differs from many journal policies in that it not only requires conflicts of interest to be declared, but also prohibits individuals with certain financial interests from being involved in the production of Cochrane Reviews. Conflict of interest declarations are also routinely published as part of each Cochrane Review and protocol. This level of transparency serves to enhance the public's trust in our research.

We have also developed a robust policy implementation process, which includes reviewing and managing conflict of interest issues when they arise. Central to that implementation is our [Conflict of Interest Panel](#), a team with expertise in systematic reviews, clinical research and conflicts of interest, which advises us on applying the policy and arbitrating potential breaches. [Information on the implementation of our Conflict of Information Policy, including training materials, is available on our website](#). We would encourage the Task Force to review this and consider if it may contribute to your own approach to conflicts of interest.

Managing potentially problematic studies

Cochrane is also trying to improve research integrity through the identification and management of ‘potentially problematic’ studies, which our authors and editors may encounter during a systematic review. We currently define a problematic study as “any published or unpublished study where there are serious questions about the trustworthiness of the data or findings, regardless of whether the study has been formally retracted”. The inclusion of data from such studies in our reviews has the potential of undermining their quality and reducing trust among our readers. For example, a [Cochrane Review of a treatment for serious head injuries led to questions about whether the original studies informing practice ever took place. Cochrane Reviews have been withdrawn from the Cochrane Library](#) when such concerns are identified and supported by the available evidence.

As a result, we recently launched a policy on [Managing Potentially Problematic Studies](#); an [editorial which explains the rationale behind the policy](#) has also been published. Further work to develop and validate methods to reliably identify problematic studies is also underway as part of our research integrity agenda.

Reporting practices that promote transparency in the implementation of agency scientific integrity policies and in the handling of any allegations of misconduct

Cochrane has long been an advocate of transparency in research as a means of allowing people to be able to confirm the integrity of data – and, therefore, trust it. To ensure the quality and reliability of research, improve transparency and increase access to research results, we require authors to publish their protocol before the review is conducted. These protocols are peer reviewed before acceptance or publication to enhance methodological rigor. Cochrane was the first organization to publish peer reviewed protocols in 1993, a practice which is now becoming more widespread through the publication of registered reports.

Data sharing

We would like to congratulate the US Government for the development and maintenance of [ClinicalTrials.gov](#), a vital and ground-breaking tool which supports transparency of clinical trial data on a global scale. The passing of the [Food and Drug Administration Amendments Act in 2007 \(FDAAA 801\)](#), which mandated prior registration and summary results reporting for many clinical trials, also showed a clear intention to ensure that this information be publicly available.

However, [the current reporting rate](#) shows that the information held on ClinicalTrials.gov is still incomplete. While the missing results do not always pertain to research that is federally commissioned or conducted, the incomplete enforcement of this policy to date could be perceived as laying the ground for “suppression or distortion of scientific or technological findings, data, information, conclusions, or technical results”, as described in the Request for Information. We would therefore strongly encourage the relevant agencies in the Task Force to strengthen enforcement of FDAAA 801 and review other possible policy pathways to increase transparency.

Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices

Handling scientific disagreements about research methods and conclusions

Cochrane is known for developing evidence-based methods and setting methodological standards used widely in research conducted outside of our organization – and, as such, has experience of handling scientific disagreements in relation to methods. Cochrane’s Methods Groups are led by pioneering methodologists with strong links with academia from across the globe who produce ground-breaking methods research. [Our methods evolve to meet new challenges and are developed based on empirical evidence and consensus.](#)

To guide research conduct and minimize possible disagreement on methods, we have produced and maintain the [Cochrane Handbook for Systematic Reviews of Interventions](#), which includes the [Methodological Expectations of Cochrane Intervention Reviews \(MECIR\)](#) standards, to which all Cochrane Reviews, protocols and updates are expected to adhere.

Supporting scientists and researchers of all genders, races, ethnicities, and backgrounds and advance the equitable delivery of the Federal Government’s programs

Equity is a key issue for Cochrane. We are proud to have a dedicated [Cochrane-Campbell Equity Methods Group](#), which aims to encourage our review authors to explicitly include equity considerations in their work and has developed a range of tools and training materials to support this.

We recently established an advisory group on diversity and inclusion to support researchers in our own community and to learn more about how we can improve our own practices. Cochrane has a strong commitment to capacity building and has [developed a wealth of training materials](#). Our Cochrane Groups also lead the way in this work. For example, the [Cochrane US Network regularly conducts training in review methods \(both in person and virtually\) and is leading a pilot mentoring program](#), which aims to support a diverse group of mentees from a range of backgrounds as they engage in evidence synthesis and health science careers. Further examples include our [Early Career Professionals \(ECPs\) Group](#), which aims to provide ECPs in our community with opportunities to enhance their knowledge, skills, and expertise by providing a platform for international networking. We also run an [International Mobility Programme](#), an exchange scheme to enhance international collaboration and learning opportunities which has carried on virtually during the COVID-19 pandemic.

Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information

Cochrane uses a knowledge translation (KT) approach to communicating about our work and supporting the use and relevance of Cochrane Reviews. We have invested considerable resource in developing and implementing a [Knowledge Translation Framework](#), which we are embedding throughout our work. More information on [how we have adopted KT and training materials](#) are available on our website. In terms of dissemination, science communication experts within our

community have also devised a [Dissemination Essentials Checklist](#) to support our researchers in their science communication efforts.

Conclusion

Many thanks for this opportunity to contribute to the efforts of your Task Force.

Cochrane, as a trusted source, has for years been at the forefront of promoting the use of best evidence in practice and policy-making, along with combatting misinformation and rebuilding trust in real science, rather than the generation of false controversies and the misinterpretation of data. In the context of the COVID-19 pandemic, this has never been more relevant and crucial. Three further papers which may be of interest to your Task Force include an [editorial about the challenges facing policymakers, recognizing that they must sometimes act on incomplete or weak evidence](#); one on the [challenges which dominated the assessment of hydroxychloroquine and chloroquine](#); and one [outlining how Cochrane adapted its work to respond to the pandemic](#).

Given our extensive experience in this area, we would be open to discussing any of the issues raised above with you further and would be happy to share additional information to support the work of your Task Force. Please contact us if we can offer further assistance.

Electronically submitted to ScientificIntegrityRFI@ostp.eop.gov

Respondent name: Cochrane and the Cochrane US Network

Respondent type: academic; not-for-profit

Contact: Emma Thompson, Advocacy and Partnership Officer, ethompson@cochrane.org

From: [Wiatrowski, William - BLS](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Cc:
Subject: SI-FTAC RFI
Date: Wednesday, July 28, 2021 12:32:24 PM
Attachments:

Here is a comment from the Bureau of Labor Statistics on the Request for Information To Improve Federal Scientific Integrity Policies:

The Bureau of Labor Statistics recommends that work on a Scientific Integrity policy include a separate statement specifically focused on the commitment to scientific integrity and mission autonomy by statistical agencies. Such a statement could mirror an existing statement:

[>https://www.census.gov/content/dam/Census/about/about-the-bureau/policies_and_notices/scientificintegrity/Scientific_Integrity_Statement_of_the_Principal_Statistical_Agencies.pdf<](https://www.census.gov/content/dam/Census/about/about-the-bureau/policies_and_notices/scientificintegrity/Scientific_Integrity_Statement_of_the_Principal_Statistical_Agencies.pdf)

The statement should include references to existing material on statistical principles and practices, such as material published by the Committee on National Statistics of the National Academies of Sciences, Engineering, and Medicine:

[>https://www.nationalacademies.org/our-work/7th-edition-of-principles-and-practices-for-a-federal-statistical-agency<](https://www.nationalacademies.org/our-work/7th-edition-of-principles-and-practices-for-a-federal-statistical-agency)

William J. Wiatrowski
Deputy Commissioner
Bureau of Labor Statistics



From: [Charles Gasparovic](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] comments in response to SI-FTAC RFI
Date: Wednesday, July 28, 2021 12:36:03 PM
Attachments:

Charles Gasparovic, PhD
The Mind Research Network
Albuquerque NM, USA

Dear Committee Members:

I would like to submit the following (and attached) comments for your consideration regarding SI-FTAC RFI.

Science is a pillar of modern democracies

Healthy democracies support the well-being of their citizens through policies based on objective facts and analyses.

Science is the method of inquiry that aims precisely at objectivity. It does this by collecting and analyzing data in a manner that is as free as possible from personal or ideological biases or other conflicts of interest.

The process of peer review is the enforcer of this objectivity. The vast majority of scientific studies are critically reviewed by other experts in their research field at an international level. To reduce the possibility of favoritism or coercion, the authors of the study are generally not aware of who their reviewers are. Additionally, conflict-of-interest disclosures are mandated for most journal publications as well as federal grant applications.

What is scientific consensus?

Scientific consensus emerges when the available data, state-of-the-art methods, and the majority of studies on a research topic, often numbering in the thousands and conducted over decades globally, point to similar findings and conclusions.

Uncertainty, debate among experts, and constant re-evaluation of theories with new data or methods of analysis all lie on the road to these consensus. In fact, they are essential to the practice of science. All modern scientists are skeptical by nature, or at least should be by training. This is not a shortcoming of science. It is its strength.

It is this fluid, self-critical process that makes scientific consensus our best unbiased attempt at understanding what are often very complex phenomena. As a medical

researcher since the 1980's, I can say that this is very much the case for science on public health and environmental issues facing our nation.

How is scientific consensus sometimes ignored or misrepresented when forming public policy?

I have been greatly concerned during my career when the scientific consensus appears to be ignored or subverted by political and/or financial interests the during the formation or enforcement of government policies on public health and the environment issues.

These influences are sometimes brought to bear via administrative appointees to oversight agencies or advisory committees. At times, appointees not only disagree with the scientific consensus but promote minority if not marginal opinions that are more favorable to an industrial or financial interest. Such appointees may misrepresent the 'doubt' or 'division' within a scientific community on an issue, ignoring the true large degree of agreement.

The most outstanding example of this today is certainly the issue of climate change. A climate change "skeptic," Andrew Wheeler, was appointed to head the Environmental Protection Agency during the past administration. Wheeler, who had worked as a lobbyist for the coal industry, oversaw the scaling back of CO₂ and air pollution regulations in the country, even though over 97% of published climate scientists agree that fossil fuel emissions are a major cause of climate change (Cook et al, 2013) and several thousands of studies in the last few decades have demonstrated their toxicity. Fine particulate matter alone is a cause of tens of thousands of premature deaths in the US yearly (Vorha et al, 2021).

How can we guarantee that scientific consensus is always considered in policy making?

The question of how to insure that the scientific consensus always plays a dominant role in health and environmental policy formation, or at least is represented accurately, is obviously a difficult one. Outside the national laboratories, hospitals and health institutes, appointees are generally not scientists or physicians, and sometimes not even true "experts" on topics overseen by the agencies.

It would be hard to imagine that a supreme court justice could be appointed without having a law degree or judicial experience. But, in a sense, this is very similar to appointing a lawyer and coal lobbyist, with no scientific or "environment protection" experience, to head the EPA.

Ideally, appointees to lead agencies that rely heavily on science like the EPA would be vetted for their expertise relevant to the agency, just as judicial appointees are, as well

as any conflict of interests (e.g., anti-science positions or strong financial ties to industries the agency regulates). However, this may not be practical without procedural changes in how federal agency appointees are approved by the Senate.

If the scientific expertise and integrity of the agency head cannot be vetted and ensured, then its scientific and technical employees should be granted the power and, in fact, encouraged to exercise their own integrity. For example, if a worker publically disagrees with a policy change on scientific grounds, their job should not be put in jeopardy.

Among other measures, this might come in the form of existing federal whistle-blower protection, along with adequate training to be aware that such protection exists and how to exercise one's rights within an agency to speak on issues of scientific accuracy. Such measures might also include procedures to present a formal evidence-based challenge to a particular policy or policy change within an agency, which might be elevated to the Office of Science and Technology Policy for review and possible action. Experts in the field from the national laboratories and institutes might serve as ad hoc reviewers of the scientific issues disputed.

Given the current divisive political climate in our country, this will obviously be a very challenging problem to solve. Ironically, it is science itself that is often at the center of the divisiveness, with disinformation about the scientific consensus fueling public doubt and influencing policymaking on issues ranging from climate change to air and water pollution to the current deadly pandemic.

This targeted disinformation, or perhaps often simply a lack of understanding about the science, impede taking effective action to combat these very real threats to the sustainability of our nation.

I therefore urge the Office of Science and Technology Policy (OSTP) to undertake the task of strengthening our scientific integrity policies across federal agencies with ample input from government scientists and administrators and other agency members. Paramount among the steps taken should be to insure that real experts in the appropriate fields of science can be heard within the agencies and are not muted out of fear of administrative reprisal.

References:

Cook et al., Quantifying the Consensus on Anthropogenic Global Warming in the Scientific Literature, *Environmental Research Letters*, Volume 8, Number 2, 2013.

Vorha, et al, Global mortality from outdoor fine particle pollution generated by fossil fuel combustion: Results from GEOS-Chem, *Environ Res.* 2021 Apr;195.

July 28, 2021

Dr. Eric S. Lander, Ph.D.
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

RE: Office of Science and Technology Policy’s Request for Information to Improve Federal Scientific Integrity Policies

The American Society for Biochemistry and Molecular Biology is an international nonprofit scientific and educational organization that represents more than 11,000 students, researchers, educators and industry professionals. The ASBMB strongly advocates for strengthening the science, technology, engineering and mathematics (STEM) workforce, supporting sustainable funding for the American research enterprise, and ensuring diversity, equity and inclusion in STEM.

Scientific expertise is vital for federal science agencies to fulfill their missions, such as the [National Institutes of Health’s mission](#) to “seek fundamental knowledge about the nature and behavior of living systems” and the [Department of Energy’s mission](#) to “ensure American’s security and prosperity by addressing its energy, environmental and nuclear challenge through transformative science and technology solutions.” Historically, there have been [consistent attacks](#) on science, federal scientists, and their work. The ASBMB applauds the Office of Science and Technology Policy’s efforts to address the harm those attacks caused to the public’s trust of federal agencies and science at large.

The ASBMB has a series of recommendations to improve the effectiveness of federal scientific integrity policies to enhance public trust in science. These recommendations are focused on restoring public trust in science federal funding agencies, attracting a skilled scientific workforce and promoting transparency in policymaking.

1. Strengthen whistleblower protections and refine conflict-of-interest policies

The effectiveness of Federal scientific integrity policies in promoting trust in Federal science

Recommendation 1: To protect against improper interference in the conduct of scientific research, we urge federal agencies to fully enforce and defend all whistleblower protections guaranteed by the Department of Labor’s Occupational Safety and Health Administration, and we urge federal agencies to establish mechanisms for anonymously reporting violations of scientific integrity policies. In a [recent survey of more than 3,000 scientists](#) at nine government agencies, “two in five said they feared retaliation for speaking out about their agency’s work.” [Whistleblower protections are vital](#) to ensure that government institutions are held accountable for their actions, to ensure regulatory compliance and to protect the public’s interest. Furthermore, it is imperative that federal agencies use a consistent set of guidelines for whistleblower protections. In addition to establishing reporting mechanisms, federal

agencies must inform and train their employees on their rights laid out in the [Whistleblower Protection Enhancement Act of 2012](#).

Recommendation 2: To protect against disproportionate harm to federal scientists and researchers from groups that are historically underrepresented in science, technology and related fields, federal funding agencies must address non-financial conflicts of interest, such as foreign affiliation, in their conflict-of-interest policies. In the past several years, there have been concerns that federal agencies are [racially profiling Asian and Asian-American scientists](#) and profiling scientists who collaborate with Chinese institutions. [According to a U.S. Government Accountability Office report on addressing foreign influence](#), the National Institutes of Health's conflict-of-interest policy focuses on financial conflicts but does not address or define non-financial conflicts, including professional appointments. As a result, universities that receive federal funding lack sufficient guidance to manage these conflicts appropriately, and a [handful of scientists have been accused](#) of economic espionage or grant fraud even though there was little evidence to support those claims. Despite [prosecutors dropping charges](#) against some of these scientists, these researchers' careers have suffered and there has been an overall chilling effect on scientific international collaboration.

2. Encourage preprints and media engagement

Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information

Recommendation 1: To speed up and broaden the communication of scientific and technological information, OSTP should examine the impacts of encouraging both federally employed and federally funded scientists to publish their research results as preprints. As demonstrated by the [preliminary results of the NIH Preprint Pilot](#), publishing preprints hastens the dissemination of scientific research. [Other studies](#) have illustrated how preprints foster scholarly discourse and accelerate scientific discovery.

Recommendation 2: To increase engagement of federal scientists with news media, OSTP should establish a policy allowing all civilian employees and contractors to speak with reporters without agency approval or pre-coordination if they are not speaking as official representatives of their agencies. Federal agencies' media policies [are inconsistent](#). By establishing a uniform policy, OSTP will ensure that the nation's experts are accessible to the media, contributing to the public dissemination of scientific findings and contributing to public education about the scientific process.

3. Study and remedy funding inequities and other professional barriers

Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce

Recommendation 1a: To ensure equitable support for researchers of all genders, races, ethnicities and backgrounds and advance the equitable delivery of federal programs, funding agencies must first track how much funding goes to underrepresented groups versus well-established groups. For example, [an NIH-funded study](#) found that more funding goes to late-career investigators, men, white scientists and

holders of medical degrees. Now NIH can identify the steps necessary for achieving equity. Other science agencies should follow this example.

Recommendation 1b: In addition, federal funding agencies must ensure that funds are available for researchers who have been historically neglected, such as [Black scientists](#) and [LGBT!+ scientists](#). One example of a successful funding mechanism that supports an underrepresented group in science and technology is the [NIH's Centers of Biomedical Research Excellence award](#). This award funds health-related research by investigators at institutions in states with historically low aggregate grant success rates. Similar award programs should be established across all federal funding agencies.

Recommendation 2a: To support the professional development of federal scientists and retain talent, agencies must address workplace harassment and impediments to participating in conferences. According to the GAO's [Strengthening and Sustaining the Federal Science and Technology Workforce report](#), sexual harassment and limitations on engagement with peers are two significant factors that push scientists out of the public sector. Federal funding agencies must mitigate sexual harassment and must remove barriers for scientists to present their work and forge collaborations at scientific meetings.

Recommendation 2b: To support the professional development of federal scientists and retain talent, it is essential that federal agencies develop consistent and robust policies with regards to mitigating sexual harassment as stated above. Policies, created in partnership with awardee institutions, should include enforcement that is consistent across the entire federal funding landscape.

4. Make scientific integrity matters public

Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices

Recommendation 1: To improve transparency of scientific integrity practices, federal agencies should be required to release a public annual report on the state of scientific integrity. This will give the scientific community and other important stakeholders a better understanding of governmental scientific integrity policies and the progress on upholding scientific integrity at federal agencies. This will also help make federal agencies accountable to the public.

July 28, 2021

Scientific Integrity Fast-Track Action Committee (SI-FTAC)
Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, DC 20504

BY EMAIL TO: ScientificIntegrityRFI@ostp.eop.gov

RE: Association of American Publishers Response to Request for Information “To Improve Federal Scientific Integrity Policies” (86 FR 34064)

Dear Members of the SI-FTAC:

The Association of American Publishers (AAP) applauds OSTP for its efforts to support scientific integrity and enhance public trust in science, and we are grateful for the opportunity to respond to this Request for Information.

AAP represents the leading book, journal, and education publishers in the United States on matters of law and policy. We believe strongly in the role of publishing in a democratic society, and advocate for outcomes that incentivize the publication of creative expression, professional content, and learning solutions to the benefit of the public. As key contributors to the global economy, publishers invest in valuable intellectual property that supports scientific integrity and furthers the scientific progress and intellectual advancements that are at the core of the research enterprise.

AAP’s membership is diverse but united by the goal of disseminating knowledge, particularly in the realm of professional and scholarly publishing. From scientific societies to university presses to commercial publishers, our members collectively publish thousands of scholarly journals, covering nearly every academic and professional field in science, technology, medicine, social sciences, and the humanities. Publishers not only invest in content, but also in the tools by which to make it available, investing billions of dollars to produce high-quality, peer-reviewed and validated articles, and disseminate them to readers around the world.

Trusted Publications Are a Cornerstone of Scientific Integrity¹

Rigorous publications are essential to support scientific integrity and public trust in science. Researchers, doctors, engineers, and myriad other professionals must be able to rely on the integrity of the scientific publications that inform their decisions. The public, in turn, must be

¹ This section addresses Topic 2 of the RFI, focusing on issues related to “improv[ing] the communication of scientific and technological information,” and Topic 5 on “other important aspects of scientific integrity.”

able to feel confident that practitioners' and policymakers' scientific and technical decisions are grounded in accurate information. Publishers are deeply committed to supporting this integrity and trust in science by building and maintaining infrastructure that enables the widespread production and communication of validated and reliable reports on scientific research.

Among other things, this includes creating scientific journals and staffing their editorial boards with experts that read and evaluate thousands of submitted manuscripts for quality and relevance. These experts curate the highest quality submissions and manage the peer-review process—identifying and engaging reviewers, coordinating reviews, and conducting editorial synthesis and assessment of the reviews and authors' changes. Publishers also invest in making significant post-review improvements to articles, such as copy editing, layout and design edits, and creating or improving graphic presentations. Furthermore, publishers work to ensure the integrity of journal articles by verifying references, assessing articles for ethical considerations, managing and underscoring authors' potential conflicts of interest, and conducting plagiarism checks.

Importantly, publishers' investments in support of scientific integrity do not end when a peer-reviewed article is published. Publishers also play a critical role in maintaining the long-term integrity of articles, including by investing in archiving to preserve access to the scientific record. As stewards of the version of record—the validated official published version—publishers update articles for correction and addenda, update links, and conduct ongoing plagiarism and copyright protection to safeguard the integrity of the work and ensure articles are not modified or pirated in misleading and harmful ways. Upholding the version of record, and providing the clarity necessary to easily distinguish between the version of record and earlier, less reliable versions of an article, is a key principle of scientific integrity. In order to build trust in science, readers must be able to easily identify trusted peer-reviewed content.

Publishers also make important investments to ensure that the version of record is distributed and discoverable to readers around the world. This can include building direct-to-reader distribution platforms or securing distribution through partnerships with other publishers or platforms. It also includes facilitating discovery by assigning digital identifiers, providing metadata, conducting search engine optimization, tracking citations and other important metrics, and submitting articles to abstracting, indexing, and discovery services. These valuable services support scientific integrity by pointing readers to the highest quality scientific publications.

At a time when concerns around misinformation—including on critical issues of science and medicine—have become a national priority, there is an urgent need for stakeholders that support scientific integrity to work together and uphold the role of objective, trusted information in a democratic society. Although the growth of technology platforms and other economic challenges have reduced the availability of high-quality journalism in many communities, the United States remains home to a world-leading and vibrant professional and scholarly publishing sector that is a bedrock for scientific integrity here and around the world. This sector requires a strong enabling framework to protect and sustain it.

As OSTP considers its policies related to scientific publications—and particularly with respect to public access requirements for certain publications—it is important to recognize the role of peer-reviewed journals in supporting scientific integrity. Likewise, it is essential that any policies

related to publications ensure that scientists and publishers can continue producing and disseminating the trusted, peer-reviewed, version of record of scientific articles. Given the billions of dollars of publisher investments that support this process, any policy discussions on how to increase the proportion of articles made freely available online immediately upon publication (i.e., open access articles) will need to focus extensively on how to ensure these critical investments in the scientific integrity of articles can continue. In particular, it will be essential to ensure that public access policies provide sufficient funding for researchers who choose to publish open access to support investments in publishing their works in high-quality journals that uphold scientific integrity.

Public Access Policies Should Support Scientific Integrity Through Flexible Frameworks that Empower Authors to Publish High-Quality Works²

Publishers are committed to promoting open science and public access through sustainable models that support scientific integrity by empowering all researchers to publish rigorous, trusted, peer-reviewed articles. AAP's members are working to achieve this goal by developing an ever-increasing array of open access and public access business models, as well as tools to enhance the dissemination and impact of publications. Through these innovations, publishers are continuously creating options by which researchers can communicate their ideas and discoveries to the world while ensuring the accuracy and peer-review that are essential to scientific integrity. Our members are also working with their communities on initiatives to advance data sharing, foster open practices, reduce bias, and increase diversity, strengthening the integrity of scholarly communication through voluntary partnerships and innovation.

In order to sustain these important efforts, it is critical that government public access policies continue to promote open science through flexible frameworks that uphold the value of the version of record and empower researchers from all backgrounds to publish high-quality works. Last month, a coalition of more than one hundred scientific societies, publishers, and research-related organizations issued a statement that lays out important principles for successful public access policies (the statement is included here as an Appendix). These principles will prove valuable in ensuring that public access policies continue to support scientific integrity.

A few key points in particular are worth highlighting:

a. Promoting equity

To support scientific integrity for *all researchers*, public access policies should promote equity through author choice, and should give consideration to the broad diversity among authors. Many researchers—whether by virtue of their background, career stage, discipline, institution, or personal circumstances—do not have the funding for open access publishing costs. Public access policies should therefore support choice for researchers in where and how they publish their

² This section addresses issues in Topic 3 of RFI related to “supporting the professional development of Federal scientists” and “supporting scientists and researchers of all genders, races, ethnicities, and backgrounds and advance[ing] the equitable delivery of the Federal Government’s programs.” It also addresses Topic 2 of the RFI, focusing on issues related to “improv[ing] the communication of scientific and technological information,” and Topic 5 on “other important aspects of scientific integrity.”

works. In particular, policies should continue to allow authors to publish through publisher-financed public access models that carry an embargo period (such as the one-year embargo in current policy) to ensure that publishing is economically sustainable. Failing to do so would effectively force many authors to limit how many articles they publish, or could create incentives to publish in outlets that invest less in article quality, such as predatory journals. Not only would this reduction in article output and quality be harmful to scientific integrity, it would also exacerbate inequalities in the research ecosystem that already favor researchers at better-funded institutions, in better-funded disciplines, and in later stages of their careers.

b. Protecting academic freedom

Public access policies should protect academic freedom. Freedom to publish is a fundamental principle of academic freedom, and it is of vital importance to scientific integrity, ensuring that researchers—including government researchers and grantees—can share their views, foster debate, and advance knowledge. Researchers should be able to choose to publish in the outlets where their work will be most fitting and trusted, have the most impact, and best meet their needs as well as the needs of their research community. Public access policies should support this choice and should ensure that authors can select from the wide range of high-quality journals (and publication options within journals) that publishers offer. In particular, policies should never require or encourage authors to publish under economically unsustainable business models that could reduce their publication options or compromise the quality or integrity of their work, such as the so-called “zero-embargo green” model. Likewise, policies should never prevent or discourage authors from publishing open access articles in a specific journal merely because the journal also publishes subscription content.

c. Supporting intellectual property and innovation

Public access policies should support intellectual property and innovation. Intellectual property is critical to scientific integrity and security—it provides incentives that enable market investments and innovation in the quality of scientific publications, and it ensures that authors can protect their works against downstream manipulations, misappropriations, or distortions that would compromise their integrity. Public access policies should allow authors to choose copyright license terms that safeguard the quality and integrity of their works. In particular, policies should avoid compulsory license requirements that undermine copyright and jeopardize scientific integrity by reducing investments in article quality and reducing authors’ ability to prevent downstream manipulations of their works.

As OSTP continues its important work to enhance scientific integrity and promote public trust in science, the publishing community looks forward to partnering with you in support of policies that facilitate publication and dissemination of rigorous, trusted, scientific content. Publishers are important government partners in promoting scientific integrity and maximizing the value and impact of investments in research. AAP’s members are proud to have developed the world’s most celebrated scholarly journals, created the infrastructure to peer-review and publish more than three million English-language articles annually, and invested in the business models that

make public access and open access possible. By working together, we can ensure that OSTP's policies and publishers' investments in advancing scientific integrity and scholarly communication complement one another, thereby maximizing the benefit to the public.

Thank you for the opportunity to submit these comments, and we look forward to collaborating on this important work.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read "Matt Bar", with a stylized, flowing script.

Matthew Barblan
Vice President, Public Policy



PPC

PESTICIDE POLICY COALITION

A Coalition Working for Sound Pest Management Policies

July 28, 2021

Dr. Eric S. Lander, Director

White House Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

Submitted via e-mail to: ScientificIntegrityRFI@ostp.eop.gov

Dear Dr. Lander,

The PPC is an organization of food, agriculture, forestry, pest management and related industries, including small businesses/entities, which are dependent on the availability of pest management tools. PPC members include nationwide and regional farm, commodity, specialty crop, and silviculture organizations; cooperatives; food processors and marketers; pesticide manufacturers, formulators and distributors; pest and vector-control applicators and operators; research organizations; equipment manufacturers and other interested stakeholders. PPC serves as a forum for the review, discussion, development and advocacy around pest management regulation and policy.

PPC members confront changing pest and disease threats introduced into the United States via weather, trade, and other factors. Pesticide manufacturers work diligently to make pest control products available through, among other entities, a web of seed, fertilizer, and pesticide distributors, transportation networks, and pesticide application services. These efforts help ensure farmers, ranchers, public health officials, and other pesticide applicators have the tools they need to continue to produce America's food, fiber, and biofuel and to protect our public health and infrastructure. Many of these participants are small businesses reliant on annual, time-sensitive sales and labor to support American agricultural production and small businesses.

In this RFI response, the PPC comments are based mostly on our experience as stakeholders impacted by science policies and decisions made by Federal agencies involved in the regulation of pesticide products, whose decisions affect the agricultural, forestry, turf, and structural pest control industries. Pesticide product use is affected by the activities of various agencies, including the Environmental Protection Agency (EPA), the Food and Drug Administration

FDA), the National Marine Fisheries Service (NMFS), the Fish and Wildlife Service (FWS), and the US Department of Agriculture (USDA).

1. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science.

Policies that support transparency, inclusion, and the opportunity to interact with scientific reviewers advance stakeholder understanding and acceptance of science decisions made by Federal agencies. When the public, industry, academics, research institutions, and other interested parties can interact with scientific reviewers and provide their perspectives and relevant information, the credibility of decisions based on such science assessments is enhanced.

For the PPC, when assessing decisions made by EPA according to the implementing regulations of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), affected stakeholders need to understand the basis of EPA decisions, in terms of the underlying science, sound risk assessment approaches, and proper application of the FIFRA requirements. When agencies explain how the science supports a decision, following established regulations and scientific review practices, scientific integrity and trust in regulatory outcomes are advanced.

Government policies should encourage Agencies to use plain and accessible language to describe their process for considering sources of scientific data, and to discuss the robustness and level of certainty in data and risk assessments supporting regulatory actions.

Agencies should provide clear and understandable descriptions of the risk assessment methods used, how they accounted for scientific uncertainty, and the criteria applied to balance risks to advance trust in the underlying regulatory decision. Science-based agencies should provide plain-language summaries of proposed and final risk assessment and decision documents, including clear explanations of data quality and reliability criteria, and descriptions of how and whether those criteria are satisfied by the data, scientific studies, and literature relied upon.

A consistently troubling PPC concern regards the “compounding conservatism” which underlie many scientific models used in EPA regulatory assessments. The basis of decisions can remain opaque when modeling estimations are used instead of field monitoring data (even when provided by sister Federal agencies). Transparency around when and how data from stakeholders is (or is not) incorporated into scientific risk assessments would be helpful. The credibility of decisions would be improved if greater resources could be devoted to narrow the uncertainty around decisions with more refined assessment methods that more accurately reflect realistic, “real-world” conditions.

Policies that require science to be reproducible, including making the data and results available, also will advance trust in the underlying science. When decisions are based on study results that are withheld from public review or are not reproducible, the confidence of affected stakeholders in the scientific honesty behind the decision is eroded.

Scientific integrity should encompass policies to support agency adoption and incorporation of emerging science, and require science-based agencies to review and revise risk assessment models, tools, guidelines, and policies to reflect new developments in science and technology. Policies regarding the recruitment and pay of Federal personnel also affect the ability of an agency to maintain the scientific quality of work products. Personnel policies should also stress the need for continuous training to enable staff to constantly reflect the latest and best capabilities in the respective fields of expertise.

2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information.

Clear and concise communication of scientific and technical information about science issues is essential for building awareness and understanding of Federal science decisions. Translating complex scientific work into accessible web pages, fact sheets, and social media posts requires personnel trained in risk communication, data visualization, and infographics.

The PPC encourages and supports practices that promote hiring science and risk communication professionals into science-based Agencies. In addition, risk and science communication training for scientists can advance scientific integrity by increasing the ability of Agency experts at all stages of their careers to be able to answer questions, explain decisions, and increase trust in Agency science to a variety of audiences clearly, correctly, and confidently.

The science communication skills of the Federal workforce are increasingly important, as complex innovations in biotechnology, nanotechnology, application technology, and other advanced science approaches permeate modern agricultural production, crop protection, and public health protection (many pesticide products have public health uses, as much of the public came to rely on new COVID-related pesticide products).

3. Effective policies and practices Federal Agencies could adopt to address scientific issues and the scientific workforce.

In addition to personnel recruitment and training, Agencies should find ways to retain scientific staff and expand existing policies that require routine scientific workforce training on scientific integrity principles. This training should be accompanied by consistent messaging from top Agency leadership on the importance of scientific integrity and maintaining the highest level of scientific competence for all relevant staff positions.

Policies and practices should further the scientific workforce attending educational programs to obtain experience with and exposure to emerging scientific tools and developments. Such training and exposure also will promote retention of scientific talent. Many excellent training

programs exist through academic partnerships, internal agency mentorship and coaching programs, and opportunities for Federal scientists to detail to other science-based Federal agencies.

The technological capability of science-based agencies should be on par with the private sector and with global trading partners. Acquisition of cutting-edge technology will ensure that U.S. science-based agencies are global leaders in science and technology.

4. Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices.

Often scientists may disagree with the program leadership, sometimes leading to allegations that scientific integrity has been breached. Clear delineations can be made between a management decision and a violation of scientific integrity. Transparency about how and why decisions are made (including explanations internal to the agency) can reduce confusion about what is a disagreement over “science” and what is a management decision based on other relevant and lawful considerations.

Regulatory decisions, even if steeped in science, need to take account of other factors relating to the underlying legislative mandate that can include food security, protecting public health, trade obligations, and national interests. It should not be considered lack of integrity if appropriate legislative or other programmatic considerations leads to an outcome about which some scientific staff may disagree. Program management on such occasions will also benefit by clear adherence to scientific assessment review procedures and policy guidance established by open, reliable, and consistent methods as outlined earlier.

At the same time, resolution of any internal disagreements about scientific interpretations should minimize delays in finalization of important regulatory decisions and policies.

5. Other important aspects of scientific integrity and effective approaches to improving trust in Federal science.

Peer review panels are a critical additional source of scientific expertise for Federal agencies. We support scientific integrity policies that recognize that scientists from all backgrounds – non-governmental organizations, academia, and industry – are valued in peer review, and that bias will not be presumed solely because of the scientists’ employer. Policies supporting balanced peer review panels that consist of a breadth of expertise with scientists from all backgrounds will advance trust in their work.

The goal is to have peer review policies that insulate review procedures from political changes, as independent panels make for greater integrity and credibility of the decisional outcome. At

the same time, some agencies appear to exert influence to support tentative agency decisions through the selection of panel members or the wording of questions before review panels. A further concern is that at times the final summary report of some review committees, often drafted or interpreted by agency staff, seem to be inconsistent with the real-time proceedings according to those who attend or participate in the review meetings.

Transparency and openness, discussed earlier, are ways to combat even subtle bias that might permeate the selection of review panel members or agency-drafted conclusions summarizing independent reviews.

Thank you for the opportunity to comment on these important issues.

Sincerely,

A handwritten signature in black ink that reads "Steve Hensley". The signature is written in a cursive, flowing style.

Steve Hensley

Chair, Pesticide Policy Coalition

A handwritten signature in black ink that reads "Beau Greenwood". The signature is written in a cursive, flowing style.

Beau Greenwood

Vice Chair, Pesticide Policy Coalition

From: [Hayat, Aatif](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Wednesday, July 28, 2021 1:10:15 PM

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1. Consider if existing policies prevent political interference and promote trust; Leaders of government and state agencies are typically political appointees. Unfortunately this can lead to scientific policies and outcomes being influenced by these leaders. Sometimes the leaders have the appropriate scientific knowledge and background to promote the correct science, however, this is not always the case. Many of the technical personnel with the scientific knowledge are not taken into consideration. Greater collaboration needs to exist with administrators and technical personal.
2. Analyze instances where communication policies have not been followed: I don't have specific knowledge of this
3. Identify effective policies to implement: Care should be taken to ensure that leadership utilizes their subject matter experts when putting out policy. Many agencies have experts who have spent their careers focusing on scientific details that need to be utilized by leaders particularly during times of crisis.

Aatif Hayat MD MPH

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From: [Glenn Hampson](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Wednesday, July 28, 2021 1:18:31 PM

Dear OSTP Officials,

Thank you for hosting today's listening session on improving scientific integrity. I would like to add a brief statement to the record of today's discussion, with regard to good practices Federal agencies could adopt for communicating scientific information. Specifically, my statement has to do with so-called "open" solutions.

For the past six years, I have been privileged to coordinate the work of a large, multidisciplinary, international group of thought-leaders in the open solutions space (known as the Open Scholarship Initiative, or OSI). Working together in partnership with UNESCO, we have published a number of papers on this topic, spoken at numerous conferences, and are currently working with UNESCO to develop a policy framework that reflects the thinking of this group. You can read more about our work at osiglobal.org.

To be brief, the central recommendation of our group is this: There are no one-size-fits-all solutions for open. Open access, open data, open science, open educational resources, open source/code, open government, and generic open solutions and processes have evolved independently over decades and even centuries in some cases. These philosophies have developed different definitions (even within each movement) as well as different responses to different needs. Motives and methods vary widely by institution, region, field, and researcher career stage, evidence of what works and why is still sparse, and unintended consequences are everywhere (including increasing global access inequities instead of reducing them).

Our goal is to try to stay grounded in the reality of open solutions while still working to fulfill their vast potential. For example, data networks are a critical tool of researchers, but they don't operate the way many open advocates think they should operate, with free (to everyone) and immediately-accessible information. We should build on the success of these networks, learn from best practices, and invest in the infrastructure to help them succeed at scale. Similarly, while the majority of new journal articles published today are in open access format, open access isn't the ideal choice for all research---the highest impact journals are still overwhelming subscription based. Therefore, while we should continue looking for ways to improve open access, we also need to acknowledge the reality that blanket mandates only work for some fields, institutions and regions. And finally, open solutions in and of themselves are not panaceas that will cure all that ails research. There is some overlap between open solutions and issues like integrity and reliability, but in truth, a wide array of other issues also needs to be addressed in parallel, from peer review to impact factors to research fraud, embargoes, tenure policies (which heavily weight research publishing), and more.

The approach we're advocating is to find our common ground and common goals in this space, and from this position, build policies, processes, and tools that will help bring about a future for research where information is more accessible, the research ecosystem will grow stronger as a result, and both research and society will reap the benefits. Rather than continuing to implement an array of

separate open solutions policies and tools, starting instead from our common ground is the best way to ensure that we get to an "Open Renaissance" and begin using science to our full advantage to address our many pressing global challenges.

Two documents are linked here for your reference and review. The first is our most recent open solutions report, at <https://bit.ly/3ytMeLE>. The second document is our slide presentation made a few months ago for the UN's 2021 World Summit on the Information Society (WSIS), at <https://bit.ly/3f6XBB0>. And again, for more information about OSI, please visit <https://osiglobal.org>.

Thank you for your time and best regards,

Glenn Hampson

Glenn Hampson
Executive Director
Science Communication Institute (SCI)
Program Director
Open Scholarship Initiative (OSI)



OSI is managed by the Science Communication Institute (SCI), a US-based 501c3 nonprofit public charity. For more information about SCI, see sci.institute.

July 2021

Response to Office of Science and Technology Policy: Request for Information To Improve Federal Scientific Integrity Policies

Name & role of respondent: James Worron; Director, Policy & Engagement

[Elsevier](#), a global information analytics business specializing in science and health, welcomes the opportunity to respond to this Request for Information. Elsevier helps researchers and healthcare professionals advance science and improve health outcomes for the benefit of society. Elsevier shares the goal of promoting rigor, integrity and trust in research by providing high-quality academic publications and services to the research community. We are active in many of the areas outlined in this Request for Information and have shared our insights below, for consideration and potential implementation by OSTP where appropriate. In addition, we recommend future collaborations on the range of issues highlighted in this document.

1. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science; including strengths and weaknesses

Now more than ever, trust in science is crucial in enabling society to address key global challenges, including the novel Coronavirus epidemic; long-standing issues such as climate change; plus the new risks we face regarding the spread misinformation, for instance via fake news and social media rumors and conspiracy theories.

Investments by publishers in systems, processes and policies ensure high quality standards and rigorous, independent peer review and the dissemination and long-term preservation of authoritative, reliable research findings. We enhance trust through established and respected scientific journals and promote the transparency and reproducibility of all forms of research outputs. These investments also ensure that the scientific record is up to date, enabling publishers to implement editorial decisions to correct or retract inaccurate or unethical outputs. We also aim to improve innovation and increase the impact of research by advancing diversity and inclusion. We explore these mechanisms in further detail below.

Rigorous standards, as well as protection against the risk of improper interference and the suppression of research, should be embedded throughout the research lifecycle: from effective design methodology through submission of proposals for funding and then also in research activity, article submission, through to management of reviewed publications and making research data available for re-use. Alignment across the research lifecycle requires collaboration among stakeholders in the research community, including publishers, funding bodies, researchers and policy-makers.

Elsevier embeds the principle of research integrity through our work. Our journal editors are members of COPE, the [Committee on Publication Ethics](#), a forum for editors of peer-reviewed journals to align on key policies and practices related to publication ethics, including issues such as plagiarism and the integrity of the scientific record.

Tools can also be used by organizations to systematically promote research integrity. For instance, the [Elsevier Expert Lookup](#) tool helps to match researchers with funding opportunities and locate the right reviewers for papers. It can also be used to identify potential conflicts of interest around co-authorship and funding streams.

Recommendation

We would welcome discussion of the potential for collaboration with OSTP and Federal agencies, to emphasize the importance of reliable and authoritative science in public discourse.

2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information

Federal agencies can support the communication of scientific information by drawing on industry best practice and standards, where appropriate. These standards are embedded in our work to communicate authoritative research and to support transparency and reproducibility.

Scientific communication

Publishers are communicators of science and we have a duty to promote research integrity by ensuring that the scholarly works we produce are factually sound, transparent, and based on solid and reproducible evidence. The protection of scientific independence during submission and review processes depends on independent peer review to protect against improper interference. Publishing must therefore retain an appropriate level of independence from government, funding bodies and institutions.

Publishers engage expert, independent editors and peer reviewers to assess submissions for validity, significance, and originality. Elsevier invests extensively to find, recruit and train 18,000 editors and editorial board members across our publications each year. Our [Editorial Independence Policy](#) supports our core value of intellectual freedom and editorial independence and forbids company executives from interfering with, or even commenting on editorial decisions. We are committed to rigorous application of this principle. Furthermore, we provide specialist systems and tools (e.g. the Find Reviewers Reviewer Recommender reference tool for editors) which removes or flags reviewer candidates based on potential conflicts of interest with the submission authors.

We also invest in a range of systems to ensure the integrity of the research findings that we publish. Examples include systematic approaches to duplication and plagiarism detection: we

collaborated with other publishers to develop [Crossref Similarity Check](#), in order to detect plagiarism before publication. We have ongoing pilots, collaboration and investments to detect other publication infringements, such as citation pushing, fake article detection from paper mills, or image manipulation. Responsible application of these Artificial Intelligence (AI) tools will require human oversight, provided by editors. We also collaborate on image manipulation detection: Elsevier chairs an [STM Association Working Group on image alterations and duplications](#).

Federal agencies should also consider the implications of the sharing of early versions of research. During the Covid-19 pandemic, researchers, policy makers and the press have often referred to new information available in preprints. These do not incorporate the extensive integrity checking and verification applied to journal articles – over 90% of final published articles incorporate editorial changes compared to pre-submission papers. Preprints should only be posted in locations from which they can be retracted, as they can be from the Elsevier [SSRN](#) preprint server.

Accepted Manuscripts (AMs) are early versions of research which have undergone peer review and reflect significant value add from publishers. However, they are not formally published works and the majority of Published Journal Articles incorporate substantive changes compared to the AM. Consequently, in order to maintain quality and integrity in the research system it is necessary to adopt sustainable and responsible approaches to Open Science, including Public Access rules, for instance by maintaining the current 12-month embargo period. Responsible approaches also include government support for enforcement against large-scale illegal repositories, which provide articles without noting corrections and retractions appropriately.

We encourage Federal agencies to support and invest in specific approaches that incentivize transparency, accountability, and reproducibility as part of communicating research findings. Examples of these are below.

- Creating a rigorous, transparent and credited ecosystem of research outputs through Digital Persistent Identifiers. Persistent IDs, including standardized, prevalent [ORCID identifiers](#), help to ensure correct citations; to attribute funders to particular articles; or authors unambiguously to their works.
- Federal agencies should encourage the development of semi-automated processes for tracking use and sharing of research and data. For example, Elsevier was a co-founder of [Scholix](#), which established an interoperability framework for information exchange across both research and data.
- Rigorous reporting methods: Elsevier has also introduced [STAR](#) (Structured, Transparent, Accessible Reporting) Methods in journals to encourage rigorous, transparent, comprehensive, and detailed reporting of methods in research.

- The [Registered Reports initiative](#). Registered reports comprise reviews of study protocols shared before experiments are conducted to ensure they are methodologically sound. Similarly, [Results Masked Review](#), is a new form of peer review which allows an article to be judged on the merits of its research question(s) and methodology, not the findings.
- Encouraging the sharing and discoverability of all forms of research output: Elsevier [Research Elements](#) journals enable the sharing of a range of outputs, including the technical aspects of research, methods and open source software and hardware.
- Elsevier has worked in collaboration with a range of research institutions, publishers, funding agencies, standard organizations, and other to establish the [CRediT](#) initiative. This provides greater recognition for authors by clarifying what they actually contributed to a paper, clearly defining different roles, and reducing authorship disputes.
- To facilitate authors disclosing any interests, essential for legal and ethical reasons, patient safety, and trust in science more broadly, we have developed a [Declarations Tool](#) which helps authors step-by-step through the preparation of relevant statements.

Sharing research data supports reproducibility and rigor

Open Research Data is a pillar of Open Science. Elsevier encourages and enables researchers to store, share, discover and re-use data in repositories including through the [Digital Commons](#) platform, which enables data sharing to be incorporated seamlessly into the research life cycle, improving the transparency and reproducibility of research. We encourage Federal agencies to support existing standards and initiatives which incentivize researchers to share data, including:

- The [FAIR data principles](#), published in 2016 (of which Elsevier is a co-author), offer guidelines to support communities' needs on data sharing and optimizing use of data.
- Elsevier has also developed journal data guidelines that align with the [Transparency and Openness Promotion](#) (TOP) Data Standards. We have implemented these across our journals, enabling authors to easily share and link to their data.
- The [Research Data Alliance](#), of which Elsevier is a founder member, works to develop data sharing infrastructure.

Recommendations

- Federal agencies could support and draw from the initiatives seen in industry that incentivize authoritative, replicable and transparent scholarly communication.
- We also recommend that Federal agencies can incentivize and encourage, through their approach to funding and evaluation, all forms of research output, including research methods.
- We recommend that Federal agencies work with all stakeholders to continue to develop and invest in tools that incentivize sharing of high-quality research data.

3. Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce

We explore below some of those practices identified in OSTP's RFI in the context of our specific activities, which could be incorporated by Federal agencies to address key scientific issues and ensure an inclusive, pragmatic approach to enhancing research integrity.

Handling scientific disagreements

Independence and commitment to high publication standards enables publishers to take a neutral approach to scientific disagreements, such those as regarding patent matters, forensics, or conflicts between authors, and instead focus on the curation of reliable information as the basis for scientific debate. Scientific disagreements may happen many years after publication, giving publishers responsibilities into the long-term.

Citizen science and community-engaged research

Making research publicly available enhances citizen science and therefore more community-engaged and inclusive research. Examples of how Elsevier makes research available include:

- We provide free access to research in public health emergencies, including the Covid-19 pandemic.
- Patients and caregivers are provided with papers related to medicine and healthcare upon request to help them better understand the latest research on their conditions.
- We open the archives for 140 journals, including Cell Press journals, after 12 months.
- Through Research4Life, institutions in 120 low- and middle-income countries receive affordable access to nearly 100,400 peer reviewed resources. As a founding member, Elsevier provides over a quarter of that content.

Supporting scientists and researchers of all genders, races, ethnicities, and backgrounds and advance the equitable delivery of the Federal Government's programs

Science needs diversity. Creating an environment where everyone has an equal opportunity to succeed is not only fair, but – [evidence shows](#) that diversity leads to increased innovation, improved team performance and better, more impactful, scientific research.

Elsevier supports fostering a culture of inclusion. Our Inclusion & Diversity (I&D) Strategy translates our vision into practical action. Elements of this include:

- Inclusion & Diversity Advisory Board: to further improve gender balance and inclusive research both within Elsevier and across academic research globally, our CEO Kumsal Bayazit and Editor of *The Lancet* Richard Horton have established a distinguished board of academic scientists, policymakers, I&D/gender researchers, and professionals in STEM who are committed to driving change in gender balance and more inclusive research.

- The Elsevier Foundation: Since 2006, the [Elsevier Foundation](#) has contributed more than \$3 million to over 50 projects and partnerships to advance women in science.
- We have made progress in gender representation: we have a 50:50 gender balance across the editorial Boards of the Lancet journals; and 45% of Cell Press journals have at least 40% female representation.
- Supporting inclusive name changes: In March 2021 we launched an [inclusive name change policy](#) which supports ‘invisible’ author name changes to published works for transgender authors, and other authors with a strong need for privacy, enabling them to claim ownership of their published works in their chosen name.

We are keen to explore key challenges related to diversity and inclusion, for instance in the following areas:

- *Increasing awareness of differences in participation:* It is important to understand how participation varies through the research journey, including collaboration and participation and career stages. Elsevier has looked at these issues, for example in 2020 Elsevier published [The Researcher Through a Gender Lens](#), examining in detail how gender impacts on the research journey, including both participation and collaboration.
In the peer review process: In a September 2019 [Cell Press Editorial on peer review](#), colleagues shared the numbers (painstakingly aggregated by hand): 82% of reviewers were identified as men and only 18% as women. We are committed to improving this and incorporating gender self-identification fields to track these numbers across our journals.

Recommendations

- We welcome discussion with Federal agencies on enhancing the accessibility of research across the ecosystem: from accessing research content to raising awareness of opportunities to participate in this sector.
- We welcome the opportunity to collaborate with OSTP to both gather evidence and to develop solutions on inclusion and diversity challenges, such as those referenced above.

4. Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices

Training and education promote research integrity

Federal agencies should encourage training in research integrity and can draw in the experiences of publishers to support them in these efforts. We welcome cross-stakeholder discussions regarding existing and future education and training options for scientific staff.

Elsevier provides education and training sessions through research institutions on the integrity of research including dedicated resources for authors, reviewers and editors.

- The [Elsevier Researcher Academy](#), an e-learning program, includes a dedicated ‘[Ethics](#)’ topic with modules on publishing ethics, permissions and plagiarism. We supplement this learning hub with webinars, conferences sessions and workshops on this and related topics.
 - The Academy also supports research integrity through a [Certified Peer Reviewer Course](#). Our journals also offer a Reviewer Recognition which aims to create a standardized way for reviewers to record and acknowledge their achievements in peer review.
- The [Publishing Ethics Resource Kit](#) provides online resources to support editors, including [issues to consider](#) around ethics integrity including originality, conflicts of interest, reporting standards, addressing errors and handling concerns raised, and the ethics of research with human and animal subjects.

Additionally, Federal agencies could support the promotion of best practices and approaches that enhance research integrity, transparency and reproducibility. Examples of these are set out in our above response to Question 2, and including [FAIR data principles, Transparency and Openness Promotion](#), sharing all forms of [research output](#) and methodologies.

Recommendation:

- We suggest that Federal agencies draw from industry initiatives and encourage training in research integrity, publishing ethics and on sharing outputs and enabling reproducibility.

5. Other important aspects of scientific integrity and effective approaches to improving trust in Federal science

Approaches to research integrity need to be considered within the context of the growing demand for seamless access to research content and an environment in which it is possible to develop and share content ever more rapidly. New technologies have created new possibilities for the infringement of research integrity, and these can only be detected only by information technology and advanced analytics.

We would welcome the opportunity to collaborate in the development of discourse and recommendations around sustainable open science practices which promote research integrity and quality. Sustainable open science will also depend on diverse approaches to funding, drawing on funding from across the research community as appropriate.

We would also welcome the opportunity to discuss recognition of the importance of the published journal article, or Version of Record. Readers can rely on this version which provides an up to date, authoritative version of research, incorporating any corrections or retractions.

From: [Steve Milloy](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Wednesday, July 28, 2021 1:34:17 PM

As requested, below are my comments "to improve the effectiveness of federal scientific integrity policies to enhance public trust in science."

OSTP should adopt the following 10 basic principles:

- <!--[if !supportLists]-->1. <!--[endif]-->Stop government-funded scientists from lying.
- <!--[if !supportLists]-->2. <!--[endif]-->Stop covering up when lying and or mistakes occur.
- <!--[if !supportLists]-->3. <!--[endif]-->Minimize/stop taxpayer funding of scientific research.
- <!--[if !supportLists]-->4. <!--[endif]-->Make all taxpayer-funded research data and all taxpayer-funded studies available free-of-charge on the Internet.
5. Require that federal agencies clearly distinguish and explain science policy vs. actual science knowledge in all discussions of science.
- <!--[if !supportLists]-->6. <!--[endif]-->Require that government-funded scientists and agencies respond in detail to specific criticism of their research and scientific claims.
- <!--[if !supportLists]-->7. <!--[endif]-->Require that federal scientific advisory committees be balanced in terms of views, interests and backgrounds.
- <!--[if !supportLists]-->8. Bar taxpayer-funded researchers and their colleagues from serving on advisory committees or otherwise participating in peer review of their own, their colleagues', their institution's and their funding agency's research.
- <!--[if !supportLists]-->9. Strictly enforce the Nuremberg Code when human research is conducted.
- <!--[if !supportLists]-->10. <!--[endif]-->Conduct an annual review of the actual costs and benefits of taxpayer-funded research and report the results to the public.

Sincerely,

Stever Milloy
Publisher, JunkScience.com

July 28, 2021

Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

RE: Request for Information to Improve Federal Scientific Integrity Policies (86 FR 34064)

Dear Members of the Scientific Integrity Fast-Track Action Committee:

We appreciate the opportunity to comment on ways to strengthen federal scientific integrity policies and support the work of the Scientific Integrity Fast-Track Action Committee (SI-FTAC).

Wiley is a global leader in research and education, unlocking human potential by enabling discovery, powering education, and shaping workforces. For over 200 years, Wiley has fueled the world's knowledge ecosystem. Today, the company's high-impact content, platforms, and services help researchers, learners, institutions, and corporations achieve their goals in an ever-changing world. As the nation's largest research publisher and world's leading society publishing partner – with 1,900 peer-reviewed journals covering all major fields of research – scientific integrity is a cornerstone of our company, our values and the communities that we serve.

The supply chain for research, the process through which research is curated, vetted, held to high standards, and distributed, is critical to the health of the ecosystem and the integrity of the final output. We have seen in the news what has happened to the disintermediation of the pipeline. The demand for volume of content and the engagement with it has pushed to the side many of the incentives to produce high-quality journalism with dangerous ramifications for the integrity of the information the public consumes. We should guard against research content following down that same path. Curation, quality control, and standards for review matter.

Publishers play vital and multifaceted roles in advancing scientific integrity and preserving the health of the research ecosystem. We take extremely seriously our direct responsibilities and significant investments in managing peer-review, publication and the record of science. Through our wider engagement with the research community, we also support ongoing dialogues around research ethics, transparency, open science, inclusion and related issues that affect the integrity of the system of scholarly communication.

We understand that the pursuit of integrity and trust in research is an ongoing project, and we welcome the opportunity to support the efforts of the SI-FTAC and collaborate to advance these important goals. We would offer several initial recommendations on opportunities to strengthen federal efforts to promote scientific integrity:

Ensuring federal policies and practices uphold the Version of Record (i.e., the final published version of a peer-reviewed article hosted on the publisher's platform).

One of the unintended consequences of the moves toward open access for accepted manuscripts of research has been the repackaging of that work and its presentation as equal to the version of record (VoR), which it is not. The VoR is the embodiment of our ongoing investment in and commitment to scientific integrity. Prior to publication of the VoR, publishers play a vital role in vetting research information: this includes creating journals that meet the unique needs of authors (and readers) seeking to share their discoveries, curating hundreds of thousands of submissions, managing the peer-review process and conducting various systemic checks (e.g., for plagiarism, conflicts of interest, and research ethics).

Not only have publishers invested in the vetting and curation of clinical and scientific research, but we have also invested heavily to ensure that all information related to the quality control measures followed by each individual journal are transparently and easily accessed on the host platform. This is essential for upholding the credibility and scientific integrity of the author's work and maintaining the public's trust in the scientific record. The publisher's platform, which hosts the articles on the journal homepage, provides direct access to all of the policies followed by the journal including publication ethics, Conflict of Interest policy, animal use and patient consent guidelines, peer review model, business model, archiving and preservation policy, and the journal's indexing status, which is an important external validation of publication and scientific ethical compliance. Without direct access to this information, the VoR as a stand-alone document, will lose value and the public will lose trust in the measures that have been put in place to uphold the integrity and credibility of author's work.

Importantly, this work does not end upon publication: we actively manage the VoR on a permanent and ongoing basis to ensure that any post-publication changes (e.g., corrections, retractions) are properly traced and recorded. We constantly invest in and fine-tune our policies and procedures to investigate and resolve any questions that are raised as to the accuracy or integrity of a published work.

We welcome working with federal agencies to support steps to uphold the VoR on the publisher's platform. These can include:

- Ensuring that federal websites link to the VoR on the journal platform and that any other versions (e.g., preprints, accepted manuscripts) made available by agencies are clearly labelled to distinguish them from the VoR, and are not altered, which could create confusion between versions.
- Ensuring that the VoR resulting from federally funded research remain on the publisher's platform or journal homepage, alongside documentation of publication ethics guidelines and all other scientific integrity checks that are native to the journal's guidelines will ensure that the public has unhindered, transparent access to all of the necessary quality control assurances.

- Providing additional funding to researchers and strongly encouraging them to use that funding to publish their VoR open access (i.e., freely available upon publication).
- Ensuring that federal public access policies do not undermine the ability of publishers to invest in producing and managing the VoR, and do not create new risks to scientific integrity. For instance, lower embargo periods on their own have the effect of devaluing the investment publishers make in curating submissions and managing the global peer-review process and undermining investments in developing models to make the VoR open access. Similarly, licensing requirements could have the effect of undermining sustainability, discouraging the consumption of curated work, and allowing the creation of new versions of articles without quality control.

Partnering with publishers to address questions of research integrity and ethics.

The publication process is dynamic: our efforts to ensure the most rigorous levels of research integrity and ethics is an ongoing effort, and one that publishers are constantly seeking to build upon and enhance. New technologies, such as for the systematic checking for plagiarism, have helped to increase research integrity. New ethical questions, including in emerging areas of research and technology, require continual engagement with the research community to develop and ensure proper safeguards. Efforts to enhance transparency, including in the peer-review process and in making available the data underlying publications, are creating new avenues to support scientific integrity and trust in research. There is significant opportunity for federal agencies to participate in and support these evolving discussions involving researchers, universities, societies, publishers and other stakeholders. Steps could include:

- Building on this RFI by encouraging longer-term, systemic, constructive dialogue between the SI-FTAC and the stakeholder community.
- Developing public-private working groups or convenings focused on specific integrity or ethics topics to gather views, share case studies and best practices, and identify appropriate steps.
- Encouraging federally funded authors to take advantage of the technology and open research components inherent to the VoR on the publisher's platform that directly support reproducibility, scientific integrity, and provide transparent and full access to all of the research artifacts resulting from federal funding that informed the publication, e.g. supplementary information, Registered Reports, Persistent Identifiers (PIDs), and Data Availability Statements.

Ensuring freedom to publish and participate in the scholarly communication ecosystem.

Federal researchers, contractors and grantees are vital members of the research community. Freedom to seek publication, serve in various roles (e.g., as peer reviewers, editors, editorial board members, society leaders), participate in professional conferences and meetings, and

otherwise engage in the scholarly discussion are crucial to protecting scientific integrity. Federal agencies can ensure that:

- Existing and future policies and practices do not limit or burden researchers' freedom to fully participate in the scholarly community and communication ecosystem.
- Researchers are provided the funding to publish, travel to meetings and conferences, and otherwise participate in scholarly communications.

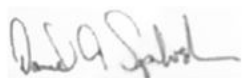
Addressing concerns related to predatory journals.

One emerging risk to scientific integrity is the spread of predatory journals, which provide little or no quality control and engage in deceptive practices. This risks harm to researchers and can make it more difficult for readers to distinguish between rigorously peer-reviewed publications and those that have not been appropriately vetted. The NIH released a notice ([NOT-OD-18-011](#)) in 2017 which encouraged authors "to publish papers arising from NIH-funded research in reputable journals" in order to "protect the credibility of published research." Federal agencies could consider additional steps to address this emerging risk, such as by:

- Building on NOT-OD-18-011 to provide similar and updated guidance to all federal researchers, contractors and grantees to raise awareness of these risks.
- Developing additional tools and training to help researchers identify predatory journals.

Thank you for the opportunity to provide comments on this important issue.

Sincerely,



Daniel Sepulveda
Vice President for Global Government Partnerships and Public Policy
Wiley



July 28, 2021

Scientific Integrity Fast-Track Action Committee (SI-FTAC)
Office of Science and Technology Policy
White House
1650 Pennsylvania Avenue NW
Washington, DC 20502

Re: Request for Information to Improve Federal
Scientific Integrity Policies (86 FR 34064)

Members of the Scientific Integrity Fast-Track Action Committee:

Collectively, the Computing Research Association and the Association for Computing Machinery's U.S. Technology Policy Committee represent more than 80,000 computing professionals in North America and more than 200 academic and industrial institutions engaged in computing research. We appreciate the opportunity to respond to this request for information, provide perspective on some of today's challenges to scientific integrity and highlight opportunities arising from the ubiquity of computing across modern research environments.

We respectfully submit the following observations, which address concerns raised in multiple topics in the RFI, but particularly those concerning Topic 1 "*The effectiveness of Federal scientific integrity policies in promoting trust in Federal science*," Topic 3 "*Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workplace*," and Topic 5 "*Other important aspects of scientific integrity and effective approaches to improving trust in Federal science*":

1. **Repeatability, reproducibility, and replicability of research: scientific results/data produced by computational artifacts.**

Virtually all of today's science – from life sciences to the physical, social, behavioral and economic sciences – relies upon computational artifacts. Computational artifacts are digital objects used or generated as part of a study or experiment. They can include: databases and spreadsheets that store data collected during an experiment; code to run experiments or simulations; code to produce visualizations of data; large datasets used to train machine learning algorithms; and scripts and software packages that are used to analyze results. Such digital artifacts create significant and multiple new challenges to repeating, reproducing, or replicating scientific results. For example, a 2017 study in the *Proceedings of the National Academy of Sciences* that attempted to reproduce the findings from a random sample of 204 scientific papers published in *Science* highlighted the extent of this problem. The study authors

were able to obtain the artifacts used from just 44 percent of the papers and could reproduce the findings from just 26 percent.¹

The computing research community has been confronting these issues for many years, and as technology has evolved, it has developed and refined best practices addressing many of them. These include guidance on ensuring reproducibility of results, including the use of source code and data repositories, software version control, recording random number seeds and run-time parameters, and the use of virtual machines and software containers (e.g., Docker). The ACM Task Force on Data, Software and Reproducibility is incentivizing reproducibility by introducing “Result and Artifact Review and Badging” for journal and refereed conference paper submissions.² This policy defines various badges that will be listed with ACM publications and in digital libraries to recognize papers that have been independently verified. Different badges are awarded for “Results Replicated,” “Results Reproduced,” “Artifacts Evaluated -- Functional”, “Artifacts Evaluated -- Reusable,” and “Artifacts Available.”

Specifically, we recommend that Federal science agencies: a) consider both cultural and technical obstacles to reproducibility when developing scientific integrity policies; b) recognize the ubiquity of digital artifacts across the sciences, and c) monitor and adopt procedures and policies used in computer science research, tracking changes that are necessitated by continuing technological advances.

2. Machine Learning contributes its own special challenges for reproducibility, explainability, and transparency of algorithms and datasets.

While Machine Learning (ML) has been incredibly useful for research and in enabling scientific discovery, its use also creates new challenges for maintaining scientific integrity. As applied, almost all applications of ML effectively function as a black boxes, providing no understandable, explainable or transparent results. Together these and other challenges to repeatability in ML threaten the integrity of research.

ML requires datasets to “train” models for the problems researchers hope to solve. But those training datasets are often proprietary and thus unavailable for reproducibility studies. Even when the data and algorithms are available, they often require exorbitant levels of computational resources to analyze that are not available to most researchers. This is a particular problem because datasets may have biases in them that are challenging to detect or verify without access to the data. The problem can be compounded by the fact that some biases are inherent in what often are considered to be best practices. For example, choosing the largest possible

¹ Importantly, prose descriptions of computational artifacts do not necessarily reflect what the associated code actually does when it is executed. Other examples of hurdles that can face researchers attempting to reproduce the computational work generated by other parties include: the rapidly declining lifespans of both software and hardware before they become obsolete often prevent repeating a calculation or rerunning code under the identical conditions that existed when an experiment was first conducted; data management plans may rely on assumptions that certain public repositories are permanent when they are not; documentation of software configurations, libraries, and experimental setups are often insufficient for an independent party to replicate; and results that depend on proprietary code that is not maintained, easily available, or inspectable.

² Boisvert, Ronald F., “Incentivizing Reproducibility,” *Communications of the ACM*, Vol. 59, No. 10., p5 <https://dl.acm.org/doi/pdf/10.1145/2994031>

dataset will inherently bias against groups underrepresented in the dataset.³ Further, the algorithms themselves used by the ML systems on the training data are also often proprietary, inhibiting the ability of others to inspect the code and understand how results are derived.

To successfully address challenges around ML and training data, it is critically important for the AI research community that key components of its recently released *20-Year Community Roadmap for Artificial Intelligence Research in the U.S.*⁴ be robustly supported. These elements must include, specifically: AI-Ready Data Repositories, AI Software and AI Integration Frameworks, an Open Knowledge Network, and AI Testbeds. Support also is vital to the basic research outlined in the AI Roadmap, and also for data collection, preparation, and maintenance activities that are conducted for the “common good” of the research community, but often do not receive the same degree of recognition (and hence are traditionally less incentivized) within the community. Federal agencies likewise should be encouraged to engage with the community to make their own data more available for AI and ML research.

With respect to the important issue of the privacy of personal and health-related information, the use of synthetic data in machine learning research appropriately is receiving increased attention given its potential to solve several key problems, including: the high cost of collecting and labeling very large datasets needed to train and test such algorithms: the inherent difficulty -- maybe even impossibility -- of safely anonymizing data so that sensitive personal details are never exposed; and, ultimately, the reproducibility of important categories of machine learning research.

These key problems must be solved for everyone to compete on a level playing field that is built on synthetic data protocols. At the same time, however, the usefulness of techniques developed with synthetic data hinges both on the quality of the simulation and the effectiveness of transfer learning (a branch of machine learning aimed at adapting concepts learned in one (artificial) situation to the real world with its real-world potential for unpredictability). This is an active area of research deserving of additional Federal support, along with theoretical techniques for privacy-preserving data mining, differential privacy, and secure multi-party computation.

There is also a need for hypothesis-driven research in ML. Current ML embeds many of the risks of data mining. Lack of integration of hypotheses and failure to seek root causes of failures exacerbate the risks of using ML in security- and safety-critical domains. Without hypothesis-driven research, systematic failures in data labeling may be impenetrable to analysis with data-only ML approaches.⁵

³ Bender, Emily M., et al. "On the Dangers of Stochastic Parrots: Can Language Models Be Too Big? 🦜." Proceedings of the 2021 ACM Conference on Fairness, Accountability, and Transparency. 2021.

⁴ Y. Gil and B. Selman. A 20-Year Community Roadmap for Artificial Intelligence Research in the US. Computing. Community Consortium (CCC) and Association for the Advancement of Artificial Intelligence (AAAI). Released August 6, 2019. p. 88-93. arXiv:1908.02624 <https://cra.org/ccc/wp-content/uploads/sites/2/2019/08/Community-Roadmap-for-AI-Research.pdf>

⁵ Moriano, P., Pendleton, J., Rich, S., & Camp, L. J. (2017, October). Insider threat event detection in user-system interactions. In Proceedings of the 2017 International Workshop on Managing Insider Security Threats (pp. 1-12).

3. The distribution of false, misleading, or inaccurate information with the intent to deceive is an existential threat to the United States.

Relevant to topic #4, *Effective policies and practices Federal agencies could adopt to improve the communication of science and technological information*, the spread of mis- and disinformation in the current media environment threatens to undo even the best efforts to communicate accurately about Federal science efforts. In a 2020 Quadrennial Paper⁶, CRA's Computing Community Consortium outlined the threat:

In the 21st Century information environment, adversarial actors use disinformation to manipulate public opinion. The distribution of false, misleading, or inaccurate information with the intent to deceive is an existential threat to the United States – distortion of information erodes trust in the socio-political institutions that are the fundamental fabric of democracy: legitimate news sources, scientists, experts, and even fellow citizens. As a result, it becomes difficult for society to come together within a shared reality; the common ground needed to function effectively as an economy and a nation.

Computing and communication technologies have facilitated the exchange of information at unprecedented speeds and scales. This has had countless benefits to society and the economy, but it has also played a fundamental role in the rising volume, variety, and velocity of disinformation. Technological advances have created new opportunities for manipulation, influence, and deceit. They have effectively lowered the barriers to reaching large audiences, diminishing the role of traditional mass media along with the editorial oversight they provided.

The digitization of information exchange, however, also makes the practices of disinformation detectable, the networks of influence discernable, and suspicious content characterizable. New tools and approaches must be developed to leverage these affordances to understand and address this growing challenge. Tools must be developed for security agencies, educators, journalists, civil society organizations, and citizens at large to make sense of, and counter, information pollution. These solutions must incorporate better understandings and models of the “demand side” of the disinformation ecosystem—the consumers of the content—as much as the detection, attribution and characterization efforts support recognition and interdiction on the “supply side,” where it originates. Development of such tools and approaches will require collaboration of computer and computational scientists with cognitive and social scientists to better understand this ecosystem and model vulnerabilities in a comprehensive way. As a research topic, the disinformation landscape is a socio-technical ecosystem; research approaches need to meet the new challenges of such a landscape, including adversarial actors and platform companies whose product decisions shape the nature of the threat and its diffusion. Critically, all disinformation solutions must respect ethical principles that balance the privacy and autonomy of individuals online with the societal benefits of understanding and mitigating the threat.

The Quadrennial Paper also delineates the research challenges that need to be addressed to mitigate the threat of mis- and dis-information and calls on Federal science agencies to help:

⁶ Bliss N., Bradley E., Garland J., Menczer F., Ruston S., Starbird K., & Wiggins C. (2020) An Agenda for Disinformation Research.
<https://cra.org/ccf/resources/ccf-led-whitepapers/#2020-quadrennial-papers>

- initiate dedicated interdisciplinary research programs at the National Science Foundation;
 - create public-private partnerships to support accessible research infrastructure;
 - foster cross-agency collaboration, especially between NSF, Department of Defense S&T, Department of Homeland Security S&T Directorate, and the Intelligence Community's S&T efforts, to support the transition of promising research outcomes and secure the integrity of the information ecosystem;
 - form cross-agency/cross sector partnerships -- with engagement from the media and industry, among others -- to support education and workforce training initiatives; and perhaps most crucial:
 - encourage active, transparent, and good faith participation of the platform companies, whose algorithms and product decisions shape the spread and amplification of disinformation online.
4. **Computational expertise is sorely lacking in most agencies not related to the military or intelligence communities.**

Computation and digital artifacts play an ever-increasing role in citizens' everyday lives, the routing business and government transactions, and both the civil and criminal justice systems. While the legislative branch has made significant strides to institutionalize and fund its consistent access to competent technical expertise, many federal agencies and the judicial branch, in particular, often still lack sufficient such expert input to conduct their mission with scientific integrity and assure the full and fair administrative and judicial process often required by law. Technical fellowship or liaison programs across government should thus be encouraged and supported to a substantial degree and as a high federal priority. Programs like the Jefferson Fellowship program at the Department of State, or the AAAS Science Policy Fellowships ought to be seen as exemplar efforts, broadened and increased, with a special focus on infusing computational expertise throughout government.

5. **The ACM Code of Ethics and Professional Conduct can provide SI-FTAC with useful input about inspiring and guiding ethical conduct across scientific disciplines beyond computing.**

Revised in 2018 after a three-year and highly collaborative international process, ACM's benchmark [Code of Ethics and Professional Conduct](#) (ACM Code) has guided the work of professionals in all aspects of computing for almost 75 years. Relevant to Topic 5 "*Other important aspects of scientific integrity and effective approaches to improving trust in Federal science,*" to the extent that ethical professional conduct in science (not simply in computing) will foster both integrity in its practice and public faith in scientifically grounded products and policy, ACM and CRA commend the ACM Code to SI-FTAC to be shared with all scientific professionals. It also may be productively "mined" in the context of this proceeding for fundamental precepts of general applicability and potential public benefit.

The Code's Preamble states in relevant part:

Designed to "inspire and guide the ethical conduct of all computing professionals . . . and anyone who uses computing technology in an impactful way. . . [t]he Code includes [25] principles formulated as statements of responsibility, based on the understanding that the public good is always the primary consideration. Each principle is supplemented by guidelines, which

provide explanations to assist computing professionals in understanding and applying the principle.” While “not an algorithm for solving ethical problems,” the Code “rather serves as a basis for ethical decision-making. . . . Questions related to these kinds of issues can best be answered by thoughtful consideration of the fundamental ethical principles, understanding that the public good is the paramount consideration. The entire computing profession benefits when the ethical decision-making process is accountable to and transparent to all stakeholders. Open discussions about ethical issues promote this accountability and transparency.”

CRA and ACM respectfully submit that the ACM Code, appropriately extrapolated from and used to inform targeted messaging to all scientific professionals can help SI-FTAC achieve its goals in this proceeding across all applicable scientific fields and endeavors.

ACM’s U.S. Technology Policy Committee and CRA, and their thousands of expert members, look forward to assisting the SI-FTAC and OSTP throughout their work on this crucial set of with any questions concerning these comments, or for assistance on any computing-related technical matter within the scope of this proceeding, or other matters with which ACM’s and CRA’s expert members may be of assistance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Nancy Amato". The signature is fluid and cursive, with the first name "Nancy" being more prominent than the last name "Amato".

Nancy Amato
Chair
Computing Research Association

A handwritten signature in black ink, appearing to read "Alec Yasinsac". The signature is cursive and somewhat stylized, with the first name "Alec" being more prominent than the last name "Yasinsac".

Alec Yasinsac
Vice Chair
ACM U.S. Technology Policy Committee

Scientific Integrity RFI Response

Response from the Texas Advanced Computing Center at the University of Texas at Austin

The USA has room for many diverse opinions. However, we do not have room for "alternate" facts. Policy debates cannot proceed in a meaningful way without some shared understanding of what constitutes fact, what constitutes evidence, and what constitutes conjecture.

In academia as with the US Government, ensuring that the public can trust information produced by our research -- whether they choose to agree with it or not -- is crucial to sustaining our mission and the role of science and the research university in our civilization.

We'd like to thank the committee for their critical work in this area, and respectfully request that their response consider scientific integrity not only within federal agencies, but from all entities receiving federal funds, including university sponsored research projects through grants and contracts with federal agencies.

From our perspective, the actual mechanisms to preserve the integrity of science are by and large effective. There are exceptions, of course, but most research is done to the highest standards and performed with integrity. Perhaps the largest failing is in the **perception** of the public regarding scientific integrity, and how the few exceptions to the rule, in conjunction with misinformation, have undermined public confidence.

As we make our recommendations, we also ask the committee to continue to be mindful of the burden any new regulations might place on researchers and carefully consider the impacts - though we all recognize more must be done, the administrative burden of research work is ever growing, and a fine balance must be sought.

We believe a positive step would be to pair any disclosure of fraud with a statement discussing how rare fraud is (e.g., pointing out that a fraud determination happened on 1 in X thousand grants for a given agency), and stating that exposing said fraud demonstrate the effectiveness of the measures to regulate and detect research. Perhaps a broader approach would be to publish with **any** research work broad statements about how the work was funded, that conflicts of interest have been vetted and reported, whether the work was peer-reviewed for both funding and publication, etc.

There have been extensive pushes at numerous agencies to make data publicly available, in support of reproducibility and transparency. While these efforts are laudable, the raw data is often voluminous and indecipherable to the lay public. While it should be made available, perhaps an accompanying statement explaining in lay terms the methodology by which it was collected, the confidence this creates in the data, etc. would make published results more difficult to refute.

We believe better messaging is needed about the scientific method and the research process. We all wish the public would have a better understanding of the checks and balances against fraud (and the rarity of it occurring), the true financial incentives researchers have or don't have, the fundamental difference between "fraud" and "error", the reasons different studies may produce different results, etc. We are mindful that the public is already bombarded by a cacophony of information, and a government sponsored literacy campaign may not be the best or only approach to accomplish this. However, some broader attempt at messaging is important, whether it is a public campaign, inclusion of more content on scientific integrity in coursework, targeted training for specific audiences, etc.

We also recommend that any such effort include some form of pushback against misinformation -- perhaps in the form of "consumer protection against misinformation", though we recommend this be structured as an independent watchdog, to avoid any perception of creating a "propaganda" office for science.

The public is one audience – scientific results must also be used effectively and responsibly when communicating with peers. Mathematical modeling and computational science are playing an increasing role in supporting critical decision-making across science, engineering, and society. Necessarily, decisions

are being made on predictions of the future using powerful simulation capabilities. In many cases, these predictions must go well beyond the available data. Quantifying the uncertainties associated with these predictions – due to unknown parameters, lack of scale resolution, missing phenomena, model-form uncertainty, and much more – is clearly essential, but is currently not an integral part of most simulation workflows. This challenge will become even more pressing as we see increased reliance on artificial intelligence (e.g., machine learning models) in support of critical decision-making. Research and development investments are needed across federal agencies to advance the theory, tools and practice of uncertainty quantification in simulation-based decision-making across the physical/natural sciences, medicine, geosciences, social sciences, and engineering. Establishing discipline-specific standards for what constitutes appropriate reporting of uncertainty – and how it is properly explained – will be critical.

Thank you again for your important work and consideration of the RFI Responses.

On behalf of the staff of the Texas Advanced Computing Center (TACC) at the University of Texas at Austin –

A handwritten signature in dark ink, appearing to read 'D. Stanzione', with a stylized flourish extending to the right.

Dan Stanzione, PhD
Associate Vice President for Research, UT-Austin
Executive Director, TACC

From: Agency for Healthcare Research and Quality Evidence-based Practice Centers (EPCs)
Respondent Type: Academic
Respondent Role: Researcher

Regarding: Request for Information to Improve Federal Scientific Integrity Policies; Response to Prompt #2: Good practices Federal agencies could adopt to improve scientific integrity, including in the communication of scientific information, addressing emerging technologies and evolving scientific practices, supporting professional development of Federal scientists, and promoting transparency in the implementation of agency scientific integrity policies.

July 28, 2021

This response is provided by the [Evidence-based Practice Centers](#) (EPCs), nine not-for-profit research centers designated by [the Agency for Healthcare Research and Quality](#) (AHRQ) that specialize in evidence synthesis. We wish to highlight AHRQ's leadership, since the establishment of the EPC Program in 1997, in addressing emerging technologies and evolving scientific practices, improving scientific integrity, and communicating scientific findings. AHRQ's work, through the EPCs, embodies these good practices. AHRQ's experience serves as a model for other Federal agencies to start, maintain, or enhance scientific integrity policies and processes.

Addressing emerging technologies and evolving scientific practices

Specifically, through the EPC program—a program dedicated to producing rigorous and comprehensive systematic reviews, (that is, reviews of the evidence using systematic and explicit methods to identify, choose, and critically appraise research relevant to specific questions) and other types of evidence syntheses for more than two decades—AHRQ has set a gold standard for addressing emerging technologies and evolving clinical practices in the United States. AHRQ-supported efforts assist public and private sector organizations in their efforts to improve the quality of healthcare in the United States and promote the well-being of patients and families. AHRQ-sponsored systematic reviews and technical briefs provide organizations with a comprehensive evaluation of the best and most up-to-date, science-based information on a range of medical conditions, from common conditions to rare diseases, and new healthcare technologies and strategies. The EPCs systematically and independently review the relevant scientific literature on topics initially proposed by the public, professional organizations, and other Federal agencies that are then transparently prioritized by AHRQ. We appraise the quality and integrity of the evidence, conduct meta-analyses (quantitative summaries) when appropriate, and provide evidence users with information to guide vital policy and practice decisions. Reviews conducted by EPCs [in response to COVID-19](#) exemplify AHRQ's approach.

Ensuring scientific integrity

In conducting this work, AHRQ ensures scientific integrity by requiring that EPCs:

- Disclose and mitigate potential conflicts of interest in investigative teams.
- Conduct comprehensive searches to identify all relevant research that answer research and policy questions, rather than cherry-pick studies that support a certain viewpoint.
- Use standardized approaches to assess the risk of bias in individual studies as well as the strength of the whole body of evidence.

- Respond to an extensive peer review and public comment.
- Identify methodological and substantive shortcomings in the evidence, so that subsequent research can address these shortcomings.

Additionally, AHRQ promotes scientific integrity by supporting research on complex methodologic and statistical issues. These projects improve the quality of systematic reviews, increase the usability and accessibility of research evidence, promote transparency in use of evidence in making decisions, and inform how future primary studies are designed, conducted, and executed to provide better evidence.

Communicating scientific findings

Systematic reviews, such as those supported by AHRQ, are essential for unbiased communication of scientific information. Information from new scientific studies needs to be communicated in the context of existing evidence and not in isolation as if a single study was the only one on the topic. This approach to communication and emphasis on the consideration of results across all available studies reduces the likelihood of misleading interpretation and spin.

Communication also requires engagement of key stakeholders to ensure that the evidence synthesis answers the right questions and is accessible to a wide audience. AHRQ engages routinely with a wide array of stakeholders, including the public, patients, clinicians and other healthcare providers, the private sector, professional societies, insurers, funders of research, and other Federal agencies. These communications occur at several stages, including when

- Generating and prioritizing topics for review
- Scoping each topic to best answer the most important decisional dilemmas
- Posting key questions to generate input from the public and relevant stakeholders
- Reviewing the draft systematic review
- Communicating findings to key end-users through presentations, publications, and other media outreach.

AHRQ also ensures accessibility to its products by requiring that EPC products are compliant with Section 508 of the Rehabilitation Act of 1973.

Policy and practice informed by research evidence has the potential to improve the quality of healthcare, inform the use of resources, and ultimately improve the health and well-being of individuals and communities. The AHRQ EPC program has an almost quarter century-long track record of promoting research integrity and accessibility while evolving to rise to many challenges, ranging from changing healthcare systems to addressing a global pandemic. AHRQ's long history of collaboration with other Federal agencies (such as the Centers for Disease Control and Prevention, the National Institutes of Health, and the Centers for Medicare and Medicaid Services) and partners (such as the Patient Centered Outcomes Research Institute, and professional societies) places the agency in an ideal position to lead the mission of improving scientific integrity across Federal entities.

Evidence-based Practice Centers:

- Brown University
- ECRI Institute–Penn Medicine

- Johns Hopkins University
- Kaiser Permanente
- Mayo Clinic
- University of Minnesota
- Pacific Northwest Evidence-based Practice Center
- RTI International—University of North Carolina at Chapel Hill
- Southern California/RAND

From: [Defino, Theresa](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Wednesday, July 28, 2021 2:21:01 PM

I am a journalist who has covered research integrity since 2006 and has been a reporter generally since 1982.

I urge greater transparency and consistency between how agencies deal with research integrity findings and disclosure. I.e., NSF should disclose the names and institution of those who have findings of research misconduct. HHS ORI publishes this information in the *Federal Register*. I have been told NSF follows federal privacy rules--surely HHS does as well. Federal agency officials also should be much more available to journalists to explain how misconduct is detected, managed and common problems that result in institutions making flawed investigations that do not result in findings. Institutions should also be required to publicly report their own findings and this should be expanded to broader areas including sexual harassment, not just fabrication, falsification and fabrication.

In a related matter, OLAW and USDA should resume the process of publicly reporting on AWA violations. These have not been available for many years.

Thank you.

Regards,
Theresa Defino
Editor
Report on Research Compliance
Report on Patient Privacy

Scientific Integrity Fast-Track Action Committee (SI-FTAC)
National Science and Technology Council
ScientificIntegrityRFI@ostp.eop.gov

July 28, 2021

Re: SI-FTAC RFI

To the members of the Scientific Integrity Fast-Track Action Committee:

On behalf of STM, which supports scholarly publishers in their mission to advance research worldwide, I write to share our support of your efforts to improve scientific integrity and evidence-based policymaking within the US government and beyond. Scientific and scholarly integrity is the foundation of progress across science, medicine, and scholarship and is a crucial contributor to better outcomes for the communities that STM and our member publishers serve. STM and our member publishers are committed to improvements and innovations in the communication of research reports and data, including through Open Science, that enhance research integrity, transparency, and impact.

Federal agencies could best promote scientific integrity by supporting the ongoing efforts of the academic community to enhance the peer review and communication of research findings, improve the quality of research data, and to collaborate on other initiatives that have the potential to improve quality, reproducibility, and replicability. Examples of these ongoing efforts are included in our recommendations in response to the prompts in the RFI.

1. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science:

Unfortunately, the current information environment is rife with misinformation. Even the scientific ecosystem has not been immune from confusion and misrepresentation despite its systems to advance transparency and integrity. The threat of fake science has a particularly dangerous impact on policy making and public health.

While some of the issues raised in this prompt are outside the scope of our members' activities, publishers significantly invest in tools and systems to detect and report on the suppression or distortion of findings and results, as well as the promotion of public understanding of the strengths and limitations of scientific reports. **We would welcome opportunities to partner with the government on initiatives to advance public understanding of science, that could contribute to more appropriate engagement with evidence-based policy from the public.** We and our members have supported organizations like Sense about Science (<https://senseaboutscienceusa.org/>) to promote such understanding and engagement of a democratic citizenry in the understanding of science, which we believe help overcome some of the public's concerns about scientific integrity within the government. There may be opportunities to highlight the difference between peer-reviewed, edited, and vetted information shared on publisher platforms and the unvalidated information often shared on other platforms, including those shared on social media. The quality assurance processes managed by publishers and represented by the

scholarly record is marked by the constant iterative testing and validation of research findings, which is relied upon by scientists and scholars to make advances.

We would also point the SI-FTAC to mechanisms being used by institutions to detect or deter potential violations of scientific integrity policies before they occur, that the Federal government may wish to review and endorse. These include technological tools and human systems to detect anomalies in data or image manipulation; rules and reporting requirements to avoid conflicts of interest; and Open Science practices that can help identify problems with methodology or data provenance. **We would be willing to share our insights with the government on the implementation of such tools and practices or to have further discussions with the committee on how best to approach these issues, consistent with community standards and practices.**

2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information:

The most important action that Federal agencies can take to ensure quality and integrity in the communication of scientific and technological information (STI) is to **support and encourage the systems and services that currently exist for providing quality and integrity in scholarly communication for all engaged in the research enterprise.** These include, but are not limited to, market incentives that encourage the development of high-quality publication outlets for scholarly communication such as those produced by STM's members.

In addition, the government should ensure that adequate funding is provided to support the development of tools and outlets for the sharing of research data, the communication of research methods, and other outputs related to research that could improve quality, integrity, and transparency in the research system (including for the time and expertise needed for researchers to appropriately curate and share those research artifacts). Such investments will improve public trust in science and scholarly communication. Publishers continually invest in the systems and infrastructure linked to the reproduction and replication of research and promulgate policies that ensure open sharing to promote trust. This includes efforts to promote trust and transparency through the sharing of research data (i.e. STM's [Research Data initiative](#)) and especially the use of FAIR principles (i.e. <https://www.force11.org/group/fairgroup/fairprinciples>) in sharing research data. Federal agencies should align their STI sharing along with those in the publishing community and utilize sharing vehicles such as scholarly journals and peer-review practices developed in the publishing community.

Finally, to ensure that there is a clear audit trail for the products and producers of research, and to foster trust, the use of **persistent identifiers** should be made more widespread, not only for STI but for funding agencies, grant awards, facilities, and the like. Agencies could use existing standards and systems as well as work with stakeholders to create these where they do not exist, providing funding for their creation and registration. Publishers already invest heavily in creating persistent identifiers and machine-readable metadata that promote greater visibility of research findings and data, and these help to promote trust, reliability, and transparency for the scientific system.

3. Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce:

Federal agencies should leverage and build on efforts already underway in scientific communities to promote responsible, trusted science. Many institutions and publishers offer training and resources directly related to ethical standards to researchers, peer reviewers and editors. In addition, most publishers have developed guidance and training for researchers on how to publish their research findings in a responsible way. These guidelines typically cover practices related to replicability and reproducibility, such as ensuring that data produced adheres to the FAIR principles. Most publishers ask authors to disclose conflicts of interest when submitting their articles for consideration and to confirm that they have followed the appropriate ethical guidelines. **Similar guidance could be applied to government researchers and others who are providing scientific advice or applying evidence to policy.**

Overall, more support for education and training in scientific practices is needed. This professional development should cover methodological training, as well as education around statistical analysis, tools and limitations (including limitations of the p value) and training on open research practices. It could also include **the use of reporting checklists** and methodology annexes in reporting on science used by Federal agencies to enhance public trust in such reports. The UK Pre-registration network has a series of useful primers covering various aspects of “open and reproducible scholarship” that provides an example of this approach.

To leverage efforts that institutions and publishers have already put in place, Federal agencies should consider the following recommendations:

- A. **provide support for training and education around the responsible conduct of research (RCR).** This includes managing conflicts of interest, ensuring ethical practices have been adhered to, etc. The [Helsinki declaration](#) has been a powerful vehicle in ensuring adherence to ethical standards in medical fields and Federal agencies may wish to expand the remit of the declaration, or to adopt its principles;
- B. **include reporting guidelines** (aimed at standardizing reporting on different study designs and advocating best practice) in government STI. These guidelines can be a means to encourage ethical conduct in research; and
- C. **support the development of tools, standards and best practice** that promote the responsible conduct of research and research reports.

Publishers and service providers invest heavily in tools to reduce fraud and ensure integrity in the scholarly record, such as those that help to highlight cases of plagiarism, image manipulation, and potential misconduct. These include tools such as Crossref's [Ithenticate](#) service which checks the contents of an article against a global database of content and highlights where text has been copied from another source. **STM would be happy to share our experience with these tools and to discuss how they might be effectively applied in the Federal setting to advance responsible research conduct.**

4. Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices:

It is important to educate not only scientific staff, but anyone who uses science in their work and decision-making, about the importance of scientific integrity and markers of trust in the scientific and scholarly works upon which they may rely in their work. The recommendations below are related to both the practice of government science and the use of scientific and scholarly outputs.

- A. Consider creating an **inventory of external initiatives** and **identifying key community-based efforts for federal endorsement or support**.

Some potential examples include [a manifesto for reproducible science](#) designed to optimize key elements of the scientific process and “[STAR Methods: Structured, Transparent, Accessible Reporting](#),” designed to provide a structure for experimental methods that increases reproducibility.

- B. **Ensure that Federal agencies understand the provenance of research and the importance of peer-review and reliable publishing outlets.**

As research reports and data appear in more and more publications and other outlets and in various forms (pre-prints, pre-registered studies, open research notebooks, etc.), it is critical that users of these reports understand the reliability and status of these different types of communications. Information that appears, or even more dangerously might wrongly give the impression of being an authoritative report, without proper peer review can compromise the integrity of the scientific record if not fully understood. Pre-prints, while a valuable part of the scholarly communication, should be used with caution and clearly identified appropriately when cited.

So-called ‘predatory’ journals present a different threat. Publishers, working with the Committee on Publication Ethics (COPE), industry bodies, and advocacy groups developed the [Think. Check. Submit. Initiative](#), offering guidance around how to identify a reliable publication outlet. Similarly, existing and emerging threats to the integrity of the scholarly record (e.g., paper mills, citation rings, duplicate submissions, plagiarism, etc.) need to be understood, educated about, and addressed. Publishers can share their expertise towards the identification and prevention of such practices.

Most importantly, federal agencies need to understand the value of a strong, sustainable system of publishing and scholarly communication in the advancement of science and assurance of integrity and trust in reported scientific information. This includes the centrality of the version of record as a permanent record that can be relied upon by researchers, practitioners, and the general public. Federal agencies must ensure that policies – whether related to scientific integrity or other goals – continues to enable publishing organizations to provide these irreplaceable services to science and society.

In addition, new efforts are needed to promote peer review and the validation of shared data, code, and other research artefacts. Publishers stand ready to work with the government on such initiatives.

- C. **Learn from existing and developing peer review mechanisms** to ensure scientific information is used and communicated with integrity.

Publishers make a major contribution to research integrity through their significant investments and expertise in organizing and providing the infrastructure for peer review, amongst other things. This is a major enterprise; in 2016, publishers facilitated 13.7 million reviews to support the quality assessment, improvement and publication of 2.9 million articles.¹ Publishers also encourage equity and diversity in the research enterprise by providing an objective space in which work can be assessed by peers and are proactively driving further change through initiatives like the joint commitment on inclusion and diversity (e.g. by anonymising the names of both authors and reviewers; by developing guidelines around the peer review of articles and data, etc.).

The government could utilise such systems for the review of government science and evidence used in policymaking and learn from existing and emerging approaches to review. Current efforts include:

- open peer review, which promotes even greater transparency into the scientific process;²
- peer review taxonomies (see [here](#)), which allow for standardization of review processes across institutions, publishers, and funders;
- the appropriate use of preprint servers which allow the public to provide feedback on communications before they are finalized and become a fixed version of record; and
- utilizing [registered reports](#), in which researchers outline their proposed study, methods and hypothesis. Use of such pre-registration of research studies allows for comment on, and improvement to, the proposed study design before it is carried out.

D. **Conflict-of-interest training**

Publishers have valuable expertise in providing training, resources, and guidance to researchers at the publication stage regarding conflicts that might be of use to Federal agencies. Many publishers have implemented their own disclosure requirements, which may or may not be aligned with individual Federal agency financial conflict of interest (FCOI) regulations and policies. Having clear and uniform definitions and requirements would be helpful to socialize and align disclosure processes across the research ecosystem, including within journal policies. **Publishers welcome additional conversations about how we can work with Federal agencies to align reporting on conflicts of interest and minimize the administrative burden.**

¹ According to a [2018 study by Publons](#)

² See, for example, <https://www.elsevier.com/connect/reviewers-update/lifting-the-lid-on-publishing-peer-review-reports-an-interview-with-bahar-mehmani-and-flaminio-squazzoni> for a discussion of some of the impacts of these experiments.

In addition, there are opportunities to use tools to assist with identifying and avoiding conflict of interest. For example, [Elsevier's Expert Lookup](#) can be used to search for experts in specific fields to identify potential conflicts of interest around co-authorship and funding streams.

E. Use caution, and leverage expert advice, where discussing or using new technological developments:

Technology is developing faster than our understanding of its limitations and how best to apply it. Artificial Intelligence (AI) is one example. Although new tools and services are being created daily, the legal and social frameworks which ensure that they are used and applied with integrity are still nascent. STM recently issued a [white paper on ethics in AI](#) which addresses some of the challenges of trust and integrity in this developing area. Federal scientists and policymakers should be sure to consult the latest expert advice (including, e.g., National Academies reports) to better understand the broader context of new tools and technologies.

5. Other important aspects of scientific integrity and effective approaches to improving trust in Federal science:

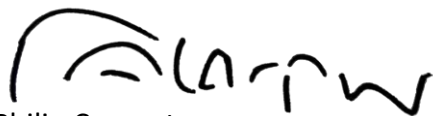
The mission of publishers is to advance trusted communications about research findings. We are committed to ensuring that the great discoveries of our time are communicated with accuracy, clarity and integrity. Together with partners across the research community, we work to develop and implement practices and standards that ensure the quality and integrity of the research enterprise. We therefore are keenly interested in working with the federal government to ensure scientific integrity. We are excited to share our perspectives and resources both for improving the accuracy and validity of the scholarly record and for educating practitioners and users of reports about research to ensure that the communication of findings is done with integrity and its impact and limitations are understood.

Publishers sit at the interface between researchers and clinicians, their articles and the rest of the world. STM and its members, together with others in the academic community, always put quality and integrity at the center of our work. Publishers serve an important role in validating and disseminating scientific reports about research findings, ensuring that they are accessible and discoverable, curating publications and related data in perpetuity and preserving the scholarly record. As independent bodies, and in many cases as the leaders in specific fields, publishers provide trusted information to users, and maintain the high standards of quality and reliability of scientific articles and related data. A sustainable system of scholarly communication, including ensuring a healthy and well-functioning publishing marketplace, is therefore essential for promoting scientific integrity in the government and beyond.

Publishers are actively working on cross-industry standards, best practices and solutions that have the potential to improve reproducibility and replicability, alongside the integrity of the scholarly record. We welcome engagement with the whole research community, including Federal agencies, to invest in and collaborate on these activities.

Publishers already partner with the Federal government to promote scientific integrity through the publication of high-quality, peer-reviewed articles that report on research that is conducted by government scientists, funded by Federal agencies, and/or relied upon by Federal policymakers. We look forward to continuing to work together to enhance not only scientific integrity but public trust in science.

Very truly yours,

A handwritten signature in black ink, appearing to read "Philip Carpenter". The signature is fluid and cursive, with the first name "Philip" being more legible than the last name "Carpenter".

Philip Carpenter
CEO

About STM

At STM we support our members in their mission to advance trusted research worldwide. Our more than 140 members collectively publish 66% of all journal articles and tens of thousands of monographs and reference works. As academic and professional publishers, learned societies, university presses, start-ups and established players, we work together to serve society by developing standards and technology to ensure research is of high quality, trustworthy and easy to access. We promote the contribution that publishers make to innovation, openness and the sharing of knowledge and embrace change to support the growth and sustainability of the research ecosystem. As a common good, we provide data and analysis for all involved in the global activity of research.

The majority of our members are small businesses and not-for-profit organizations, who represent tens of thousands of publishing employees, editors, reviewers, researchers, authors, readers, and other professionals across the United States and world who regularly contribute to the advancement of science, learning, culture and innovation throughout the nation. They comprise the bulk of a \$25 billion publishing industry that contributes significantly to the U.S. economy and enhances the U.S. balance of trade.

From: [David Parsons](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Wednesday, July 28, 2021 2:28:03 PM

EXECUTIVE OFFICE OF THE PRESIDENT

Request for Information To Improve Federal Scientific Integrity Policies

AGENCY: White House Office of Science and Technology Policy.

ACTION: Notice of request for information.

Re: SI-FTAC RFI

July 28, 2021

COMMENTS ON FEDERAL SCIENTIFIC INTEGRITY POLICY REVIEW

Submitted by: David Parsons

I served as a federal wildlife biologist (MS Wildlife Ecology) for 25 years. The last 24 years were with the US Fish and Wildlife Service (USFWS). When I began my career in 1974, agency scientists and their scientific work were generally respected and expected to apply best science in support of the USFWS mission. We authored our reports and were not asked to change results based on political pressure. That independence began to change with the Reagan Administration and the creeping politicizing of agency appointments down the chain of command to regional and state director positions. The repression of scientists and suppression of sound science persisted post-Reagan, and was especially egregious by the end of the Trump Administration.

I was the first Mexican Wolf Recovery Coordinator for the USFWS from 1990-1999, and I experienced political interference first-hand. Our science-based assessments showed that large Southwestern national forests were the most appropriate area to reintroduce and recover the critically endangered Mexican gray wolf. They had the best and most extensive habitats. But my Regional Director twice gave me verbal orders to find a way to make the White Sands Missile Range in southern NM emerge as the “preferred alternative” for the reintroduction project. Our evaluation showed that the missile range would not support sustained recovery of Mexican wolves. I learned later that the Regional Director and preceding Regional Directors had made promises to state wildlife agency directors of NM, AZ, and TX that the reintroduction of Mexican gray wolves would occur on the missile range (DOD property). Our team stuck to the best science, and Interior Secretary Babbitt ultimately approved our science-based decision over the objection of the USFWS Acting Director, John Rogers. Prior to his assignment as Acting USFWS Director, Rogers was the Southwest Regional Director who ordered me to recommend the missile range as the best site. I received a thorough chewing out from him immediately prior to the briefing of Secretary Babbitt. I also enjoyed a surprise early retirement from USFWS in 1999 at the age of 51. Stories like this, with worse outcomes for maligned agency scientists, are commonplace over the past 3 decades.

In 2014-2016, I worked with a team of independent scientists and the Union of Concerned Scientists on a successful effort to improve scientific integrity and especially the independent

peer review process within the USFWS. New policies were adopted to require independent peer reviews of controversial projects like wolf recovery. I am familiar with several independent peer reviews for policy decisions relating to both gray wolf and Mexican gray wolf decisions made under the ESA, which requires decisions to be made solely on the basis of “best science.”

Those peer reviews were almost universally critical of the agency’s “science” and some reviews clearly stated that best science was not used by the agency. However, I have yet to see a substantive revision of a proposed agency regulation or policy decision based on peer review. The independent reviewers’ findings/comments/suggestions are almost universally rejected and ignored by the agency. This renders the peer review process a complete sham. For independent/academic scientists, an adverse peer review prevents the publication of bad science. This should be the consequence of agency peer review processes – the prevention of bad policy. But agencies retain the prerogative of basing policy decisions on flawed science and/or for politically motivated reasons. When USFWS issued a proposed rule for Mexican wolf recovery, which misinterpreted some peer-reviewed scientific papers, the authors of those papers advised the agency in a letter that their findings had been misinterpreted and misapplied in a way that rendered the proposed rule insufficient to recover Mexican wolves. Nevertheless, the USFWS issued the final rule without correcting the misinterpretation. This happened under the Obama Administration.

Of course, this is the fodder for litigation by conservation organizations, which, too often, is the solution of last resort. Regarding the situation described above, the court ruled that the USFWS failed to use best science and that the revised regulation would not lead to recovery of Mexican gray wolves. USFWS is now revising the rule to comply with the court order.

In my 30-year experience with Mexican wolf recovery under the ESA, no substantive decision to move the trajectory of recovery in a positive direction (including initiation of the recovery program in the first place) was made by the agency without the threat/force of litigation. The pressure on federal decision makers to make unscientific, politically motivated decisions nearly always came from the states, either directly from wildlife agency officials or indirectly through elected officials with which state officials have undue influence.

This dynamic has led to one of my greatest frustrations as a retired federal scientist. That is, the conservation community, with which I now actively associate, is virtually the only public constituency which supports the USFWS’s (and other federal resource agencies) conservation missions, but the conservation community is almost universally despised by the agencies charged with protecting natural resources. A simplified explanation is that the conservation community is despised primarily because we resort to litigation to right agency wrongs when we have exhausted all other mainstream strategies through traditional administrative processes. The reason so many environmental lawsuits are filed is because the agencies are not following environmental laws. The conservation community and independent/academic scientists should be embraced as trusted consultants and advocates for science-based policy and decision making by resource agencies. Yet, we most often see hostility, and observe the agencies embracing constituencies which are hostile to their conservation missions – these are primarily proponents of extractive industries.

I applaud the Biden Administration for establishing the Scientific Integrity Task Force. I hope your deliberations are productive in establishing forceful policies and procedures to ensure that, where science matters or is required by law, public policies and decisions reflect thorough consideration of the best available science; and are not rendered unscientific due to

political pressure or meddling in the process.

Respectfully Submitted,

David Parsons, MS

Wildlife Biologist

US Fish and Wildlife Service – Retired

Science Advisor

Project Coyote (projectcoyote.org)

Carnivore Conservation Biologist

The Rewilding Institute (rewilding.org)

28 July 2021

American Geophysical Union input on Improving Federal Scientific Integrity Policies

Introduction

The American Geophysical Union (AGU) is pleased to submit this RFI response to 2021-13640 on improving federal scientific integrity policies. AGU is the largest global organization covering the Earth sciences with a mission “to support and inspire a global community of individuals and organizations interested in advancing discovery in Earth and space sciences and its benefit for humanity and the environment.” Fostering integrity is a key part of our new strategic plan and past activities and we are engaged in supporting integrity broadly, including with federal agencies. Although not a focus of these recommendations, AGU has often spoken up through position statements and letters related to scientific integrity. Several examples are listed in the references.

With this perspective, we urge OSTP to consider two points that we elaborate below:

- Fostering integrity--and in turn public trust in science and science policy--requires a broad, holistic view of practices that extend beyond the typical focus on transparency and ethics to include ensuring deeper public engagement, addressing diversity and inclusivity in science and supporting the backbone infrastructure that enables all of these.
- The way science is supported, practiced and conducted is changing significantly, as is its dissemination and communication, and these changes have important implications for fostering integrity in the 21st century. Specifically, parts of the culture and reward system of science need improvement to align with these changes, and OSTP and federal policy can be a strong proactive force in enabling this change. This is particularly the case if these policies and practices provide leading examples and extend to federal grants. Many other organizations would then align.

Science is embedded in and critical for nearly every major societal challenge in the 21st century, such as the current COVID-19 pandemic - which is illustrating challenges to integrity and public trust in science, all aspects of planetary sustainability, climate change, resource management, food, energy and water availability for a global population, health outcomes and more. These challenges are all transdisciplinary and require trust in science and engagement among a broad coalition of diverse communities and stakeholders. The practice of science is changing to support these needs (although not as fast as is needed given the urgency of these issues). Research is increasingly done by diverse, international teams crossing traditional disciplines. Data interoperability from new distributed instruments and sensors and processed through machine learning is growing rapidly. Information is being utilized by diverse communities who are also contributing to and co-producing science. Even the way science is communicated is changing; with fewer science journalists and more public information officers, direct and deeper public engagement is increasingly important and necessary.

Success in addressing our societal challenges requires thinking about integrity in science in broader and different ways than have traditionally been considered to build for the future. Specifically, while individual responsibility and ethical practices are important, new institutional leadership is most needed. In addition to promoting transparency, access, replicability and the ability for scientists to communicate openly, fostering integrity in science in the 21st century also requires:

1. An infrastructure to support integrity, especially around quality, machine readable and auditable FAIR data and software (The FAIR Guiding Principles for scientific data management and stewardship <https://www.nature.com/articles/sdata201618> and <https://www.go-fair.org/fair-principles/>);
2. Inclusivity and diversity, to expand perspectives and enrich science and build broad trust in its value and communication;
3. Engagement that builds trust with diverse communities globally and creates opportunities for all communities to participate in, guide, apply and benefit from science, which also enhances resilience, sustainability, improved health and equity; and
4. A culture and reward system that supports these goals.

OSTP and federal science agencies have an opportunity to lead and shape this broader perspective of science integrity for the future. AGU and other societies can be key partners.

Below we provide specific areas where federal practices can lead and incentivize important aspects of integrity and how partnerships with societies are important. Several of these emphasize recommendations in the recent National Academies Report *Fostering Integrity in Research* (<https://www.nap.edu/catalog/21896/fostering-integrity-in-research>) and in a recent book, *Scientific Integrity and Ethics in the Geosciences* (<https://agupubs.onlinelibrary.wiley.com/doi/book/10.1002/9781119067825>), but several go beyond these.

1. FAIR Data and Software

FAIR data and software across science provides integrity for published research and promotes new science, while building trust with local and global communities who increasingly use it for decision making. Although there is wide recognition of the need for FAIR data and software, specific incentives, practices and particularly investment are required to accelerate more widespread implementation. Specifically, to implement well-curated FAIR data and software, the following needs to happen:

First, federal policies and practices that require federally funded researchers to practice good data and software management that result in FAIR data are needed. Publishers are beginning to direct associated data and software to repositories that enable FAIR practices and require researchers to share and eliminate data supplements. For example, AGU has helped lead an initiative, the Enabling Fair Data Project (<http://www.copdess.org/enabling-fair-data-project/>) and developed a set of commitment tenets that many Earth, space and environmental

publishers have signed onto <http://www.copdess.org/enabling-fair-data-project/commitment-to-enabling-fair-data-in-the-earth-space-and-environmental-sciences/>. Beyond the Earth, space and environmental sciences, publishers have committed to improving data and software availability and citations through efforts from FORCE11, TOP Guidelines and other initiatives.

Even with the good intentions of requiring data to be preserved in a repository that is FAIR-aligned, however, many publishers across all disciplines are making slow progress on their commitment. In addition to specific federal mandates for good data and software management, it would also be valuable for federal agencies to provide incentives for researchers to select journals that align with these expectations as well as participate in roles serving as reviewers, co-authors, editors and in their societies, promoting that data and software be shared and cited.

Second, financial and organizational support is needed for leading domain repositories and efforts enabling real data interoperability. Domain repositories have staff skilled in curation and working with researchers on data management practices that simplify data discovery and reuse and support FAIR data and software. Quality curation and robust metadata in turn enable interoperability. Domain repositories also help set best practices around what parts of large or processed data and model output can and should be preserved. Many repositories support data deposition throughout the research cycle, creating a community of practice around data stewardship where publication is just one outcome. Most domain repositories are federally supported but not at a sustained level and would benefit from expanded support and improved coordination across the repository landscape.

Substantial directed funding and collaboration are also needed to encourage alliances between institutional repositories, whose curation services vary, and domain repositories. Such alliances could be mutually supportive; institutions could provide support to leading domain repositories who could then support their FAIR data needs more efficiently. One example is the Woods Hole Oceanographic Institution's support of the Biological Chemical Oceanographic Data Management Office (BCO-DMO). Support will also be important for related organizations—such as Research Data Alliance, FORCE11 and Earth Science Information Partners, among others—that ensure best practices and develop interoperability between research data and software services. In addition, because not all types of data have a repository home, new repositories will need to be started.

Third, researchers and their institutions need stronger incentives to practice FAIR data management and the federal grant process is a key lever. Many grant programs now require data management plans (DMP's), but such requirements should be expanded to mandate best practices and indicate that appropriate repositories have been consulted. To be specific, where “intellectual merit” is emphasized over reproducible outcomes (see guidelines, including for reviewers at NIH and NSF), we recommend extending or changing the “intellectual

merit” statement to include or become a broader “outcome” statement. An example would be: “Please indicate how this proposed research will advance science, provide tangible outcomes such as data, software, methods, and/or samples that will be shared using best practices, and provide societal impact. Reference your data management plan and broader impact statements directly.” This type of statement in conjunction with review and funding requirements would elevate data curation as a necessary practice, and emphasize the value of tangible outcomes for researchers, their institutions and reviewer. These reforms would incentivize recommendations in the recent National Academy reports *Open Science by Design* (<https://www.nap.edu/catalog/25116/open-science-by-design-realizing-a-vision-for-21st-century>) and *Reproducibility and Replicability in Science* (<https://www.nap.edu/catalog/25303/reproducibility-and-replicability-in-science>).

Finally, guidelines—including for repositories— need to be aligned with the reality that science teams and data increasingly span institutions, agencies and countries—again a reason for diverse institutions and agencies to support domain repositories.

2. Diversity, Equity and Inclusivity

The U.S. science workforce, including at the federal agencies, is not diverse. Expanding diversity and inclusivity in the science workforce at all levels is critical both to produce better science and to enhance integrity and public trust in science. A diverse and inclusive workforce improves both communication with the public and co-creation and engagement of communities in science; both engender trust in science. In turn, this trust and expanded awareness of science will attract interest in science from a broader pool of people, leading to greater diversity in science. Promoting and increasing diversity and inclusivity should thus be key parts of federal practices promoting integrity. It is our premise that excellence and integrity in science are not achievable without attention to inclusion.

Visible federal science leadership in diversity and inclusivity, tied to integrity, would send a strong signal to other stakeholders, such as universities and private research groups, to establish new norms. Federal guidance can also be extended and provided through grant programs. For example, AGU’s new LANDInG program, funded by the National Science Foundation, is aimed at empowering key leaders with the skills and resources needed to enact diversity practices at institutions, including agencies (<https://www.agu.org/AGU-LANDInG>). AGU and other societies have also helped form a consortium aimed at addressing harassment and bias in science (<https://societiesconsortium.com/>). These groups would be thrilled to partner further with federal agencies to expand these efforts.

3. Community Science and Engagement

The need to apply science to global challenges is critical. However, the use and benefits of science are not distributed widely or equitably across communities in the U.S. or globally. As such, there is an urgent need to

expand community-led initiatives that use science to address regional and local problems. Federal agencies are in a position to lead on these goals and build scientific integrity and trust in science by incentivizing community engagement and community science.

Several specific recommendations and opportunities are included in recent reports by societies, including from AGU (<https://www.essoar.org/doi/abs/10.1002/essoar.10507256.2>), to the National Science Foundation on supporting climate change solutions (<https://fromtheprow.agu.org/agu-community-provides-recommendations-and-ideas-for-implementing-climate-change-solutions-to-nsf/>). For example, among the recommendations are for federal agencies to develop grant programs to incentivize co-creation of science and deeper engagement with communities and for the creation of and/or support for a climate science corps and regional climate change solution centers. The federal workforce could be engaged in all these steps, which would serve to enhance inclusivity and diversity in science and help address inequities in access and resources, improving overall resilience.

AGU has developed a program around community science, the Thriving Earth Exchange (<https://thrivingearthexchange.org/>), that, in partnership with other societies and organizations, helps match science expertise with communities to address their unique needs. Working with community leaders, the Thriving Earth Exchange board found that expanding the concept of scientific integrity to include equitable and ethical engagement with community partners has been instrumental in achieving successful outcomes in these communities. This approach is captured in the “principles for integrity in community science” (<https://thrivingearthexchange.org/wp-content/uploads/2018/02/TEX-Statement-on-Integrity-in-Community-Science-05022018.pdf>) that the board has developed, adopted and shared. The National Park Service is already working with the Thriving Earth Exchange to train and mentor Park Service employees as they lead community science projects in their region.

The Thriving Earth Exchange, as well as a related AGU effort, Voices for Science (<https://www.agu.org/Share-and-Advocate/Share/Sharing-science-network/Voices-for-science>), are providing enormous benefits to communities and helping increase awareness of and engagement with science. Voices for Science offers mentorship and training to scientists looking to engage more deeply with their policymakers and their communities. These are examples of programs and practices that increase trust in science and foster integrity that could be scaled and expanded for greater impact. AGU and other societies will soon launch *Community Science*, a platform for sharing data from community science projects aimed at amplifying these efforts, developing a community of practice to empower the co-development of science with communities and providing connections for meaningful public science policy.

4. Reward and Incentives and a Culture for Integrity

Incentivizing integrity broadly in these ways requires a culture and career paths that reward these behaviors. Providing direction through federal grants, agency practices and programs are important ways for leading this reform. Aligning federal science hiring and promotion guidance toward these goals, as well as to promote team-oriented and convergent science, would also send a strong signal about the importance this Administration and the federal government places on scientific integrity.

Collaboration with Scientific Societies

AGU and other scientific societies are integral partners for the federal government in fostering culture change that supports open science, integrity and trust. Society groups have long benefited from supporting integrity in science and have a vested interest in supporting programs in these broader aspects around integrity, including in promoting diversity, workforce development, and community engagement and communication.

Societies encourage open science in various ways, including opening meeting content, hosting preprint servers, leading in expanding diversity and inclusion in science, addressing harassment, fostering community engagement and supporting FAIR data standards.

Many societies are also leading publishers with a mission of advancing their science and fostering quality and transparency. AGU and other societies are supportive of expanding open-access publishing—in the standard open-access publishing model, integrity is tested directly because there is a direct payment for publication. Societies have a vested mission in quality and open governance and oversight that can help assure accountability and broad and equitable participation globally in this model of open access (see *The New Landscape of Ethics and Integrity in Scholarly Publishing* <https://agupubs.onlinelibrary.wiley.com/doi/abs/10.1002/9781119067825.ch8>). Many are engaged in promoting quality science communication.

AGU and other societies are also key in disseminating leading practices around integrity to the scientific community, in part through meetings and conferences that offer opportunities for networking, learning and sharing. The federal workforce is part of this community, as many federal researchers are members of multiple societies. Further, many early career scientists, who participate actively in science societies, will likely work at or with federal agencies, through meetings, workshops and direct training.

In sum, ensuring and promoting integrity and trust for science in the 21st Century requires a broader approach to the issue than has been previously recognized. It requires a renewed commitment to ethics and professionalism for scientists and agencies, but it also requires a recognition for how science is already changing and needs to progress further. Only this type of broad view can get at the larger issues of societal trust in science and to help science live up to its promise of addressing some of our most pressing societal challenges. AGU is eager to be a

partner in these efforts, and we look forward to continuing to work with OSTP and the agencies on this important initiative.

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Additional Resources

- AGU Strategic Plan https://news.agu.org/files/2020/05/Final_AGU_Strategic_Plan_2020_Final.pdf
- AGU Position Statement on Data
https://www.agu.org/Share-and-Advocate/Share/Polymakers/Position-Statements/Position_Data
- AGU Position statement on Free Communication of Research <https://www.agu.org/Share-and-Advocate/Share/Polymakers/Position-Statements/Free-and-open-science>
- AGU Position Statement on Rights and Responsibilities of scientists <https://www.agu.org/Share-and-Advocate/Share/Polymakers/Position-Statements/Rights-and-responsibilities-of-scientists>
- Other recent letters and policy statements related to integrity and trust:
 - Coalition Letter on Whistleblower protection
<https://whistleblower.org/wp-content/uploads/2021/04/GAP-264-Organizations-Whistleblower-Support-Letter-1.pdf>
 - Letters on EPA's Science Transparency Rule
 - <https://whistleblower.org/wp-content/uploads/2021/04/GAP-264-Organizations-Whistleblower-Support-Letter-1.pdf>
 - <https://www.agu.org/-/media/Files/Share-and-Advocate-for-Science/Letters/2020-Letters/AGUJointLetterMichaelJFoxEPAHouseScience111319.pdf>
 - <https://www.agu.org/-/media/Files/Share-and-Advocate-for-Science/Letters/AGU-Letter-EPA-Secret-Science-23-Apr-2018.pdf>
 - HONEST ACT – Letter of Concern
<https://www.agu.org/-/media/Files/Share-and-Advocate-for-Science/Letters/AGU-Letter-HONEST-Act-8-Mar-2017.pdf>

July 28, 2021

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Re: Docket No. OSTP 2021-13640 - Request for Information To Improve Federal Scientific Integrity Policies

Introduction

The Brennan Center for Justice at NYU School of Law submits this comment to the Office of Science and Technology Policy (OSTP).ⁱ

Episodes of political interference in the last several presidential administrations demonstrate the need for clear scientific integrity standards, procedures, and effective enforcement and accountability mechanisms at agencies across the federal government.ⁱⁱ Building on President Obama’s 2009 scientific integrity memorandumⁱⁱⁱ and former OSTP Director John Holdren’s 2010 memorandum providing guidance to agencies for the adoption of scientific integrity policies,^{iv} President Biden’s January 27, 2021 Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking states that it is the policy of his administration to make evidence-based decisions guided by the best available science and data and calls for swift action to ensure “scientific findings should never be distorted or influenced by political considerations.”^v

The Covid-19 pandemic has made clear the critical role that science, data, and expertise must play in federal policymaking and the need to protect against undue political manipulation. The Brennan Center documented numerous improper political interventions to suppress and manipulate government research and data, as well as to intimidate and muzzle government experts, especially during the first several months of the pandemic.^{vi} Even before the pandemic, politicization of government research and data had reached a crisis point, hampering effective policymaking and eroding public trust in government.^{vii}

Scientific integrity policies are a critical tool to safeguard against political interference and ensure that expertise plays a role in the policymaking process. This proved true, for example, in the wake of “Sharpiegate,” when, following President Trump’s repeated false claims that a hurricane would hit Alabama, the acting White House chief of staff instructed the secretary of commerce to have the National Oceanographic and Atmospheric Administration (NOAA) publicly disavow an earlier statement by NOAA’s National Weather Service (NWS) clarifying that Alabama was not in the storm’s path, and the secretary of commerce reportedly threatened to

fire top NOAA employees if they did not repudiate NWS's statement.^{viii} NOAA subsequently led an investigation pursuant to the agency's scientific integrity policy,^{ix} which determined that the policy had been violated and recommended the implementation of measures to safeguard against future abuse.^x

Sharpiegate shows that scientific integrity policies are critical, but there is a troubling lack of uniformity among policies across federal agencies. We applaud the administration's efforts to improve scientific integrity standards throughout the federal government. In response to OSTP's request for information,^{xi} we respectfully submit the following recommendations for OSTP to consider as it implements the president's directive to strengthen scientific integrity in the federal government.

Recommendations

I. Scientific Integrity Policies Should Be Required to Address Certain Critical Topics and a Have Broad Scope of Applicability

As noted above, agency scientific integrity policies are not uniformly robust, nor are they uniformly enforced.^{xii} That is why clear standards are needed across the board to better safeguard against abuse. First, scientific integrity policies should make clear that science and the scientific process at federal agencies shall be free from politics, ideology, and financial conflicts of interest.^{xiii} Second, they should prohibit politically motivated manipulation and suppression of government research and data, while also prohibiting discrimination and retaliation against government researchers on the basis of their scientific conclusions.^{xiv} Third, scientific integrity policies should apply to both employees and contractors who perform government and government-funded research at federal agencies, as well as federally funded research and development centers.^{xv}

II. Scientific Integrity Policies Should Have Standard Procedures for the Evaluation and Public Presentation of Research and Data

In order to further maintain scientific integrity and safeguard against abuse, scientific integrity policies should contain standard procedures for the evaluation and public presentation of government-generated research and data. First, agencies should have a procedure for handling disagreements about scientific method and conclusions, such as a dispute resolution process that ensures the merit of scientific conclusions, as proposed in the Scientific Integrity Act.^{xvi} Second, agencies should have a procedure for experts at federal agencies to review content released publicly in their names or that significantly relies on their work as government scientists. This would enable them to respond to changes to, or inaccurate representations of, their work.^{xvii} Third, agencies should have a clear, consistent, transparent, and predictable procedure for agency approval of government scientists' publications, presentations, and participation in scientific conferences.^{xviii}

III. Scientific Integrity Policies Should Contain a Presumption That Research and Data Be Publicly Disclosed and Lay out Clear Standards for the Withholding of Such Publication

There should also be standard procedures to increase public access to government research and data and safeguard against suppression of scientific information.

Disclosure of Data and Research

Agencies should establish standard procedures for the collection and prompt online disclosure of data and completed, peer-reviewed research that is federally funded.^{xxix} Agencies should also establish clear standards for withholding research or removing it from public access.^{xxx} This would help safeguard against a practice common throughout the Trump administration, but most prominently during the pandemic, of senior government officials restricting public access to politically inconvenient government research and data by slow-walking it, removing it from public view, and suppressing it outright.^{xxxi} Safeguarding against this abuse is critical because withholding or removing completed taxpayer-funded research and data from public access hinders scientific progress, puts the health of the American people, the environment, and the economy at risk, and allows political officials to manipulate public support for their policies and avoid responsibility for negative consequences.^{xxxi}

Disclosure of Data and Research in the Regulatory Process

A final measure to consider is to require agencies to publish the nonpolitical expert analysis underlying regulatory actions as part of the administrative record, along with any substantive alterations of the regulatory analysis made by or at the suggestion of political officials and an explanation of the changes made to the analysis.^{xxiii} This would shine a light on, and potentially deter, alteration and suppression of analyses of proposed regulations that hide politically inconvenient facts about the consequences of policy decisions.^{xxiv}

IV. Scientific Integrity Policies Should Have Effective Enforcement and Accountability Mechanisms

The abovementioned standards and procedures are critical to protect scientific integrity, but there must be effective enforcement and accountability mechanisms built into agencies' scientific integrity programs to make sure that policies are respected and there are consequences when they are violated.^{xxv} Agency personnel should be educated about scientific integrity protections, protocols should be put in place to safeguard against violations, and there should be staff dedicated to administering scientific integrity policies, with relevant expertise and insulation from political pressure.

Training

Agencies should be required to conduct routine scientific integrity training for all agency personnel who use science to any significant degree in their jobs.^{xxvi} This would help experts and political officials alike learn what procedures and standards are in place to safeguard against abuse.

Protocols to Regulate Communications from Political Officials

Another measure to improve accountability would be to require agencies to establish protocols to regulate communications between political officials and career researchers about substantive research issues during the technical stages of regulatory development and the preparation of scientific reports for Congress and the public.^{xxvii} This would deter political pressure and create an accountability mechanism if the protocol were breached.

Scientific Integrity Officers

Finally, agencies should be required to designate a nonpolitical agency official or officials, with relevant scientific expertise, to be charged with monitoring and supporting scientific integrity, with appropriate insulation from political officials.^{xxviii} Scientific integrity officers should have the authority to investigate alleged violations of the policy, craft remedies when violations are found, and have effective avenues to obtain compliance with those remedies.

Conclusion

Thank you for your consideration of these recommendations for federal scientific integrity policies. Additionally, we urge OSTP to make comments submitted in response to this Request for Information accessible to the public.

Sincerely,

Martha Kinsella, Senior Counsel, on behalf of the Brennan Center for Justice

ⁱ The Brennan Center advocates for reforms to improve scientific integrity and evidence-based policymaking, as well as to improve government accountability and systems of democracy. Our bipartisan National Task Force on Rule of Law & Democracy — a group of former senior government officials who have served in both Republican and Democratic administrations, co-chaired by former Environmental Protection Agency Administrator Christine Todd Whitman and former United States Attorney for the Southern District of New York Preet Bharara — has laid out a comprehensive agenda to safeguard against politicization of science and ensure that federal policy decisions are based on evidence and expertise. Preet Bharara, Christine Todd Whitman, et al., *Proposals for Reform, Volume II*, National Task Force on Rule of Law & Democracy, 2019, <https://www.brennancenter.org/our-work/policy-solutions/proposals-reform-volume-ii-national-task-force-rule-law-democracy>. The Brennan Center has also issued a set of recommendations for executive actions to safeguard scientific integrity in the federal government. Martha Kinsella et al., *Executive Actions to Restore Integrity and Accountability in Government*, Brennan Center for Justice, 2020, <https://www.brennancenter.org/our-work/policy-solutions/executive-actions-restore-integrity-and-accountability-government>. Additionally, our organization signed on to numerous recommendations for executive action to restore the critical role of science in federal policymaking in a report published by several organizations last year. Union of Concerned Scientists et al., *Restoring Science, Protecting the Public: 43 Steps for the Next Presidential Term*, 2020, <https://ucs-documents.s3.amazonaws.com/science-and-democracy/restoring-science-protecting-the-public.pdf>.

ⁱⁱ See Bharara, Whitman, et al., *Proposals for Reform, Volume II*, Appendix, 29. For examples, see, e.g., Helene Bottemiller Evich, “Agriculture Department Buries Studies Showing Dangers of Climate Change,” *Politico*, June 23, 2019, <https://www.politico.com/story/2019/06/23/agriculture-department-climate-change-1376413>; Annie Snider, “White House, EPA Headed Off Chemical Pollution Study,” *Politico*, May 14, 2018, <https://www.politico.com/story/2018/05/14/emails-white-house-interfered-with-science-study-536950>; Alan Rappeport and Thomas Kaplan, “Unhappy with Findings, Agriculture Department Plans to Move Its Economists out of Town,” *New York Times*, May 30, 2019, <https://www.nytimes.com/2019/05/30/us/politics/agriculture-department-economists.html>; and Andrew C. Revkin, “NASA Office Is Criticized on Climate Reports,” *New York Times*, June 3, 2008, <https://www.nytimes.com/2008/06/03/science/earth/03nasa.html>.

- ⁱⁱⁱ Scientific Integrity, 74 Fed. Reg. 46 (March 9, 2009), <https://www.govinfo.gov/content/pkg/FR-2009-03-11/pdf/E9-5443.pdf>.
- ^{iv} John Holdren, Director, Office of Science and Technology Policy, “Scientific Integrity” (official memorandum, Washington, D.C.: Executive Office of the President, 2010), <https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf>.
- ^v Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking, 86 Fed. Reg. 26 (February 10, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-02-10/pdf/2021-02839.pdf>.
- ^{vi} Martha Kinsella et al., *Trump Administration Abuses Thwart US Pandemic Response*, Brennan Center for Justice, last modified July 26, 2021, <https://www.brennancenter.org/our-work/research-reports/trump-administration-abuses-thwart-us-pandemic-response>.
- ^{vii} Preet Bharara and Christine Todd Whitman, “Under Trump, The Integrity of Government Research Is In Shambles,” *Washington Post*, October 3, 2019, <https://www.washingtonpost.com/opinions/2019/10/03/age-trump-its-clear-government-scientists-need-protection-political-interference/>; and Union of Concerned Scientists, “Attacks on Science,” last modified July 13, 2021, <https://www.ucsusa.org/resources/attacks-on-science>.
- ^{viii} Matthew Choi and Rishika Dugyala, “Trump Secures a NOAA Walkback, Bending Another Agency to His Words,” *Politico*, September 6, 2019, <https://www.politico.com/story/2019/09/06/noaa-defends-trump-alabama-hurricane-claims-1484326>; Christopher Flavelle, Lisa Friedman, and Peter Baker, “Commerce Chief Threatened Firings at NOAA After Trump’s Hurricane Tweets, Sources Say,” *New York Times*, September 9, 2019, <https://www.nytimes.com/2019/09/09/climate/hurricane-dorian-trump-tweet.html>; and Peter Baker, Lisa Friedman, and Christopher Flavelle, “White House Pressed Agency to Repudiate Weather Forecasters Who Contradicted Trump,” *New York Times*, September 11, 2019, <https://www.nytimes.com/2019/09/11/us/politics/trump-alabama-noaa.html>.
- ^{ix} Craig N. McLean, “A Message from Craig McLean: Hurricane Dorian and Exceptional Service,” NOAA Research News, September 10, 2019, <https://research.noaa.gov/article/ArtMID/587/ArticleID/2489/A-Message-from-Craig-McLean-Hurricane-Dorian-and-Exceptional-Service>.
- ^x Andrew Freedman and Jason Samenow, “NOAA Leaders Violated Agency’s Scientific Integrity Policy, Hurricane Dorian ‘Sharpiegate’ Investigation Finds,” *Washington Post*, June 15, 2020, <https://www.washingtonpost.com/weather/2020/06/15/noaa-investigation-sharpiegate/>.
- ^{xi} Request for Information to Improve Federal Scientific Integrity Policies, 86 Fed. Reg. 34064 (June 28, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-06-28/pdf/2021-13640.pdf>.
- ^{xii} See Public Employees for Environmental Responsibility, “Scientific Integrity Policies by Agency,” accessed July 27, 2021, <https://www.peer.org/resource-center/scientific-integrity-policies-by-federal-agency/>; Gretchen Goldman et al., *Preserving Scientific Integrity in Federal Policymaking: Lessons from the Past Two Administrations and What’s at Stake under the Trump Administration*, Union of Concerned Scientists, 2017, <https://www.ucsusa.org/sites/default/files/attach/2017/01/preserving-scientific-integrity-in-federal-policymaking-ucs-2017.pdf>; and United States Government Accountability Office, *Scientific Integrity Policies: Additional Actions Could Strengthen Integrity of Federal Research*, GAO-19-265 (Washington, D.C.: Government Accountability Office, 2019), <https://www.gao.gov/assets/gao-19-265.pdf>.
- ^{xiii} See Scientific Integrity Act, H.R. 849, 117th Cong. § 2(3) (2021). While the Scientific Integrity Act would mandate certain safeguards, the president has ample authority to require them on his own initiative, even absent legislation.
- ^{xiv} See Scientific Integrity Act, H.R. 849, 117th Cong. § 3 (2021).
- ^{xv} The 2017 version of the Scientific Integrity Act would have required that scientific integrity policies apply “to each employee or contractor who conducts, handles, communicates, supervises, or manages federally funded scientific research for the [f]ederal agency or for a federally funded research and development center sponsored by the [f]ederal agency.” Scientific Integrity Act, H.R. 1358, 115th Cong. § 6(a) (2017); and Scientific Integrity Act, S. 338, 115th Cong. § 6(a) (2017). Of note, some of the scientific integrity policies that agencies have adopted apply to contractors, states, and other partners. Public Employees for Environmental Responsibility, *Scientific Integrity Report Card Factors*, § I(B)(2), accessed July 27, 2021, https://www.peer.org/assets/docs/Factors_RC_Point_System.pdf; and Public Employees for Environmental Responsibility, *Scientific Integrity Report Card Comparison Charts*, accessed July 27, 2021, https://www.peer.org/assets/docs/SI_Report_Card_Comparison_Chart%20-%20Sorted%20by%20Score.pdf.

^{xvi} Scientific Integrity Act, H.R. 849, 117th Cong. § 3 (2021). See also Holly Doremus, “Scientific and Political Integrity in Environmental Policy,” *Texas Law Review* 86 (2008): 1645 (advocating for creation of dissent channels at agencies where scientific research is performed).

^{xvii} See Scientific Integrity Act, H.R. 849, 117th Cong. §§ 2(5), 3 (2021).

^{xviii} See Scientific Integrity Act, H.R. 849, 117th Cong. § 3 (2021); and Doremus, “Scientific and Political Integrity,” 1647–48 (“Outside of regulatory agencies, federal research units modeled along academic lines should allow scientists to speak out just as academic scientists are free to do. Within regulatory agencies, there is some justification for overseeing contacts with the press; at some level those agencies must speak with one voice. But no such concern exists with respect to research science units. . . . It is never appropriate for any political appointee or public affairs officer to screen submissions of scientific literature.”).

^{xix} Sarah Lamdan, “Lessons from DataRescue: The Limitations of Grassroots Climate Change Data Preservation and the Need for Federal Records Law Reform,” *University of Pennsylvania Law Review Online* 166 (2018): 242 (noting that the Freedom of Information Act makes federal agency records access a right, part of which is the proactive disclosure of records of public importance, see 5 U.S.C. § 552(a)(1)–(2)(2012) (requiring proactive disclosure of many types of public records), and arguing that all federal records management rules should be crafted with this right in mind). The Fair Access to Science and Technology Research Act (FASTR Act) would require public dissemination within six months after publication in peer-reviewed journals. H.R. 3427, 115th Cong. § 4(b)(4) (2017); and FASTR Act, S. 1701, 115th Cong. § 4(b)(4) (2017).

^{xx} Kinsella et al., *Executive Actions*, 14.

^{xxi} Kashmira Gander, “Coronavirus Cases Tested in U.S. Removed from CDC Website, According to Congressman: ‘American People Deserve Answers,’” *Newsweek*, March 3, 2020, <https://www.newsweek.com/coronavirus-cases-tested-us-removed-cdc-website-according-congressman-american-people-1490158>; Richard Rubin, “Treasury Removes Paper at Odds with Mnuchin’s Take on Corporate-Tax Cut’s Winners,” *Wall Street Journal*, September 28, 2017, <https://www.wsj.com/articles/treasury-removes-paper-at-odds-with-mnuchins-take-on-corporate-tax-cuts-winners-1506638463>; Union of Concerned Scientists, “Department of Treasury Deletes Economic Science Paper from Website,” September 28, 2017, <https://www.ucsusa.org/center-science-and-democracy/attacks-on-science/departments-treasury-deletes-economic-science-paper#.WphdW2rwbc>; and Helene Bottemiller Evich, “Agriculture Department Buries Studies Showing Dangers of Climate Change,” *Politico*, June 23, 2019, <https://www.politico.com/story/2019/06/23/agriculture-department-climate-change-1376413>.

^{xxii} Kinsella et al., *Executive Actions*, 14.

^{xxiii} Bharara, Whitman, et al., *Proposals for Reform, Volume II*, 14; and Kinsella et al., *Executive Actions*, 14.

^{xxiv} See, e.g., Lydia Wheeler, “Report: Labor Department Hiding Unfavorable Report on Impacts of Tip-Pooling Rule,” *The Hill*, February 1, 2018, <http://thehill.com/regulation/labor/371798-report-labor-department-hiding-unfavorable-report-on-impacts-of-tip-pooling>; Eric Levitz, “Trump DOL Hid Report Showing Its Tips Rule Would Likely Cost Workers Billions,” *New York Magazine*, February 1, 2018, <http://nymag.com/daily/intelligencer/2018/02/dol-hid-study-showing-tips-rule-could-cost-workers-billions.html>; and Ben Penn, “Mulaney, Acosta Override Regulatory Office to Hide Tips Rule Data,” *Bloomberg Law*, March 1, 2018, <https://news.bloomberglaw.com/daily-labor-report/mulaney-acosta-override-regulatory-office-to-hide-tips-rule-data-1>. There are many other examples detailed in the appendix of the Brennan Center task force’s report. See Bharara, Whitman, et al., *Proposals for Reform, Volume II*, Appendix, 36–37.

^{xxv} Bharara, Whitman, et al., *Proposals for Reform, Volume II*, 8–9.

^{xxvi} See Scientific Integrity Act, H.R. 849, 117th Cong. § 3 (2021); Doremus, “Scientific and Political Integrity,” 1648 (advocating training on the roles of technical and political staff); and Kinsella et al., *Executive Actions*, 12.

^{xxvii} Kinsella et al., *Executive Actions*, 13. The Scientific Integrity Act calls for agencies to have “the appropriate rules, procedures, and safeguards . . . in place to ensure the integrity of the scientific process within the covered agency.” Scientific Integrity Act, H.R. 849, 117th Cong. § 3 (2021); and Dana Remus, Counsel to the President, “Prohibited Contacts with Agencies and Departments” (official memorandum, Washington, D.C.: Office of Counsel to the President, 2021), <https://www.whitehouse.gov/wp-content/uploads/2021/07/White-House-Policy-for-Contacts-with-Agencies-and-Departments.pdf>.

^{xxviii} Kinsella, et al., *Executive Actions*, 12; Scientific Integrity Act, H.R. 849, 117th Cong. § 3 (2021); and Doremus, “Scientific and Political Integrity,” 1645–46 (calling for independent scientific ombudsmen to whom agency technical staff could forward concerns about scientific underpinnings of regulatory decisions and public communications). Congress has created similar positions, such as the director of the Office of Research Integrity in

HHS. 42 U.S.C. § 289b(a)(2). The director is required by statute to be experienced and specially trained in the conduct of research and have experience in the conduct of investigations of research misconduct and is appointed by the secretary of the department.

Some agencies have scientific integrity officers to administer scientific integrity policies. See, e.g., U.S. Environmental Protection Agency, *Scientific Integrity Policy* (Washington, D.C.: Environmental Protection Agency, 2017), 10, https://www.peer.org/assets/docs/epa/17_EPA_Final_SIP.pdf; Centers for Disease Control and Prevention, “Maryam Daneshvar, PhD, Director, Office of Scientific Integrity,” accessed July 27, 2021, <https://www.cdc.gov/od/science/aboutus/maryam-daneshvar.htm>; U.S. Department of the Interior, “Scientific Integrity Officers,” accessed July 27, 2021, <https://www.doi.gov/scientificintegrity/Scientific-Integrity-Officers>; U.S. Department of Agriculture, “Agency and Departmental Scientific Integrity Officers,” accessed July 27, 2021, <https://www.usda.gov/our-agency/staff-offices/office-chief-scientist-ocs/agency-and-departmental-scientific-integrity>. See also Jeff Ruch, “Emerging Law of Scientific Integrity — A Bumpy Birth,” *Fisheries* 42 (2017): 354–55 (emphasizing need for independent review of scientific integrity complaints).

July 28, 2021

Eric S. Lander
Director
White House Office of Science and Technology Policy
Executive Office of the President
725 17th Street Room 5228
Washington, DC 20502

Re: SI-FTAC RFI To Improve Federal Scientific Integrity Policies

Dear Dr. Lander:

The American Institute of Biological Sciences (AIBS) appreciates the opportunity to provide comments in response to the Request for Information To Improve Federal Scientific Integrity Policies issued by the White House Office of Science and Technology Policy (OSTP) on June 26, 2021.

AIBS is a non-profit scientific society dedicated to increasing our understanding of all life. We work with our members and other partners to promote informed decision-making that advances the biological sciences for the benefit of science and society. Our more than 110 organizational members collectively represent more than 100,000 scientists, science educators, and students.

Independent science that is free of political, ideological, or financial influence is critical to the government's ability to make informed decisions that impact our public health, economy, environment, and national security. Transparent decision-making that is based on unbiased and independent scientific research and data is important for building public trust in government decisions. We applaud the Administration's intentions to help agencies

strengthen their scientific integrity policies to improve the use of science in policymaking.

In order to be effective in their jobs, it is important for federal scientists be able to communicate freely about their work with peers, journalists, and the public. It is critical for OSTP to ensure that each agency develops a public communications policy that promotes and maximizes openness and transparency. Such a policy should include a provision to allow agency scientists to speak freely to the media and the public, including on social media, about scientific and technological matters based on their official work without the need for approval or clearance by the agency. Additionally, we encourage OSTP to ensure that government scientists are allowed to present viewpoints publicly that extend beyond their scientific findings, for example about policy or management matters, so long as they make clear that they are presenting their individual opinions and not speaking on behalf of the agency.

Additionally, more safeguards are needed to ensure that scientific information that is being communicated to the public is accurate, based on research, and clearly communicates scientific uncertainties. In recent years, there have been many instances of pseudo-scientific information being published on an agency's website. To prevent future instances of false information being shared, agencies should include scientists in the process of preparing and reviewing science-based content for public dissemination.

It is also critical to establish clear guidelines and procedures for federal employees, as well as federal contractors and scientists supported by federal funding, for reporting violations of scientific integrity. Policies should explicitly prohibit retaliation against employees, contractors, or grantees who raise concerns about scientific integrity or express scientific opinions that diverge from those of the Administration or the agency.

Political interference in science erodes public trust in the federal government. Decision-making should be based on unbiased scientific evidence and expert advice. Scientific integrity policies at all federal agencies must protect science and scientists from undue political interference by establishing scientific integrity officials who have the power to oversee the implementation and improvement of these policies. These officials should also be empowered to independently investigate political interference and other violations of scientific integrity policies, including those coming from agency and Administration leadership, by working with and informing the Inspector General.

Peer review is a central tenet of science. The OSTP should ensure that all data and research findings used to support policy decisions undergo rigorous peer review by qualified experts. Agencies that perform research should aim for independent review of its research in order to ensure that its work is of the highest quality and to sustain public trust in its scientific work. Furthermore, it is important to establish mechanisms to prevent the politicization of research funding by ensuring that grant review processes are independent and based on scientific merit.

Federal scientific advisory committees, whose members are drawn from academia, state and local governments, industry, and the nonprofit sector, provide valuable expertise and advice on a variety of issues that impact government decision-making. To prevent politicization of these panels, it is imperative that agencies establish clear policies that improve the transparency and accountability of the processes and criteria for nominating and selecting qualified committee members. The OSTP should ensure that agencies work to establish guidelines around disclosure of conflicts of interest and to identify which conflicts would disqualify individuals from serving on advisory committees.

Finally, as the January 2021 Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking suggests, it is important for each agency to conduct routine scientific integrity and ethics training for all its employees and contractors who work on science or related issues to ensure they are fully aware of their rights and responsibilities, including their rights regarding dissemination of research findings and their responsibility to report waste, fraud, abuse, and scientific misconduct.

We appreciate the opportunity to weigh in on this important issue. Please do not hesitate to contact Dr. Jyotsna Pandey.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott Glisson".

Scott Glisson
Chief Executive Officer

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Dr. Eric S. Lander
President's Science Advisor and
Director of the White House Office of Science and Technology Policy

July 28, 2021

Dear Dr. Lander,

UC San Diego, one of the top research universities in the United States, appreciates OSTP's Request for Information "to help improve the effectiveness of Federal scientific integrity policies to enhance public trust in science." UC San Diego prides itself on fostering and facilitating scientific integrity in all disciplines as a critical component of scientific inquiry itself, as well as to promote public trust in science. Scientific integrity is and must remain a matter of the highest priority for Federal agencies, OSTP and researchers. Integrity can be threatened intentionally by bad actors and unintentionally by uninformed or confused researchers, as well as by those distorting the objectivity of scientific research for political or other reasons. We recognize that the matter of public trust in science requires a broad understanding of cultural factors that Federal agencies should be aware of, as these will necessarily shape effective strategies for establishing or enhancing public trust in science and in evidence-based policymaking. For this reason, UC San Diego prioritizes creating communication across disciplines and between experts in all fields and the public. While many elements contribute to the effectiveness of Federal policies designed to promote scientific integrity and public trust in science, three factors are centrally important:

1. increasing consistency and standardization of requirements and guidance across federal agencies, and ensuring timely notification of requirements and guidance;
2. communicating effectively to the public about the scientific method, as well as the guardrails in place to ensure scientific integrity;
3. prioritizing required training in responsible conduct of research, research integrity and effective research communications for trainees, principal investigators, research scientists and staff.

Attention to these issues will enhance scientific integrity and will help bolster public trust in science, and should inform the work of the Scientific Integrity Fast-Track Action Committee (SI-FTAC).

- 1. Inconsistent and disparate requirements and guidance across Federal agencies substantially diminish the effectiveness of Federal scientific integrity policies both generally and specifically in promoting trust in science.**

Different Federal agencies have divergent requirements, creating confusion and hampering transparency and compliance; even the best-intentioned researchers can find it challenging to

comply with disparate requirements. An individual lab may have two or more sources of funds, and different members of the lab may be supported by different fund sources. This makes compliance with different requirements very time consuming and challenging. For example, there are disparities in the Federal regulations regarding the disclosure of conflicts of interest. Two Federal sponsors require COI disclosures (Public Health Services (PHS) and National Science Foundation (NSF)), while other Federal sponsors have no COI disclosure policies. PHS disclosure thresholds (governing NIH, FDA and CDC proposals) require disclosure of income/compensation, travel support, or intellectual property royalties of >\$5,000; NSF disclosure thresholds in each of these categories are \$10,000; and no disclosures are required for DOE, DOD or NASA. These disparities not only risk confusion and added administrative burden for researchers and institutions, but can also undermine public confidence in scientific research. Inconsistent or conflicting regulations may create the impression of something illicit or dishonest even when research is conducted in full compliance with the requirements of a specific Federal agency. A consistent standard for COI disclosures applied to all Federally sponsored research will help to ensure full transparency and compliance while enhancing public trust in the integrity of the scientists engaged in the research.

Conflict of Interest disclosures are one of many areas where inconsistencies across Federal agencies create confusion among researchers and potentially reduce public confidence in the integrity of scientific research. Other areas related to Federal scientific integrity policies with similar inconsistencies are:

- a. Other support
- b. Biosketches
- c. Foreign influences
- d. Participation in foreign talents programs
- e. Requirements for data management plans
- f. Authorship criteria

In some instances, increased consistency can be obtained relatively easily. For instance, “other support” (NIH) is included within “Current and pending support” disclosures required by NSF and DOD – using the same approach to reporting across agencies would simplify the process for everyone. In other instances, collaboration across agencies and with stakeholders will be required to develop appropriate and consistent guidance that will most effectively ensure scientific integrity.

In short, public trust in Federally funded science requires well-justified standards of scientific integrity applied consistently across all agencies. Where needed, disparate requirements should be clearly articulated and explained. Such consistency and transparency can only enhance efforts to promote public trust.

As Federal agencies develop policies and guidance, it is important to recognize that shifting requirements usually increase the administrative burden of proposal submission, the conduct of research, and grant reporting. F&A rates must be adjusted to accommodate these burdens in order to facilitate compliance. Additionally, it is important for Federal agencies to avoid repeated changes to policies and implementation guidance, as this creates confusion and administrative burdens. It is equally important that when policies are made or changed and guidance is offered, sufficient time be given for institutions to implement new practices. In large institutions like UC San Diego, a seemingly ‘minor’ change to requirements for reporting other support (for instance) impacts thousands of individual proposals and grants. At least 9-12 months’ notice of such changes should be given in order to enable institutions to get clarification on requirements and adjust their systems and processes to comply.

2. **Efforts to ensure public trust in science are hampered by ineffective communication to the public about science (writ large):** the scientific method, the policies and procedures in place to ensure integrity, the beneficial impact of Federally funded research, and even the motivations of scientists themselves are largely foreign to many. For this reason, effective communication is the linchpin for enhancing public trust in science. In fact, many universities and advocacy groups have worked on effectively communicating their research to the public. As an example, APLU has created a “public impact research” framework and communications campaign to make sharing such work easier for researchers and research institutions.¹ is important, necessary work, but is only one element of a necessarily comprehensive approach to research communication – a small piece of a much larger puzzle. Trust in science ultimately relies upon addressing the deeper causes of distrust.

Contrary to the implicit view that has shaped many science communication training programs, a comprehensive approach recognizes that effective communication is about more than transmission of facts. Communicators must be responsive to the values of their audiences and they must approach communication from a place of deep authenticity that humanizes science and scientists.

It follows that science communication requires professional learning that should not be viewed as a one-and-done training, but rather a process that begins early and continues throughout a researcher’s career. Furthermore, although courses and workshops in research ethics and science communication have historically been separate, we suggest a new vision that would link the two.

As a step toward this new vision, UC San Diego’s Research Communications Program² collaborated with the Institute for Practical Ethics, a unique resource at UC San Diego that aims to further both the theoretical and practical analysis of problems that relate to policy. The result was a guiding framework, in the form of a set of competencies, to foster effective communication with diverse audiences about scientific research and its implications.³

Informed by the framework, UC San Diego’s Research Communications Program combines perspectives from journalism, theatre and the learning sciences to help scientists communicate in clear, compelling language, while bringing their humanity to the table. This is also supported by providing safe spaces where diverse scientists can communicate from their authentic voices, such as in two new lecture/discussion series on campus “The Graduate Diversity in Science Lecture Series” (DASL) and “Scientific Queers United in Academic Discourse” (SQUAD).

Building on this work, including the principles and practices of effective research communication in mandatory research ethics trainings would help promote and systematize practical research ethics among all Federally funded scientists. Doing so would underscore the relationship between communication, ethics and values. It would also help researchers identify the competencies they need to develop through future communication workshops and immersive experiences, with the goal of becoming authentic communicators who speak to people’s hearts and minds and earn their trust.

¹ See Association of Public and Land-Grant Universities (2019). *Public Impact Research: Engaged Universities Making the Difference*. <https://www.aplu.org/library/public-impact-research-engaged-universities-making-the-difference/file>.

² <https://physicalsciences.ucsd.edu/centers-outreach/research-communications/index.html>.

³ Seethaler, S., Evans, J. H., Gere, C., & Rajagopalan, R. M. (2019). Science, values, and science communication: Competencies for pushing beyond the deficit model. *Science Communication*, 41(3), 378-388. <https://journals.sagepub.com/doi/abs/10.1177/1075547019847484>.

It is important to note that we need to go beyond investing in training for our scientists by also providing the tools and infrastructure for them to be able to share their research more broadly. Efforts to accelerate public access to research data⁴ are one element of this infrastructure that Federal agencies, policies, and funding should support. The University of California System and UC San Diego have invested in University of California TV, an online broadcast platform that allows our faculty to share their research more broadly with audiences that may not otherwise be able to engage with the information. It is essential to develop content that is engaging not only on traditional channels, but also on social media channels where our audiences are going more often to receive their information. This means updating how we create content to ensure that it is easily digestible to lay audiences.

3. ***To develop institutional cultures prioritizing scientific integrity and transparency into scientific integrity practices, training requirements should be consistent across Federal agencies. Participation in a curriculum of responsible conduct of research, research ethics and research communications should be required for trainees, principal investigators, key personnel and research staff.***

The responsible conduct of research (RCR) is defined as "the practice of scientific investigation with integrity." It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research. Projects funded by the NIH, NSF, and National Institute of Food and Agriculture (NIFA) have specific requirements regarding training in RCR -- but these are the only Federal agencies with RCR training requirements. There are disparities among these agencies regarding training content, who is required to complete training, number of hours for training, methodology and frequency. Training requirements should be consistent across agencies, should be expanded to include researchers at all stages of their careers, and should be based upon a systemic approach to training that broadens researchers' expertise in multiple facets of RCR as well as in communicating to the public about their research. In this way, training will foster both scientific integrity and enhance public trust in research.

The domain of "research integrity" is large, but much training about research ethics/integrity has a singular focus on research misconduct (which is defined as fabrication, falsification and/or plagiarism). This focus can be problematic. Research misconduct should certainly be discussed, but it should ideally be framed as a small part of a more comprehensive conversation and in a way that addresses multiple risks. Most importantly, research integrity and ethics should be framed as integral practices of research that will contribute to rigor, reproducibility and reliability – all of which will also contribute to public trust in science.

A single course on research ethics and integrity taken in isolation is not likely to have a positive impact if other components (institutional leadership, policies, procedures, resources) are not also aligned with a research integrity agenda. The enterprise of science would be greatly helped by emphasizing that coursework and training should be only one part of a systemic approach to creating a culture of integrity. As an example of such a systemic approach, current guidance for RCR training is the expectation (within NIH) that trainees should receive at least eight hours of

⁴ See Association of American Universities and Association of Public and Land-grant Universities (2021). *Guide to Accelerate Public Access to Research Data*. Washington, DC. DOI: [TKTKTK CC BY-NC-SA](https://doi.org/10.26434/chemrxiv-2021-08-01), based upon work supported by the NSF and NIH.

training every four years. This raises the question of whether the trainee should repeat the same course or have the opportunity to learn about a range of topics relevant to RCR and scientific integrity. Institutions can be incentivized to broaden training opportunities through increased Federal investment in the development and implementation of a comprehensive curriculum promoting scientific integrity. A foundational element of such a comprehensive approach is for Federal agencies and stakeholders across the research ecosystem to collaboratively develop the goals for such training and create consistent requirements for training across all Federal agencies, scientific disciplines and stages of the research career.

This is not to say we advocate a single line of training for all. For instance, non-federally funded staff should be given discretion in how to meet training requirements. Graduate students and others may benefit from program-based training tailored to the type of research they do, rather than from a one-size-fits-all model. Program or discipline based training is more easily assimilated and relevant to research of new investigators. The goal is not to be overly prescriptive, but to provide a consistent foundation to elevate research integrity and ethics into practice.

Good Clinical Practices (GCP) training is an example of an area in which requirements are inconsistent. The principles of GCP help assure the safety, integrity and quality of clinical trials. GCP provides a standard for ensuring clinical trial compliance, implementation, data collection, monitoring and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems or final data), and outline the responsibilities of Institutional Review Boards (IRBs), investigators, sponsors and monitors. The National Institutes of Health (NIH) however, is the only federal agency that requires GCP training by the study's Principal Investigator and staff who are involved in the design, conduct, oversight or management of clinical trials. However, other agencies (and private funders) sponsor human subjects research – and consistent efforts to assure the safety, integrity, and quality of that research would improve research broadly and contribute to public trust in such research.

At a minimum, a comprehensive and consistent strategy for training in scientific integrity should address the following topics:

<ul style="list-style-type: none"> • Conflict of interest – personal, professional and financial • Policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices • Mentor/mentee responsibilities and relationships • Collaborative research including collaborations with industry • Social responsibility and whistleblowing • Effective communication strategies 	<ul style="list-style-type: none"> • Data acquisition and laboratory tools; management, sharing and ownership • Research misconduct and policies for handling misconduct • Responsible authorship, peer review and publication • The scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research
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To the extent courses are used for promoting research integrity, it is good that NIH has recognized the importance of active learning and engagement. This is the reason that the current version of the RCR requirement emphasizes in-person training. However, it is clear there is a flaw in the way this

has been interpreted. The point is not whether a course is in person or online, but *how* it is taught. A classroom course can be taught in a passive way even though it is in person; an online course, properly constructed, can be taught with active learning methods even though not in person. The forced move to online education during the COVID-19 pandemic required that UC San Diego re-tool our courses to fit the online environment. Courses in RCR were well-received by researchers, resulting in highly productive discussions, and even had some advantages over in-person courses. Federal agencies working with research institutions to develop a comprehensive approach to training in RCR and scientific integrity should consider all models of education, including looking for ways we might take advantage of the geographical reach and flexibility of online learning environments to foster cross-institutional, cross-agency opportunities for participants across the country, and even (given the internationalization of scientific research) around the world.

Such a comprehensive approach will require considerable investment. OSTP should work with Federal agencies and appropriations to secure that investment, as scientific integrity is a crucial element of research and central to undergirding public trust in science.

In sum, UC San Diego welcomes the opportunity to work with The White House Office of Science and Technology Policy, Federal agencies, and partner institutions and organizations to increase public trust in science through enhancing the effectiveness of Federal scientific integrity policies. Increasing the consistency of such policies and their implementation across agencies and disciplines is a necessary step toward that goal. Reconceiving how we communicate research to the public, and developing a comprehensive curriculum for training of all researchers in scientific integrity and research communication are equally valuable and necessary approaches.

We look forward to continued discussion about this important work.

Sincerely,

A handwritten signature in black ink, appearing to read "Sandra A. Brown". The signature is fluid and cursive, with a large, stylized initial "S" and a distinct "A" and "B".

Sandra A. Brown
Distinguished Professor of Psychology and Psychiatry
Vice Chancellor for Research
UC San Diego

July 28, 2021

White House Office of Science and Technology Policy
Via email: ScientificIntegrityRFI@ostp.eop.gov

Re: Request for Information To Improve Federal Scientific Integrity Policies (86 FR 34064)

The Jacobs Institute of Women's Health appreciates the opportunity to comment in response to the "Request for Information to Improve Federal Scientific Integrity Policies" (86 FR 34064). The Jacobs Institute of Women's Health strongly supports the work of the White House Office of Science and Technology Policy (OSTP) to improve the effectiveness of federal scientific integrity policies and practices to enhance public trust in science.

The Jacobs Institute of Women's Health's mission is to identify and study aspects of healthcare and public health, including legal and policy issues, that affect women's health at different life stages; to foster awareness of and facilitate dialogue around issues that affect women's health; and to promote interdisciplinary research, coordination, and information dissemination, including publishing the peer-reviewed journal *Women's Health Issues*.

Below we provide brief examples of problems that existing scientific integrity policies did not prevent and offer recommendations for strengthening scientific integrity policies and practices. The identified issues and recommendations below focus on three areas: Strong scientific integrity policies, Evidence-based distribution of grant funds, Transparency of federal advisory committees, and Enforcement of scientific integrity policies.

I. Strong scientific integrity policies

The Jacobs Institute of Women's Health is one of a wide range of organizations that contributed to the 2020 publication *Restoring Science, Protecting the Public: 43 Steps for the Next Administration*.ⁱ That document describes numerous examples of recent scientific integrity abuses (some of which we mention below) and offers suggestions for improvements. Consistent with that document, we recommend that OSTP require scientific integrity policies to:

- Protect the right of scientists to share scientific data and analysis with the public and lawmakers free from political interference and filters, and to review content that will be released publicly

in their names or that significantly relies on their work.

- Explicitly prohibit retaliation against government employees who raise concerns about scientific integrity or offer scientific opinions that differ from those of the administration or their agency.
- Specify that media policies allow scientists to share their expertise without political vetting, and advance other initiatives to improve scientific communication.
- Provide a clear, detailed policy and procedure for addressing allegations of scientific integrity violations, including appeal rights, and for publicly reporting their resolution.

Because the last of these items is so important, we address it separately in Section IV.

II. Evidence-based distribution of grant funding

In the reproductive health area, several of the scientific integrity problems during the Trump administration occurred in the area of grant distribution. Three examples—which are presented in greater detail in the Department of Health and Human Services (HHS) memoⁱⁱ of a set of agency-specific memos to which the Jacobs Institute contributed (*Restoring Science, Protecting the Public: Recommendations for Federal Agencies in the Next Presidential Term*ⁱⁱⁱ)—illustrate problems that scientific integrity policies and practices should guard against:

- **Teen Pregnancy Prevention grants:** The abrupt cessation of Teen Pregnancy Prevention (TPP) program grants while grantees were in the midst of data collection halted promising research and the delivery of services to adolescents across the country; although courts eventually required HHS to restore grantees’ funding, the damage to their staff capacity and research processes could not be repaired with that reversal. The Trump administration also weakened evidence standards in grant announcements for new funding, and selected unqualified or lesser-qualified external reviewers for the proposal reviews.
- **Title X family planning program:** The regulation known as the “domestic gag rule” effectively prohibits providers that receive federal Title X family planning grants from providing evidence-based and ethical care to pregnant patients; it resulted in the Title X network losing roughly half its capacity to serve female clients in the year following its implementation.^{iv} Commenters on the proposed rule warned, based on evidence from a similar move in Texas, that it would cause such a drop in capacity. HHS brushed these concerns aside and asserted, without compelling evidence, that new providers who could meet clients’ needs would enter the program.

- **NIH grants for research involving human fetal tissue:** The Trump administration ended longstanding NIH grant funding for research relying on fetal tissue, and then discontinued funding of future research requiring newly acquired fetal tissue. For advice on continued funding for some existing grants, it formed a Human Fetal Tissue Ethics Advisory Board. The majority of the board's members had expressed outright opposition to fetal tissue and stem cell research, and their names were not released until the day of their first meeting. The board recommended against funding for 13 of 14 NIH grants using fetal tissue that they reviewed; the only study that was recommended for funding investigates alternatives to fetal tissue research.

Although courts have reversed many of the TPP program changes and the Biden administration has lifted the fetal-tissue research prohibition and begun the process of reversing the domestic gag rule, they cannot undo the damage that communities across the country have suffered as TPP programs, Title X clinics, and research studies shut down.

Agencies must do more to ensure that grant funding decisions are based on evaluations by experts with relevant qualifications, and they must guard against political interference with funding programs' criteria and awards. We recommend that OSTP take the following steps:

- Scientific integrity policies should require that agencies make publicly available both the criteria for selecting evaluators and the criteria they will apply when scoring funding applications. When stakeholders raise concerns about either of these—as our organization and others did in response to the domestic gag rule and the TPP program's weakening of standards—agencies must be ready to either provide a sound explanation for keeping them or make modifications.
- Agencies must better guard against politically motivated interference with grant programs. The firewalls between political leadership (whether from the administration, Congress, or other political entities) and program managers, evaluators, and grantees must be strengthened through specific policies and protocols.

III. Transparency for federal advisory committees

Federal advisory committees (FACs) are essential to the effective functioning of agencies that protect the public's health. Examples of FACs of particular interest to the Jacobs Institute include the CDC Advisory Committee on Immunization Practices, the HHS/DOJ National Advisory Committee on Violence Against Women, and the many advisory committees that advise FDA on approval of drugs and devices. Consistent with the FAC memo^v of the *43 steps* documentⁱ, we recommend that OSTP require agencies to take the following steps:

- Publish clear criteria for nominating and selecting qualified committee members, while prohibiting current members from having veto power over candidates.
- After selecting candidates for membership, make that roster public and request comments.
- Identify and make public the process used for committee formation, including how agencies screen members and assess committees for balance.
- Publish background information on each committee member on a public online portal (e.g., integrity.gov), including information on qualifications, employers, and funding sources for the previous five years, along with any conflict-of-interest waivers granted.
- When allowing FACs to expire, archive their websites and all related documents so agencies and the public can still access the information.
- Instruct agencies to identify outstanding complaints made against existing FACs, investigate those complaints, and take corrective action where warranted.

In addition, OSTP should ask the Office of Government Ethics to provide clear guidelines that:

- Explicitly define what constitutes a conflict of interest and transparently outline the degree to which a conflict of interest would disqualify a nominee from participating on a committee.
- Direct agencies to clarify their criteria for appointing advisory committee members as individuals or as organization representatives, and take steps to ensure that conflicts of interest are properly scrutinized.
- For committees with a mission solely dedicated to providing objective scientific advice (as opposed to committees designed to gather input from diverse stakeholders), ensure members are appointed as special government employees and vetted for financial conflicts of interest. They should recuse themselves from scientific discussions with which they have a direct conflict of interest, and those recusals should be announced to the public at the start of meetings and be included on meeting notes, reports, and other documents.

- Ensure that scientists who have taken public positions on issues or received government funding for scientific work are not excluded from advisory committees because of unfounded concerns about bias.

Scientific FACs play a key role in providing scientific advice to policy makers, regulators, and the public. Although agencies are not bound to follow FACs' advice, acting against it risks compromising public trust. We therefore recommend:

- When recommendations and/or advice are given, particularly in the regulatory setting, the response by the relevant agency (e.g., FDA, EPA) should be transparent and scientifically valid. Agencies should establish a process that gives the public access to information about the agency's rationale for actions that are not in line with FAC advice.

IV. Enforcement of scientific integrity policies

Abuses of scientific integrity were rampant during the Trump administration despite the existence of strong scientific integrity policies at several agencies. President Biden has publicly committed to scientific integrity, but recent problematic decisions regarding guidance for vaccinated individuals from the Centers for Disease Control and Prevention (CDC)^{vi} and the Food and Drug Administration (FDA) approval of Alzheimer's drug Aduhelm^{vii} raise the possibility that decisionmakers might feel pressure to inappropriately emphasize certain evidence while sidelining other data, even if that pressure is not coming from the White House.

Although many employees reported violations of scientific integrity policies during the Trump administration, such reports rarely (if ever) resulted in reversals or prevented future interference. To ensure that scientific integrity policies are effective, they must encourage reporting of violations. People who witness wrongdoing are more likely to report it if they trust that agencies will guard them against retaliation, investigate the allegation, and, when they find evidence of wrongdoing, act to correct the situation. Current policies leave agencies with too few options for taking corrective action when investigations determine that wrongdoing occurred, and inadequate responses risk deterring future reporting.

We recommend that each agency's scientific integrity policy contain the following:

- **Authority for punishing wrongdoers.** For policies to deter wrongdoing effectively, agencies must have the authority to punish individuals who are found to have violated them. Agencies

can determine the appropriate route for establishing this authority—e.g., granting it to the scientific integrity official, using Human Resources processes, or establishing a mechanism for quickly involving the Office of the Inspector General—but it is an essential step.

- **Timelines for investigating allegations.** When investigations move slowly, the policy violator has more time to continue misconduct, and the person who reported the violation can lose faith in the system. In setting timelines, agencies must balance the imperative for fair and thorough investigations with the need to deter wrongdoing. Timelines should include options for interim actions that limit the damage alleged perpetrators can continue to cause in cases where there is strong evidence of wrongdoing but the investigation is still ongoing.
- **Consequences for those found to have violated scientific integrity policies.** Consequences for those found to have violated policies must be sufficiently strong to deter future wrongdoing. All violations should become part of the wrongdoer's file, and sanctions should be in line with those for personnel policy violations such as theft and unexcused absences. The severity should not depend on whether the attempt at interference was successful or not; punishment of all violations is essential to create a culture of respect for scientific integrity.
- **Safeguards against retaliation.** To encourage individuals to report wrongdoing, policies must offer credible assurances that reporters will not face retaliation. Policies should limit the potential for the accuser's identity to be disclosed to the accused, and they should allow for individuals to report outside of their supervisory chains. Reporters should have recourse for meaningful corrective action in cases when they experience retaliation.
- **Reporting mechanisms for multiple stakeholders.** Contractors as well as employees should be able to report wrongdoing that they witness, and policies should specify mechanisms by which members of the public can report violations.

Thank you for this opportunity to comment in response to “Request for Information to Improve Federal Scientific Integrity Policies.” If you have any questions, please contact Jacobs Institute managing director Liz Borkowski at 202-994-0034 or borkowsk@gwu.edu.

ⁱ Multiple organizations. *Restoring Science, Protecting the Public: 43 Steps for the Next Presidential Term*. June 2020. Available: <http://www.thepumphandle.org/wp-content/uploads/2020/06/Restoring-Science-Protecting-the-Public.pdf>

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- ⁱⁱ Multiple organizations. Department of Health and Human Services: Sexual and Reproductive Health, Education, and Services. In: *Restoring Science, Protecting the Public: Recommendations for Federal Agencies in the Next Presidential Term*. October 2020. Available: <http://www.thepumphandle.org/wp-content/uploads/2020/10/Restoring-Science-HHS-SRH.pdf>
- ⁱⁱⁱ Multiple organizations. *Restoring Science, Protecting the Public: Recommendations for Federal Agencies in the Next Presidential Term*. October 2020. Available: <http://www.thepumphandle.org/wp-content/uploads/2020/10/restoring-science-protecting-the-public-oct2020.pdf>
- ^{iv} Dawson, R. Trump Administration's Domestic Gag Rule Has Slashed the Title X Network's Capacity by Half. Guttmacher Institute Policy Analysis. February 5, 2020. Available: <https://www.guttmacher.org/article/2020/02/trump-administrations-domestic-gag-rule-has-slashed-title-x-networks-capacity-half>
- ^v Multiple organizations. Federal Advisory Committees: Restoring the role of independent expert advice in government. In: *Restoring Science, Protecting the Public: 43 Steps for the Next Presidential Term*. June 2020. Available: http://www.thepumphandle.org/wp-content/uploads/2020/06/Restoring-Science-Protecting-the-Public_Federal-Advisory-Committees.pdf
- ^{vi} Borkowski, L. With COVID-19 Policies and Alzheimer's Drug Approval, Biden Administration Lets Us Down. June 20, 2021. Available: <http://www.thepumphandle.org/2021/06/20/with-covid-19-policies-and-alzheimers-drug-approval-biden-administration-lets-us-down/#.YP1Zly1h3UZ>
- ^{vii} National Center for Health Research. Scientific Coalition Letter on Aduhelm to HHS Inspector General, CMS, and Congress. July 7, 2021. Available: <https://www.center4research.org/scientific-coalition-letter-on-aduhelm-to-hhs-inspector-general/>

From: [Kathryn U](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Wednesday, July 28, 2021 3:16:34 PM

OSTP should adopt the following 10 basic principles:

Stop government-funded scientists from lying.

Stop covering up when lying and or mistakes occur.

Minimize/stop taxpayer funding of scientific research.

Make all taxpayer-funded research data and all taxpayer-funded studies available free-of-charge on the Internet.

Require that federal agencies clearly distinguish and explain science policy vs. actual science knowledge in all discussions of science.

Require that government-funded scientists and agencies respond in detail to specific criticism of their research and scientific claims.

Require that federal scientific advisory committees be balanced in terms of views, interests and backgrounds.

Bar taxpayer-funded researchers and their colleagues from serving on advisory committees or otherwise participating in peer review of their own, their colleagues', their institutions and their funding agency's research.

Strictly enforce the Nuremberg Code when human research is conducted.

Conduct an annual review of the actual costs and benefits of taxpayer-funded research and report the results to the public.

Kathryn Ubl

Protecting Public Information is a Critical Component of Federal Scientific Integrity

Comment submitted on behalf of the Environmental Data & Governance Initiative
by Gretchen Gehrke, Alejandro Paz, Marcy Beck, and Shannan Lenke
Respondent type: non-profit organization

Introduction

The Environmental Data and Governance Initiative (EDGI) Website Monitoring Team welcomes the opportunity to provide comment to help improve the effectiveness of federal scientific integrity policies to enhance public trust in science (Docket No: 2021-13640). EDGI is a multidisciplinary, cross-professional organization that has been documenting, analyzing, and contextualizing environmental governance actions since January 2017. EDGI's Website Monitoring Team works at the intersection of information and environmental policies, tracking changes to thousands of federal web pages related to climate, energy, and the environment in order to assess shifts in public access to or federal presentation of environmental science and policy information. Websites are the primary means by which the federal government communicates with the public,¹ and changes to website information directly affect public knowledge and participation in democratic processes. Our work helps inform and evaluate federal scientific integrity by examining the scientific information (and its regulatory context) federal websites make available to the public and their suitability for enhancing public understanding of and participation in environmental governance.

Stronger public information policies are necessary for stronger scientific integrity policies. This comment underscores that relationship by providing specific examples of federal website information management decisions during the Trump administration that were at odds with scientific integrity and undermined public trust. The website changes described here are just a few examples of more than 2,000 changes our team has documented over the last four and a half years, all of which are permissible under current information and scientific integrity policies.

This comment relays a series of recommendations to promote and protect the free flow of scientific information from the government to the public, and utilize websites as a vehicle for building public trust in the government by facilitating greater environmental, scientific, and civic literacy.

Relevant Findings: Disruptions to the Free Flow of Information

The majority of people accessing federal information do so through agency websites. While guidance exists for federal web infrastructure and the delivery of web services,² there is scant guidance regarding the content of web resources. This substantial gap in federal information policy leaves website content vulnerable to partisan political interference and breaches of scientific integrity and impedes the implementation of effective scientific integrity policies.

The Trump administration made dramatic and damaging changes to federal websites. In our study of more than 5,000 webpages across 13 federal agencies,³ we calculated that the use of the term “climate change” decreased by 38% between 2016 and 2020. These and other changes suggesting the suppression of climate change information occurred more frequently on cabinet-level agency websites, and on higher-visibility webpages that the public would be more likely to encounter. Additionally, as much as 20% of the Environmental Protection Agency (EPA) website was removed from public access. Science communication is an integral part of scientific integrity, yet there are no repercussions for failing to communicate relevant scientific information. Within the current information and scientific integrity policy landscape, agencies have license to shape a scientific topic’s narrative by simply removing the story altogether.

Many changes, such as the purging of the EPA Climate Change website, were broad information removals. In addition to these, we observed more targeted information manipulation. In a study examining significant changes to federal web resources specifically related to environmental regulations,⁴ we found that a full half of those changes were information removals, and 80% of those information removals occurred just prior to or during active regulatory proceedings.

Many of these website changes included the deletion of scientific information critical to understanding the purpose or effectiveness of an environmental regulation. For example, the EPA redirected its entire Clean Power Plan (CPP) website to a single, short webpage, entitled “Energy Independence,” about complying with former President Trump’s executive order requesting a review of the CPP. Prior to this change, the CPP website housed scientific and technological information geared toward a range of audiences, including introductory information about the impacts of carbon dioxide on the atmosphere, as well as effective strategies for power grid executives to reduce carbon dioxide emissions. Redirecting the CPP website to the Energy Independence page stripped this scientific and technological information from the public five months before the EPA officially proposed, and opened public comment, to repeal the CPP.⁵

Another prime example of foundational scientific information being divorced from regulatory information occurred with the Waters of the United States rule. The EPA’s Clean Water Rule (CWR) website had been a resource through which the public could build their understanding of a complex issue. Using text, graphics, and videos, the CWR website explained complex hydrology using basic terms. It also linked to a blog that summarized a study of results from more than 1,200 relevant peer-reviewed articles. This resource exemplified EPA’s scientific integrity goals regarding science communication for agency decisions. However, in May 2017, the CWR website redirected to a website entitled the Waters of the United States (WOTUS) rule website. The new website described the two-step regulatory process to repeal and replace the Clean Water Rule, without any information regarding streams, wetlands, water quality, or hydrology.⁶ This occurred more than two months before the EPA and Army Corps of Engineers officially proposed to repeal the CWR and invited public comment.

The WOTUS rule website later forwarded to the Navigable Waters Protection Rule (NWPR) website, which six months into the Biden administration now redirects to another WOTUS rule website with a similar structure and dearth of scientific information.⁷ One key difference is that on this website, there are still resources explaining the current implementation of the WOTUS rule (the NWPR).

There are other indications that under the Biden administration, agencies are taking science communications and scientific integrity more seriously. Within the first two weeks of the Biden administration, the EPA issued an update on its website explaining that the Toxicity Assessment for PFBS was “compromised by political interference,” removing the assessment in question and stating that the agency would review and potentially revise it. This is a step toward rebuilding public trust in federal science. It would be more transparent, however, if the PFBS toxicity assessment remained on the website with a banner stating the concerns about scientific integrity and details about the review process.⁸ Retaining historical records is important for building public trust.

Recommendations

Strengthening the effectiveness of scientific integrity policies relies on improving information policies. This includes creating policies that require both scientific and policy context to be communicated to the public, enhancing federal science communications to help people build scientific literacy, creating an archival record of evolving scientific understanding and policy context, and adopting a culture and practice of information care and maintenance.

Building public trust in the federal government will require the authentic facilitation of both public participation in and oversight of government processes and decisions. We respond to three topics distinguished in this Request for Information:

1. The effectiveness of federal scientific integrity policies in promoting trust in federal science,
2. Effective policies and practices federal agencies could adopt to improve the communication of scientific and technological information, and
5. Other important aspects of scientific integrity and effective approaches to improving trust in federal science.

However, we assert that effectively promoting trust in federal science requires these improvements in science communication and careful maintenance of accessible active and archival web content (which we describe under prompt 5).

Promoting Trust in Federal Science

At the most basic level, trust requires honest and extensive information. To promote public trust in federal science, we recommend the Office of Science and Technology Policy require federal agencies to create meaningful resources that expand civic and scientific literacy by communicating clear and visible links between existing and potential policies and their scientific bases. Ensuring relationships between regulations and their scientific context is essential for encouraging informed participation in regulatory decisions. We recommend:

- The scientific basis for proposed and existing regulations should be described on agency websites, including scientific evidence regarding the potential or actual impacts of regulations or their repeal.
- On all webpages with scientific subject matter, information regarding relevant upcoming regulatory matters should be posted, such that the public is made aware of opportunities for civic engagement in those issues.
- During active regulatory proceedings, no related public resources, including relevant scientific subject matter, should be removed from live agency websites.
- The regulatory history of an issue, including legal challenges and decisions that affected the implementation or efficacy of a rule, should be described on agency websites.
- There should be a mechanism, beyond automated surveys, for the public to provide critical feedback about information on agency websites, including perceived misrepresentations of scientific or historical matters.

Improving Communication of Scientific and Technological Information

The federal government has the opportunity to utilize its web presence to facilitate informal adult education, improving our nation's science literacy, and in turn, supporting democracy. There are several positive examples of federal websites that have curated resources that do this, such as the National Climate Assessments. However, far too many web resources consist of a three-sentence snippet of the most basic information about a subject and a link to a several-hundred page compendium of scientific information, with no support to move between beginner and expert information. To be useful vehicles for informing the public and for building public trust, resources should facilitate gaining greater understanding of

an issue. This includes understanding the context of the research and of its applications. We recommend that:

- A hierarchy of information should govern web resources. Agencies should provide ladders of information geared toward audiences with a variety of background knowledge, including general facts and guidance on topical landing pages, intermediate-level synopses of research findings, and specific scientific evidence. Each level of information should be easily navigated to from the others.
- Primary topical and landing pages should explain the relevance of related pages. It is insufficient to list several links without explaining their relevance.
- Research should be situated and contextualized. Study objectives, limitations, analogues, data provenance, and implications for each of these should be explained.

Other Important Aspects of Scientific Integrity

An essential element of scientific integrity is the stewardship of resources and the ethos of maintaining both accurate, up to date information and records of its development and evolution. With respect to web resources, information should be updated to inform the public of evolving scientific understandings, emergency situations, or policy updates, but a historical record of web resources should be archived in an accessible manner. Archival records, especially accessible on the web, are critical for the public to gain an understanding of evolving information and to exercise democratic oversight over agencies that serve the public interest. We recommend:

- Specific notice requirements should be established and implemented for any resource removals.
- Written explanations should be required for the removal of any web resource, and those explanations should be stored in a publicly accessible, searchable database on each agency's website.
- Descriptions of webpage content changes should also be required and included in the searchable database alongside resource removal explanations.
- To notify website users of recent changes, any webpage that has been edited within the last month should have a banner indicating such, and the URL for

any resource that has been removed should remain live for at least a month with the explanation for its removal presented at that address.

Conclusions

Better information policies are critical to upholding scientific integrity, building public trust in the federal government, and engendering broader and more democratic participation in setting the priorities and actions of the federal government. We have detailed a series of recommendations that stem from more than four years of research on federal agency communications, and look forward to further discussion and adoption of these principles.

References

1. OFFICE OF MANAGEMENT AND BUDGET. Policies for Federal Agency Public Websites and Digital Services. Nov 8, 2016. Available from: <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/m-17-06.pdf>
2. Digital.gov. Checklist of Requirements for Federal Websites and Digital Services. Available from: <https://digital.gov/resources/checklist-of-requirements-for-federal-digital-services/?dg>
3. Nost E, Gehrke G, Poudrier G, Lemelin A, Beck M, Wylie S, EDGI. (2021) Visualizing changes to US federal environmental agency websites, 2016–2020. PLoS ONE 16(2): e0246450. <https://doi.org/10.1371/journal.pone.0246450>
4. Gehrke G, Beck M, Paz A, Wilson A, Nost E, Poudrier G, EDGI. (2021) Access Denied: Federal Website Governance Under the Trump Administration. Available from: <https://envirodatagov.org/publication/access-denied-federal-web-governance-under-the-trump-administration/>
5. EDGI. Story of Clean Power Plan Website Removal Underscores Need for Better Information Policies. Nov 16, 2020. Available from: <https://envirodatagov.org/change-of-the-week-story-of-the-clean-power-plan-website-removal-underscores-need-for-better-information-policies/>
6. Gehrke G, Lave R. (2019) EPA Must Provide More Accessible and Informative Resources for Authentic Public Comment. Available from: <https://envirodatagov.org/wotus-rule-public-comment/>
7. Environmental Protection Agency. Waters of the United States Rule. Available from: <https://www.epa.gov/wotus>
8. EDGI. EPA Indicates Bold Support for Scientific Integrity on its Website. March 9, 2021. Available from: <https://envirodatagov.org/under-biden-the-epa-indicates-bold-support-for-scientific-integrity-on-its-website/>

Marian Keegan, R.F.

- Member of general public
- Senior Executive/Department Director for a 501(c)4 organization
- Member of Board of Directors for several non-profit organizations
- Employee of federal and state government agencies; academic research facilities; medium to large corporations; non-profit organizations; business owner.
- Candidate for State Representative

RE: The White House Office of Science and Technology Policy (OSTP) request for public comment on how to improve federal scientific integrity policy.

DATE: July 28, 2021

I've enjoyed a long and varied career in the applied and academic sciences. I have transitioned to management and most recently to politics. Scientific integrity is my hallmark, and I say with satisfaction that adhering to such principles has been a key to guiding my path. I've developed standards of practice that I applied to basic research, public scoping, decision-making, and accountability. These standards have been useful for creating value and sustainable operations. I support the Administration's efforts to raise trust in federal rule-making, decision-making and policy development after the previous Administration's actions that eroded trust and scientific integrity foundations. Therefore, I submit my comments with great interest and concern.

In my vast experience working for a number of organizations, I have found that some managers are better than others in recognizing the limitations scientists have in regards to organizational goals that conflict with scientific integrity principles. I've been in workplace situations where it seemed my only option was to resign when pressed by management to violate integrity. In other workplace situations, managers were better at explaining scientific procedures and progress in terms that relate to organizational goals. Establishing scientific integrity officials in federal agencies may be the avenue for managers, scientists, and the public to seek counsel and assistance for resolving conflicts.

I've held positions that invited and analyzed public input for organizational actions, and developed communication skills that honed listening and language abilities. Communicating with internal and external stakeholders should be accepted as integral to an organization's purpose. Also, the public has the right to access federal information not protected by other privacy rights. I know that accurately explaining science and data and projects and experiments is difficult, but necessary to transparency. My current organization and other organizations in this sector are learning to use social media and other communication channels, and are currently creating

personnel positions that are dedicated to prompt and accurate information sharing. Frankly, evidence-based communications are a body of skills that all stakeholders are asked to improve to ensure trust.

Scientists were very anxious after the 45th President was elected because they feared for the safety of their data. Science data has value. Preserving data that spans decades or centuries is very important. Scientists are personally invested in their data and quite willing to protect it, thus advancing scientific integrity. Attacks on science during the past 4 years of the prior administration has damaged federal agencies and employees. A thorough organizational review is healthy and justified. Emphasizing behavioral sciences and cumulative impacts will add scientific rigor to bringing equity to important issues such as diversity, voting rights, gun violence, opioid epidemic, COVID pandemic, wealth equity, healthcare, childcare, and other social and infrastructure needs that are important to the American people and healing a damaged country. I developed and implemented Environmental Assessments and Environmental Impact Statements for federal agencies and cumulative impacts is an effective way to holistically develop an organization's role and purpose, and see the long-term situation and impacts.

Careers in science need to be properly nurtured and guided so scientists can be employed, enjoy status in their communities, raise healthy families, and have productive lives. I've had to struggle through discriminatory employment practices, and have been brought to the brink of financial ruin more than once. It's no picnic in the park.

I run a department based on a model that hires contractors to fulfill the many and diverse natural resource and environmental needs of the organization. I consistently apply principles of integrity to guide and sustain relations between the organization and the contractors. I heartily support the federal government extending scientific integrity policies and procedures to contractors, including those that address grievances and violations.

My employment also seeks government and private grants to fund work, in addition to requesting organizational funds generated through member dues. As the administrator of grant contracts, I find it easier to apply scientific integrity when I can directly and accurately match the needs of the grant program to that of my organization. Being transparent about what the grant or agency seeks to accomplish can promote open communication with organizations applying for grants and other stakeholders.

My constant surveillance for political interference and vigilance in addressing it in my professional, personal and political life has sustained science as a driver for me. I anticipate rigorous oversight from the Biden-Harris Administration will protect federal science from political interference.

July 28, 2021

Eric S. Lander, Ph.D.
Director
White House Office of Science and Technology Policy
Executive Office of the President
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1650 Pennsylvania Avenue
Washington, D.C. 20504



Via Email: ScientificIntegrityRFI@ostp.eop.gov

RE: SI-FTAC RFI (Scientific Integrity Fast-Track Action Committee)

Dear Dr. Lander:

The Academy of Nutrition and Dietetics (the “Academy”) appreciates the opportunity to submit comments to the White House Office of Science and Technology Policy (OSTP) related to its “Request for Information to Improve Federal Scientific Integrity Policies” (the RFI) “to help improve the effectiveness of Federal scientific integrity policies to enhance public trust in science.”¹ Representing more than 112,000 registered dietitian nutritionists (RDNs), nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of food and nutrition professionals in the United States and is committed to accelerating improvements in global health and well-being through food and nutrition. Our members work in a variety of clinical, research, and community settings across the continuum of care and are committed to strong ethical standards, scientific integrity, and evidence-based policymaking.

A. The Academy’s Shared Commitment to Scientific Integrity

Scientific integrity is the backbone of research and there must be the highest ethical standards to uphold principles related to scientific integrity.² Maintaining objectivity of scientific endeavors is the cornerstone of the evidentiary quality upon which recommendations and guidelines should be based. The trust of the public and other stakeholders is dependent on the confidence in the integrity of processes of scientific discovery, review, data aggregation and publication. To that end, the Academy’s Council on Research and Board of Directors adopted six scientific integrity principles in 2015 to provide a unifying vision to which future policies can be compared and approved.³ The

¹ 86 Fed. Reg. 34064 (June 28, 2021).

² See, e.g., Integrity and Misconduct in Research: Report of the Commission on Research Integrity. Rockville, MD: Department of Health and Human Services [DHHS], 1995. 68 p.

³ Tappenden KA, et al. A Unifying Vision for Scientific Decision Making: The Academy of Nutrition and Dietetics’ Scientific Integrity Principles. *Journal of the Academy of Nutrition and Dietetics*. 2015;115(9):1486-1490.

principles of scientific integrity are intended “to ensure that scientific activities are funded, conducted, and disseminated in an ethical, credible, and transparent way.”⁴

The Academy’s scientific integrity principles are intended for nutrition and dietetics professionals to govern the ethical conduct of research and human subjects protection, publication of research, funder’s influence on research, funding of practice or public education, and the importance of absolute transparency while disclosing funding source and conflicts of interest (COI), (including perceived COI). We encourage you to review these principles in Appendix A, attached as requested in the RFI.

In addition, the Academy recognizes additional considerations that must be highlighted to ensure that equitable and ethical research is being conducted, specifically including the need to consider diversity, equity, and inclusion (DEI) at every stage of the research process, from bench to bedside. This DEI lens⁵ must be included across the research process continuum and should include awareness regarding researchers’ implicit bias, researcher diversity, how participants are being recruited, what data are collected, and how data are analyzed and reported back to stakeholders.⁶ Therefore, there is a need for additional policies to ensure that there is an acknowledgement and consideration for vulnerable and diverse populations that have many times been excluded in the research evidence.⁷

In 2019, a Scientific Integrity Consortium, comprised of U.S. government agencies, three Canadian government agencies, eleven professional societies, six universities, and three nonprofit scientific organizations, developed recommendations and best practices related to scientific integrity.⁸ These recommendations include providing training regarding appropriate research methods, strengthening oversight and transparency, and encouraging rigor and consistency for scientific integrity related policies among peer reviewed journals and the scientific community at large. Underscoring the recommendations were “two principles that represent the umbrella under which scientific processes should operate.... .
.: [First, f]oster a culture of integrity in the scientific process. [Second, e]vidence-based

⁴ *Id.*

⁵ A healthy equity lens was recently described as “the examination of who experiences the benefits and burdens of policies and programs as well as the basis for differential experiences.” (Eyler AA, Valko CA, Macchi M, et al. Adjusting the Equity Lens: Gaps in Addressing Health Equity in State Chronic Disease Prevention. *Health Equity*. 2019;3(1):86-91. doi:10.1089/heq.2018.0075. Published March 29, 2019. citing Pertillar T, Pobutsky A, Brandt G, et al. Assessment of funding and other capacity needs for health equity programming. *J Health Dispar Res Pract*. 2017;9(Special Issue):72–94.)

⁶ The Annie E. Casey Foundation. (2019). How to Embed a Racial and Ethnic Equity Perspective in Research: Practical Guidance for the Research Process. Baltimore, MD: Andrews, K., Parekh J., and Peckoo, S. Retrieved from https://www.childtrends.org/wp-content/uploads/2019/09/RacialEthnicEquityPerspective_ChildTrends_October2019.pdf.

⁷ Oh SS, Galanter J, Thakur N, et al. Diversity in Clinical and Biomedical Research: A Promise Yet to Be Fulfilled. *PLoS Med*. 2015;12(12):e1001918. Published 2015 Dec 15. doi:10.1371/journal.pmed.1001918.

⁸ Kretser, A., Murphy, D., Bertuzzi, S. *et al.* Scientific Integrity Principles and Best Practices: Recommendations from a Scientific Integrity Consortium. *Sci Eng Ethics* 25, 327–355 (2019). <https://doi.org/10.1007/s11948-019-00094-3>.

policy interests may have legitimate roles to play in influencing aspects of the research process, but those roles should not interfere with scientific integrity.”⁹

B. OSTP Requested Information

The Academy supports the “Administration’s goal to develop sound policy to make evidence-based decisions guided by the best available science and data, recognizing that scientific and technological information, data, and evidence are central to the development and iterative improvement of sound policies and to the delivery of equitable programs across every area of government.”¹⁰ In addition to issues of scientific integrity related to funding, we emphasize the importance of “regulatory scientific integrity, which encompasses how information is produced, collected, interpreted, and used by federal regulatory agencies.”¹¹ We agree that “political interference in the work of Federal scientists and other scientists who support the work of the Federal government and in the communication of scientific facts undermines the welfare of the Nation, contributes to systemic inequities and injustices, and violates the trust that the public places in government to best serve its collective interests.”¹² We respectfully offer comments below on the following requested topics, noting examples since January 20, 2017 as requested in the January 27, 2021 Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking and are constrained only by the page limits permitted for these comments:

1. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science

The Academy notes a number of serious lapses in scientific integrity during the relevant timeframe at many federal agencies, including:

- The Environmental Protection Administration (EPA), at which senior leaders “improperly meddled in the work of career scientists when reviewing the approval of certain pesticides in 2018, according to a new report and the agency’s own admission.”¹³

⁹ *Id.* at 327.

¹⁰ RFI at 34065.

¹¹ <https://legal-planet.org/2016/12/04/scientific-integrity-in-the-trump-administration/>

¹² RFI at 34065.

¹³ EPA Admits to Altering Science Under Trump, Pledges New Course. Government Executive (May 25, 2021). Available at <https://www.govexec.com/management/2021/05/epa-admits-altering-science-under-trump-pledges-new-course/174295/>, citing U.S. Environmental Protection Agency Office of Inspector General Report No. 21-E-0146. “EPA Deviated from Typical Procedures in Its 2018 Dicamba Pesticide Registration Decision.” May 24, 2021. Available at <https://www.epa.gov/sites/default/files/2021-05/documents/epaoig20210524-21-e-0146.pdf> (“The top officials changed and omitted items from documents related to the decision to grant licenses to three dicamba pesticides, the EPA inspector general found, and created a culture in which career employees felt “constrained” and “muted” from speaking up. In addition to violating EPA’s scientific integrity policies, the tampering left the agency vulnerable to lawsuits.”).

- The U.S. Department of Health and Human Services and the Centers for Disease Control and Prevention (CDC), in which political appointees pressured the CDC “‘from the top down’ to change coronavirus testing guidance”¹⁴ and insisted the CDC adjust its pandemic-related findings and recommendations, with one appointee stating “Nothing to go out unless I read and agree with the findings how they CDC, wrote it and I tweak it [sic]. . . .”¹⁵ A group evaluating the CDC scientific integrity policy recently found it “does not protect scientists from censorship or being pressured to alter their work. It also fails to grant scientists an unequivocal right to communicate with the press about their work without interference.”¹⁶
- The U.S. Department of Agriculture (USDA), in which the intentional¹⁷ recent losses of staff and infrastructure within the USDA Agricultural and Food Research Institute (AFRI) and Economic Research Service resulting from being moved from Washington, D.C. to Kansas City will have a rippling, crippling effect for years in the development of science in the areas of food and agriculture research. This loss will not only be incalculably devastating to the research needs for future iterations of the *Dietary Guidelines for Americans* and the health of the nation, it also will be woefully fiscally irresponsible to have decimated these offices and agencies by forcing an ill-considered relocation that results in mass retirements and resignations of some the nation’s leading scientists. One expert described the effort as “a move to cripple an institution that’s vital to the researchers in the U.S. and ultimately U.S. agriculture . . . [that] just hollows it out and weakens it.”¹⁸

We note that recent in-depth analyses have found that “existing policies and processes are not enough to protect federal scientists and their invaluable work[and that e]ven when agencies have strong written policies, implementation and enforcement often fall short.”¹⁹

¹⁴ CDC was pressured ‘from the top down’ to change coronavirus testing guidance, official says. CNN website (August 27, 2020). Available at <https://www.cnn.com/2020/08/26/politics/cdc-coronavirus-testing-guidance/index.html>.

¹⁵ Trump officials interfered with CDC reports on Covid-19. Dan Diamond. Politico (September 11, 2020). Available at <https://www.politico.com/news/2020/09/11/exclusive-trump-officials-interfered-with-cdc-reports-on-covid-19-412809> (“The health department’s politically appointed communications aides have demanded the right to review and seek changes to the Centers for Disease Control and Prevention’s weekly scientific reports charting the progress of the coronavirus pandemic, in what officials characterized as an attempt to intimidate the reports’ authors and water down their communications to health professionals.”).

¹⁶ Climate Science Legal Defense Fund. The Trump Administration’s Response to COVID-19 Violates Scientific Integrity. March 13, 2020. Available at <https://www.csldf.org/2020/03/13/the-trump-administrations-response-to-covid-19-violates-scientific-integrity/>.

¹⁷ Union: Mulvaney comments on USDA move to KC confirm ‘grand strategy’ to cut jobs. KSHB Kansas City (August 7, 2019). Available at <https://www.kshb.com/news/local-news/union-mulvaney-comments-on-usda-move-to-kc-confirm-grand-strategy-to-cut-jobs> (Former White House Chief of Staff Mick “Mulvaney said last week that the U.S. Department of Agriculture’s plan to relocate several hundred of jobs from Washington to the Kansas City area is ‘a wonderful way to streamline government.’”).

¹⁸ *Id.*

¹⁹ Strengthening Scientific Integrity at Federal Agencies. Center for Science and Democracy at the Union of Concerned Scientists. Available at <https://www.ucsusa.org/sites/default/files/2020-08/si-report-roadmap->

2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information and to address scientific issues and the scientific workforce

The RFI notes the importance of “[e]nsuring the independence, autonomy, and effectiveness of scientific integrity officials and chief science officers,” which the Academy believes is critical. We note the importance of ensuring agencies’ chief science officers (and those appointed to be chief science officers) meet the necessary academic qualification to perform their duties and maintain a commitment to evidence-based policymaking and scientific integrity.

The recent process by which the 2020-2025 *Dietary Guidelines for Americans* (DGA) was developed provides additional areas for potential improvement as well. The Academy reiterates our agreement with the National Academies of Sciences, Engineering, and Medicine that novel, substantial transparency is *especially* critical at the final stage of the process, when the agencies take the Dietary Guidelines Scientific Advisory Committee’s (DGSAC’s) scientific report and transform it into the official *Guidelines*. As the National Academies recommended, “The secretaries of USDA and HHS should provide the public with a clear explanation when the *DGA* omit or accept only parts of conclusions from the scientific report.”²⁰ In short, “To enhance the integrity of the process, every effort needs to be made to ensure that the *DGA Policy Report* is transparent about what decisions were made about the DGSAC’s conclusions, and the secretaries should explain why any deviations exist.”²¹

3. Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices

The Academy emphasizes the importance of ensuring U.S. Senate-confirmed appointees are leading agencies and subagencies to provide accountability, competency, and trustworthy leadership. In a survey of thousands of federal scientists conducted in 2018—years before the outbreak of COVID-19, “results indicate the significance of competent and trustworthy agency leadership as a contributing factor to federal scientists’ perception of agency scientific integrity.”²²

[for-science.pdf](#). Accessed July 26, 2021. (“To undo this damage and ensure that federal science can do its job effectively for all of us, it is crucial that federal agencies strengthen scientific integrity through actions including improved policies, educating workers about their rights and responsibilities, and open communication with the public. Congress should support this process by codifying scientific integrity standards into law and requiring all agencies to implement and enforce those laws.”)

²⁰ Redesigning the Process for Establishing the Dietary Guidelines for Americans. Washington, DC: National Academies Press (US); November 16, 2017. <https://www.ncbi.nlm.nih.gov/books/NBK469828/> ([emphasis added](#)).

²¹ Redesigning the Process for Establishing the Dietary Guidelines for Americans. Washington, DC: National Academies Press (US); November 16, 2017. <https://www.ncbi.nlm.nih.gov/books/NBK469828/> ([emphasis added](#)).

²² Goldman GT, Carter JM, Wang Y, Larson JM. Perceived losses of scientific integrity under the Trump administration: A survey of federal scientists. Vaismoradi M, ed. PLoS ONE. 2020;15(4):e0231929 (“These

Notably, additional training on or familiarity with federal scientific integrity policies is *not* guaranteed to ensure compliance in the face of intentional interference by incompetent or untrustworthy leadership. Documented violations of the EPA’s scientific integrity policy “did not occur due to a lack of awareness of or training on the agency’s scientific integrity policy,” according to Michal Freedhoff, principal deputy assistant administrator, Office of Chemical Safety and Pollution Prevention; he said, “It occurred because [the office’s] past senior leadership consciously chose to advance a policy outcome in a manner inconsistent with the scientific integrity policy.”²³

4. Other important aspects of scientific integrity and effective approaches to improving trust in Federal science

The Academy supports the work of the OSTP to coordinate an interagency task force to “improve scientific integrity and public trust in Federal science, including for proactively promoting rigorous, objective scientific research and streamlining implementation within and across Federal departments and agencies.”²⁴ We believe this work can help reduce the “considerable variability in [agencies’] implementation” of scientific integrity principles identified in a 2019 Government Accountability Office report.²⁵

In short, the Academy aligns itself with the commitment espoused by a recent administration when it developed and updated federal scientific integrity policies:

“The public must be able to trust the science and scientific process informing public policy decisions. Political officials should not suppress or alter scientific or technological findings and conclusions. If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking. The selection of scientists and technology professionals for positions in the executive branch should be based on their scientific and

findings suggest that enhancing scientific integrity at federal science agencies may necessitate competent and trustworthy leadership, a positive work environment for federal scientists and comprehensive scientific integrity policies and infrastructure.”)

²³ EPA Admits to Altering Science Under Trump, Pledges New Course. Government Executive (May 25, 2021). Available at <https://www.govexec.com/management/2021/05/epa-admits-altering-science-under-trump-pledges-new-course/174295/>.

²⁴ RFI at 34064.

²⁵ Scientific Integrity in the Federal Agencies: An Unfinished Agenda. Roger Pielke, Jr. October 26, 2020. Available at <https://rogerpielkejr.substack.com/p/scientific-integrity-in-the-federal>, citing Scientific Integrity Policies: Additional Actions Could Strengthen Integrity of Federal Research. Government Accountability Office report GAO-19-265 (April 2019).

technological knowledge, credentials, experience, and integrity.”²⁶

C. Conclusion

The Academy appreciates the opportunity to submit comments to the OSTP’s request for information on federal scientific integrity policies and strongly shares the administration’s commitment to evidence-based policymaking. we would welcome the opportunity to provide whatever input or assistance we can in this endeavor.

Sincerely,



Jeanne Blankenship, MS RDN
Vice President, Policy Initiatives and Advocacy
Academy of Nutrition and Dietetics



Pepin Andrew Tuma, JD
Sr. Director, Government & Regulatory Affairs
Academy of Nutrition and Dietetics

²⁶ <https://obamawhitehouse.archives.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09>

July 28, 2021

Dr. Eric S. Lander
Director
White House Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

Submitted via e-mail to: ScientificIntegrityRFI@ostp.eop.gov

Dear Dr. Lander,

CropLife America (CLA) and Responsible Industry for a Sound Environment (RISE) appreciate the opportunity to provide comments to the White House Office of Science and Technology Policy (OSTP) on its June 28, 2021, "Request for Information to Improve Federal Scientific Integrity Policies" (RFI) (86 Fed. Reg. 34064).

Established in 1933, CLA represents the developers, manufacturers, formulators, and distributors of pesticides and plant science solutions for agriculture and pest management in the United States. CLA's members produce, sell, and distribute virtually all the pesticide and biotechnology products used by American farmers.

RISE is a national trade association representing more than 220 producers and suppliers of specialty pesticide and fertilizer products to both the professional and consumer markets. RISE member companies manufacture more than 90 percent of domestically produced specialty pesticides used in the United States, including a wide range of products used on lawns, gardens, sport fields, golf courses, and to protect public health.

CLA and RISE members are leaders in the field, of science, technology, and innovation. Our members deploy scientific advances and technology to develop pesticide products that protect public health against vector-borne diseases and pesticides used for crop protection that are necessary to ensure safe, predictable, and adequate supplies of food, fiber, and fuel. Science, technology, and innovation are informing our members' response to changes in climate and weather patterns, helping them prevent and address disease and crop threats, and advancing the critical field of biotechnology and plant genetics to develop more resilient, healthy, and abundant crops. Advances in science and technology are key to strengthening food security and protection against emerging vector-borne diseases. Given that science and technology are fundamental to our products, CLA and RISE members have engaged in meaningful dialogue regarding scientific integrity with each Administration and intend to continue that dialogue well into the future.

In this RFI response, CLA and RISE draw upon experience with science-based Federal agencies, including the Environmental Protection Agency (EPA), the Food and Drug Administration, the National Marine Fisheries Service, the Fish and Wildlife Service, and the US Department of Agriculture (USDA).

1. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science.

Scientific integrity policies that support transparency, inclusion, and the opportunity to interact with scientific reviewers improves public trust in, and acceptance of the scientific analysis under which pesticide products are regulated, sold, and used. Federal policies should encourage science-based agencies to use plain and accessible language to describe the process used for considering sources of scientific data, as well as discussion of the robustness and level of certainty in the data, on which regulatory actions are based. Policies that support agencies providing clear and understandable descriptions of the risk assessment methods used, how they account for scientific uncertainty, and the criteria applied to balance risks will advance trust in the underlying regulatory decision.

These policies can also advance trust when they support transparent statements of where and how conservatism is included into agency scientific models, when modeling is used versus monitoring, and transparency around when and how data from stakeholders is incorporated into scientific risk assessments. Scientific integrity policies should support agency adoption and incorporation of emerging science and require that science-based agencies review and revise risk assessment models, tools, guidelines, and policies on a regular basis to reflect new developments in science and technology. Supporting agency establishment of criteria for considering emerging science, and clearly describing how advancements in science will be considered in risk assessments and regulatory actions, will advance public trust. Sharing information, data, expertise, and methods between science-based Federal agencies also advances scientific integrity. For example, CLA and RISE support the historic collaboration between USDA's Office of Pest Management Policy and EPA's Office of Pesticide Programs.

2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information.

Clear and concise communication of scientific and technical information advances scientific integrity and is essential to building awareness and understanding of Federal science. Translating complex scientific work into accessible web pages, fact sheets, and social media posts requires training in risk communication, data visualization, and infographics. CLA and RISE support practices that promote hiring science and risk communication professionals into science-based agencies, as well as policies to make risk and science communication training a requirement for a wide range of agency employees. Such training can advance scientific integrity by increasing the ability of agency experts at all stages of their careers to be able to answer questions, explain decisions, and increase trust in agency science before a variety of audiences.

By hiring experts in risk and science communication and making training for these experts readily available, Federal agencies can further establish themselves as science communication leaders. The importance of the Federal workforce having these skills is elevated by advances in GPS mapping, biotechnology, nanotechnology, and other high science approaches in modern pesticides in crop fields and in the protection of public health. CLA and RISE commend EPA's current efforts to gather input and information on the use of emerging technologies in pesticide application through the Pesticide Program Dialogue Committee.

3. Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce.

Science-based Federal agencies need to be charged and equipped with enhancing a culture of scientific integrity. CLA and RISE suggest these agencies retain and expand existing policies that require routine scientific workforce training on scientific integrity principles. This training should be accompanied by consistent messaging from top agency leadership on the importance of scientific integrity. The very

definition of scientific integrity should be broad enough to encompass not only internal interactions between management and scientists but also to include the interface with third parties.

Policies, practices, and funding priorities should support the scientific workforce attending educational programs to obtain experience with and exposure to emerging scientific tools and developments. This training and exposure also will promote the retention of scientific talent. CLA and RISE support the many excellent training programs that exist through academic partnerships, internal agency mentorship and coaching programs, and opportunities for Federal scientists to detail to other science-based Federal agencies.

In addition to prioritizing the hiring of risk and science communication experts, CLA and RISE support policies to advance the hiring and retention of leading scientists and researchers. Retention is advanced through careful succession planning, capturing knowledge prior to retirement or departure of key scientific staff, investment in training and education to retain experienced staff, and robust recruiting efforts that attract leading scientists and researchers to Federal service. When the Federal workforce consists of leading scientists and researchers, trust and integrity are advanced.

Of similar importance are policies and funding that prioritize the acquisition by science-based agencies of the latest technologies and tools to perform their core regulatory and enforcement functions. This includes policies emphasizing the importance of conducting independent verification, validation, and peer review of the procedures, measures, methods, or models used in the development of agency science-based policies. The technological capability of science-based agencies should be on par with the private sector and with global trading partners, and the acquisition of cutting-edge technology will ensure that U.S. science-based agencies are global leaders in science and technology.

Policies that promote proactive hiring and retention, as well as cutting edge tools and technology, will also ensure that agencies are resilient and equipped to adequately respond in states of emergency, such as the recent pandemic. Following the onset of the SARS-CoV-2 virus, EPA scientists evaluating anti-viral pesticidal products were stretched extremely thin and working non-stop to respond to the volume of applications for novel disinfectant product review. Their role was important to ensure that effective products entered the marketplace to help the nation respond to the virus, as well as to keep fraudulent and ineffective products out of commerce. As the pandemic has continued, the need for policies fostering a robust scientific workforce becomes even more imperative to our nation's resiliency in times of crisis.

Finally, policies that support the development of leadership skills, especially scientific leadership, are essential at science-based regulatory agencies. When the concept of being scientific leaders is core to workforce value, and training and investment in cultivating that value is available, scientific integrity is inherently advanced.

4. Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices.

Practices that foster a work environment where healthy scientific dialogue takes place, including disagreements in the science, also advance integrity. Policies that allow regulatory decisions to be made based on the best available science at the time and regularly reviewed as new data becomes available, will help improve transparency. Training on properly documenting scientific and regulatory decisions will help improve transparency and increase the public's understanding of agency decisions.

5. Other important aspects of scientific integrity and effective approaches to improving trust in Federal science.

Peer review panels are a critical additional source of scientific expertise for Federal agencies. We support scientific integrity policies that recognize that scientists from all backgrounds—non-governmental organizations, academia, and industry—are valued in peer review and that bias will not be presumed by virtue of the scientists' employer. Policies supporting balanced peer review panels that consist of a breadth of expertise with scientists from all backgrounds will advance trust in their work.

Thank you for the opportunity to comment on these important issues. Should you have any questions about, or wish to have further information on these comments, please contact us.

Respectfully,



Chris Novak
President and CEO
CropLife America



Megan Provost
President
RISE



July 27, 2021

Office of Science and Technology Policy
EEOB
1650 Pennsylvania Avenue, NW
Washington, DC 20504

RE: SI-FTAC RFI

To Whom it May Concern:

IEEE-USA appreciates the opportunity to provide thoughts on steps the OSTP can take to improve scientific integrity.

IEEE is the world's largest technical professional society, representing nearly 400,000 technology professionals world-wide. Our members include computer programmers, aerospace engineers, electrical engineers, and many other types of experts involved in the electro-technology fields. IEEE's library of technical publications, IEEE Xplore, contains over 5 million documents, including many of the seminal works on technological innovation. IEEE is also one of the world's leading standards organizations, with a portfolio of nearly 1,200 active technology standards. Since its founding by Thomas Edison and Alexander Graham Bell, IEEE has sat squarely at the center of technological innovation, first in the United States, and now worldwide.

IEEE members understand the importance of research to the innovation process. They also understand that the American economy is increasingly built on technological innovation and scientific inspiration. As such, it is essential that the public trust in those innovations. Instances of fraud and unethical behavior by those responsible for conducting research, while rare, undermine that trust and thereby weaken the foundation upon which American prosperity is built.

Because of this, it is important that the federal government take steps to strengthen engineering and scientific integrity. OSTP is uniquely placed to lead those efforts.

However, it would be a mistake to assert that it is OSTP's job alone to enforce scientific integrity measures. OSTP's reach is limited, as are the tools it has at its disposal. Ensuring that research is honest, accurate, and ethical is the responsibility of everyone in the research ecosystem, not just the government.

OSTP's most useful role, in general, is as a convener – that is, OSTP can pull the far-flung parts of the federal government together in a coordinated way, bringing the massive resources of the federal government to bear in tackling difficult problems.

OSTP has been playing that role to enhance research integrity for more than a decade. As noted in the RFI, government research agencies have already adopted rules to strengthen research integrity as a result of past OSTP efforts. This was a necessary and important step towards creating both formal rules and, perhaps more importantly, cultural norms within the federal research system that enhance research integrity.

Having created these rules, the next step would be to standardize, clarify, and publicize them. While integrity rules are relatively consistent across federal research agencies, they are not identical. That is to be expected, but it also creates confusion. OSTP can play a useful role helping agencies standardize their rules so that every federal



researcher faces the same rules regardless of which agency or agencies they are working with. This would also make the rules easier to enforce.

A standard set of federal research integrity rules will also be easier to promote. Different rules at different agencies makes it hard to discuss those rules without getting caught up in the differences between them. One set of rules for the whole government would make it much easier for researchers and those researchers' professional societies to focus on the intent of the rules, rather than nuanced differences across agencies.

It is important to note, however, that the OSTP is limited in what it can do on its own. OSTP, for example, has limited authority over privately funded research, which represents the majority of research spending in the United States. The integrity of this research is at least as important to society as federally funded research. Similarly, OSTP has limited authority over state-funded research, which is becoming an increasingly important part of the public research world.

On the other hand, there are a host of organizations outside of the government which are already working in this space. These organizations play a crucial role in enhancing research integrity across entire professions, and have been doing so for decades.

Professional societies, like IEEE, exist to help specific parts of the American workforce succeed. Among our responsibilities is enhancing our members' professional qualifications, which includes helping them understand how to do their job properly. IEEE's efforts to provide continuing education for our members extends well beyond exposing them to the latest technology. It includes helping them understand the ethical obligations that come with their work, and the impact their work will have on society.

OSTP's greatest strength is its ability to pull together different groups to achieve a common aim. In the integrity space, this ability has been mostly used to pull together the federal research agencies to adopt rules enhancing research integrity. OSTP should now use this ability to bring the private-sector into the discussion by partnering with professional societies to promote integrity-enhancing policies across, not just the federal government, but all of American society.

Societies like IEEE already play a central role in promoting professionalism within our membership. Moreover, as voluntary associations we are better positioned to create informal cultural norms of behavior that, ultimately, may be more important to preventing ethical lapses than formal rules and regulations.

IEEE has been promoting technical professional integrity since very early in our history, which began in 1884 at the start of the electro-technology revolution. We have at our disposal a host of tools that can be used to improve the integrity of technological research – in fact, that's what they have been doing since the beginning.

PUBLICATIONS:

As OSTP has noted, dissemination of research findings is an important part, perhaps the most important part, of the research process. Technological and scientific discoveries build on each other, but only if the results of research are shared widely and quickly. Technical publications exist to disseminate findings. Within IEEE, our 200 journals and library of 5 million technical articles are among the most read and cited technical publications in the world.

Beyond spreading new ideas, not-for-profit publishers like IEEE also play a crucial role in validating and enhancing the quality of those ideas, which includes protecting against unethical behavior. These include:

Peer-Review: The first line of defense against dishonest research is the peer-review process. Prior to publishing technical findings, researchers must submit their results to a panel of their peers who are empowered to assess if the results are reasonable. Peer-review panels consider the validity of the research process, examine checks researchers put in place to protect against bad results, consider the results relative to previous work, and evaluate the legitimacy of the researcher's conclusions in light of the experiments they conducted. Reviewing other researchers' work is a vital and necessary part of a professional's career, and of the research process itself. It is also the best defense against sloppy work, invalid research methodologies, and flawed findings.

Non-profit publishers like IEEE invest considerable financial resources, time, and energy in creating and empowering peer-review panels. Reviewers are not compensated for their work (which can be substantial), but rather volunteer to serve out of a sense of professional responsibility and a sincere concern for research accuracy and integrity.

Importantly, peer-reviewers act out of a sense of responsibility for their fields of research. Their loyalty is, usually, to their profession – which is also where the loyalty of not-for-profit associations lays. IEEE is able to find hundreds of engineers and scientists each year who are willing to devote many hours of work to reviewing research without any specific return primarily because we are seen as being devoted to promoting their profession. In other words, because we are allied with them, IEEE and other not-for-profit associations are able to marshal the army of volunteers required to maintain the extensive peer-review system that has been built up around the globe over the past 200 years.

More than 200,000 scholarly journal articles and over 300,000 conference papers are sent through formal IEEE peer review processes each year, and that number continues to grow substantially. In addition to requiring thousands of reviewers themselves, this effort also involves hundreds of editors, professional staff, and significant expenses in software and systems to operate, secure, and police the process.

Partnering with professional societies may allow OSTP to tap into this network to promote research integrity, but it is unlikely that OSTP could replicate our existing networks primarily because the government sits outside of our well-established professional communities.

Reproducibility: The scientific method requires that researchers publish the results of their work not only to spread those discoveries, but also to allow other researchers to replicate their results. This is essential to verify that the first researcher's results were not just the result of random chance, measurement errors, biased samples, or other research errors. Replicating other researcher's work is also an important check against research integrity. History has shown that dishonest researchers can fake research and research results, but they cannot fake results obtained by other researchers who try to replicate their experiments. In fact, a number of major cases of research fraud have been uncovered in exactly this way.

The federal government has recognized the importance of reproducing research and has invested in efforts to improve research reproducibility.

IEEE has also invested heavily in our own efforts to make it easier to reproduce research by extending the archival published research record beyond technical papers to include software and datasets. These tools have led to the creation of virtual laboratories in which, at the click of a mouse, software-based simulations can be immediately run to reproduce results.

Reproducing research demands work that is often under-rewarded in academic settings. By definition, reproducibility involves research that does not rise to the level of novelty that many scientific publications require. Such follow-on work also drives little commercial interest or revenue for for-profit publisher. Not-for-profit publishers are, therefore, key participants in advancing reproducibility in science, and IEEE is seeking ways to encourage this necessary work and to provide appropriate publishing outlets for the results.

Validating: Perhaps most importantly, not-for-profit publishers have a unique ability to independently assess the validity of published works for the purpose of detecting fraudulent or flawed papers. IEEE publications are only as valuable as the quality of work in them. This gives us a strong motivation to ensure that only the highest quality research papers are published. Moreover, we are able to respond aggressively to papers that don't meet our standards. We can remove papers found to be lacking, and can exclude researchers from future publications when we find fraud or other deliberately unethical behaviors. And we do.

Most importantly, the government simply cannot play this role alone. Should questions be raised about the work of a government researcher, any response taken by the government would have to use legal channels, which are cumbersome, expensive, and slow. There are times when this is helpful, and subjecting researchers to legal consequences for deliberate fraud is both appropriate and is a valuable deterrent. But the government cannot act as quickly or definitively as professional societies and has less authority over researchers in the private sector.

Adjudicating Disputes: Technical publications play the key role in settling professional disagreements between researchers by providing a neutral forum to present their evidence. Scientific truths must always be tested, no matter how well-established they are. Technical journals have been providing a means to do this for hundreds of years. As the pace of discoveries continues to increase, this role will only become more important. By encouraging federal researchers to engage in these debates, to question scientific truths, and challenge new claims, OSTP can help improve the quality and effectiveness of scientific disagreements.

Archiving and Preservation: Accurately preserving the history of ideas is vital to understanding contemporary standards and behavior. Like other professional societies, IEEE considers the preservation of the technical scientific record as part of its core mission and is dedicated to archiving practices regardless of their ongoing commercial value.

PROFESSIONAL ETHICS:

Unethical behavior is, unfortunately, not only found in the publishing world. Maintaining the public's trust in technology and scientific discoveries requires proper professional conduct throughout individuals' professional careers. Here too, professional societies have a powerful role to play, especially when paired with government action.

IEEE, like many other professional societies, maintains a Code of Ethics that seeks to hold IEEE members to a high standard of professional behavior. As a voluntary association, we have a greater ability to enforce ethical rules because our members have chosen to join our organization. They have voluntarily chosen to submit to our ethical rules, which were created and are enforced by their peers. Because of this, private associations have far greater freedom to act than other parts of the technological and scientific community.

Our Code of Ethics extends beyond basic legal norms and requirements that the law not be violated. It includes an expectation that IEEE members will consider the impact of their work on society and prioritize the public's safety in

their work. IEEE members, for example, are required, as a condition of their membership, to treat others respectfully and not discriminate. These are broad rules that extend beyond the more rigid and narrow laws controlling researchers' behavior.

Companies, universities, and the government can, and should, demand high ethical standards, but are limited by the necessarily legal nature of enforcement efforts. Companies are limited in how they can respond to unethical behavior from their employees and will often prioritize the company over either the profession or broader society. Professional societies, on the other hand, have much more latitude to enforce voluntary codes of conduct that extend beyond strict legal rules, and we have a clear motive to do so as unethical behavior harms our members. Ensuring that the public holds our members in high esteem and trusts their work is necessarily a priority for IEEE, which makes our Code of Ethics a priority as well.

NORMS of BEHAVIOR:

The true value of voluntary and enforceable Codes of Ethics, like those maintained by IEEE and most professional societies, is not in enforcing the rules or punishing those who violate them. This is important but represents a failure of the real purpose of voluntary codes of behavior, which is to establish behavior norms for our professions that prevent violations in the first place.

Norms, by definition, are not hard and fast rules, but rather broad expectations that communities apply to themselves. Professional societies are uniquely able to create and enforce these expectations specifically because societies are run for and by professionals. We are in the business of creating communities, and the rules that govern them. Formal and informal rules of behavior create expectations that, in time, can define a profession for its members in ways that laws or regulations simply cannot.

For example, IEEE members are required, as a condition of their membership, to avoid soliciting or accepting bribes. While this is a common-sense rule in the United States, it may not be in other parts of the world. But to be an IEEE member, engineers cannot accept bribes even if bribes are acceptable in their country. Similarly, IEEE members are expected to prioritize public safety, even if an individual's employer tells them to prioritize profits.

RECOMENDATIONS

Maintaining the integrity of technological and scientific research is a vitally important job, one which OSTP cannot do alone. Partnering with professional societies would allow the Office to leverage the unique role societies play in the STEM world to accomplish much more than the government can do on its own. IEEE recommends that OSTP take the following actions to promote a stronger partnership between professional societies and the federal research enterprise.

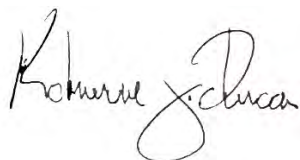
- Encourage active membership in professional societies. Federal employees and researchers should be encouraged to join the appropriate society for their field. Membership in professional societies promotes leadership and professional training, but also encourages ethical behavior. Broader membership would help extend ethical norms more deeply into the research ecosystem.
- Encourage federal researchers to play roles in technical publications and conferences. Federal researchers have important roles to play in helping to disseminate discoveries and ideas. Technical publications and conferences are the primary way these ideas are transmitted to the broader engineering and scientific communities, and the public.

- Encourage technical societies to develop, publicize, and enforce strong codes of conduct for their members. OSTP can utilize its ability to convene experts to help professional societies voluntarily strengthen their codes of ethics by learning best practices from each other. OSTP can also assist smaller societies in creating enforceable codes of conduct.
- Highlight efforts to promote research integrity by professional societies. Individual scientists and engineers devote considerable time and energy to enforcing and promoting the integrity of their work. Peer-review efforts alone consume tens of thousands of hours of volunteer time annually. These efforts are essential, but the public rarely hears about them. OSTP is much more able to educate the public about the research process than are individual societies. The Office has a unique role to play in working with the press to help the public understand the research process, and the work being done to protect it.

OSTP's role in educating the public is likely to become more important as time goes on. Engineering and science are both becoming more complicated and specialized every day. This makes it harder for the average person to understand both technology and science. Over time, cutting edge engineering and science will likely become ever more incomprehensible to the public, which, in turn, will make efforts to promote public trust in STEM research ever more important.

Professional societies, including IEEE, know this and are already working to highlight the great work being done by our members, but more is needed. Institutions, processes, and rules that promote research integrity need to be strengthened, and these efforts need to be communicated to the public. The role of peer-review, for example, in the scientific process is much easier for the public to understand than is many of the papers that are being reviewed. Helping the public trust the research process will help the public trust the research itself.

Sincerely,

A handwritten signature in black ink, appearing to read "Katherine J. Duncan".

Katherine J. Duncan, PhD
President, IEEE-USA

I am an educational psychologist who has spent my entire career helping faculty particularly in the STEM disciplines and the Health Sciences to teach better, as well as teaching in higher education. We often tell students to look at US government sites, such as CDC, EPA, NASA, DOI, etc. for accurate and up-to-date information because they should be trusted. However in the past four years both scientists and the lay public have lost their faith in what was published on government websites about scientific information particularly as it relates to climate change and the pandemic. Scientists always rely on evidence- based practice that includes data and how the data was analyzed to reach conclusions. When data are missing we cannot trust the conclusions or recommendations. The United States government and all its agencies must never misuse science or prioritize private interests over the public good.

It is unfortunate the students and the general public can no longer rely on the accuracy of information on US agency websites and have turned instead to websites from Canada and the European Union, private foundations and professional associations for more accurate information. Yet the implications are even worse for policy makers. Policy makers rely on information provided to them from government employees. These government employees must be experts in their own field, and they must have buy to buy a higher standard of morals and ethics. they should not be biased by a political orientation

Here are a few concrete suggestions:

- 1) To promote and establish trust once again in science and particularly in the scientists at the at the federal level, we need high and enforced standards of scientific integrity. Science should and does inform agency decision making and policies. Good science must be as unbiased as possible, and the science itself should be independent—in other words, free of political, ideological, or financial influence. Independent science helps our government make informed decisions to protect public health and safety, especially as they relate to climate change and the pandemic. people who work in federal agencies should be appointed to positions because of their credentials work experience and not because of their political views.
- 2) Scientists at federal agencies deserve because of their expertise. They need total protection from political interference. Without these protections, federal scientists can be, and have been, professionally undermined and scientific integrity can be lost.
- 3) Invest in a robust federal workforce that is diverse in expertise, experience, race, ethnicity, gender identity, and sexual orientation. However expertise must be the most important criteria for why people get hired. When I was in Graduate School the best students were hired by the federal government and that was an excellent career choice. Over the years working for the government has lost much of its prestige and in fact many excellent career scientists have left the federal government to work for

foundations corporations universities at non - profit organizations. Make scientists proud to work for the federal government again.

- 4) All Federal employees, including scientists and non-scientists who manage, supervise, and communicate scientific work should receive educations around scientific integrity.
- 5) Educate the public in ways that they can understand the information. this information should be conveyed accurately and consistently and without a political bias. Use varied venues such as social webinars public websites town hall style meetings to reach many audiences. information needs to be translated into several languages especially Spanish. Use graphics extensively
- 6) Involve communities, especially those most impacted by pollution, health issues in decision making earlier and more effectively, especially marginalized communities and those most likely to be affected by new or revised rules. the public comment period should become a two- way dialogue between agencies and the public
Make the public comment process more inviting and less intimidating for ordinary people.

Thank you for your consideration of my thoughts.

Sincerely,

Phyllis Blumberg, PhD

Retired professor of psychology and former Assistant Provost for Faculty Development
Concerned citizen and organizer

July 28, 2021

TO: Scientific Integrity Fast-Track Action Committee (SI-FTAC)

Effective policy making in the public interest relies on independent scientific research and data. The use of objective science, coupled with respect for experts, not only makes policies more robust but also strengthens the government's legitimacy and builds public trust in agency decisions. As advocacy organizations, ranging in expertise from scientific to government transparency and labor, we submit this joint comment for consideration.

We applaud the Office of Science and Technology Policy for leading work to help restore trust and improve the use of science in government decision-making by helping agencies strengthen scientific integrity policies, including by issuing the Request for Information to Improve Scientific Integrity Policies. Our organizations offer several recommendations to assist these efforts.

In 2020, many of our organizations endorsed recommendations to help the next administration strengthen scientific integrity at federal agencies. The endorsing organizations represent a wide range of issue areas—and share a commitment to ensuring that US policy and decision-making are informed by scientific evidence and the best available data. [*Restoring Science, Protecting the Public: 43 Steps for the Next Presidential Term*](#) contains 43 recommendations in the following areas:

- Establishing better ways for the government to receive science advice
- Ensuring federal agency leaders are qualified, ethical, and accountable
- Promoting the independence of federal government science and scientists
- Ensuring relevant federal agencies can effectively use and produce science to meet their public service missions
- Helping civil servants and contractors feel safe reporting agency shortcomings
- Ensuring public and policymaker access to independent science
- Providing public access to data collected by the federal government
- Invigorating the role of independent science in the regulatory process

We are pleased that the Biden administration has already undertaken several of the recommended actions in this report, including undoing several harmful actions of the previous administration and launching the process to strengthen scientific integrity policies. Below are recommendations from [*Restoring Science, Protecting the Public*](#) that are relevant to the RFI. We collected the most relevant recommendations from the eight issue areas above that fall into three categories: scientific integrity policies and practices, promoting transparency and restoring public confidence in agencies, and ensuring public access to data.

I. Recommendations regarding scientific integrity policies and practices

The “Agency Scientific Independence” memo of [*Restoring Science, Protecting the Public*](#) contains several recommendations related to scientific integrity policies and officials:

- 1) OSTP should require that scientific integrity policies include provisions that:

- Protect the right of scientists to share scientific data and analysis with the public and lawmakers free from political interference and filters, and to review content that will be released publicly in their names or that significantly relies on their work.
 - Explicitly prohibit retaliation against government employees who raise concerns about scientific integrity or offer scientific opinions that differ from those of the administration or their agency.
 - Provide a clear, detailed policy and procedure for addressing allegations of scientific integrity violations, including appeal rights, and for publicly reporting their resolution.
 - Specify that media policies allow scientists to share their expertise without political vetting, and advance other initiatives to improve scientific communication.
- 2) Scientific integrity officials at each agency should develop an agreement with the agency's inspector general on addressing misconduct and work with OSTP on cross-government coordination of scientific integrity practices.

II. Recommendations to promote transparency and restore public confidence in agencies

Several recommendations from [*Restoring Science, Protecting the Public*](#) aim to promote transparency and restore public confidence in agencies. Recommendations for agencies include:

- 1) Give the public access to research, sources, and correspondence involving political appointees (including meetings, telephone calls, and emails) that informed the rulemaking process. (See "Regulatory Reform and Science" for details.)
- 2) Allocate sufficient resources to substantively respond to FOIA requests in the time frames mandated by law, develop technology to streamline the FOIA process, and rescind rules that authorize the involvement of political appointees in the FOIA response process. (See "Data Collection and Dissemination.")
- 3) Establish a presumption that agency leaders' calendars will be publicly disclosed on a monthly basis, except for items subject to Freedom of Information Act (FOIA) exemptions. (See "Federal Personnel Policy.")
- 4) Allocate grant funding based on evaluations by experts with relevant qualifications, in response to criteria that are publicly available. (See "Agency Scientific Independence.")
- 5) Improve transparency and accountability around federal advisory committees (see "Federal Advisory Committees"):
 - Publish clear criteria for nominating and selecting qualified committee members, prohibiting current members from having veto power over candidates.
 - After selecting the first round of candidates for membership, make that roster public and request comments.

- Identify and make public the process used for committee formation, including how agencies screen members and assess committees for balance.
- Publish background information on each committee member on a public online portal (e.g., integrity.gov), including information on qualifications, employers, and funding sources for the previous five years, along with any conflict-of-interest waivers granted.
- When allowing federal advisory committees to expire, archive their websites and all related documents so agencies and the public can still access the information.
- Establish a process for dealing with complaints regarding federal advisory committees.

III. Recommendations for ensuring public access to data

The “Data Collection and Dissemination” section of [*Restoring Science, Protecting the Public*](#) contains several recommendations for ensuring the public can access government data:

- 1) Establish standard procedures for the collection, disclosure, and maintenance of data. Specify that research and data that are digitally formatted and in the public domain are to be made available online and freely accessible to the general public, to the extent permitted by law and with protections for intellectual property rights and other proprietary interests and for the confidentiality of individuals about whom data has been collected.
 - To the extent permitted by law, open data formats should be used that are nonproprietary and publicly available, with only the minimal necessary restrictions upon their use.
 - Full public access to government-supported publications’ metadata should be ensured without charge upon first publication.
 - Federal agencies should encourage technical and legal interoperability to facilitate international sharing of government-supported scientific data, using compatible, publicly available, open-source formats.
- 2) Require agencies to establish safeguards against the removal of government research and data, including (as required by statute) giving the archivist of the United States advance notice of planned data removal.
- 3) Create an enforcement mechanism to ensure compliance with public access requirements, along with remedies for noncompliance (for example, disclosure and restoration of the improperly withheld information, as well as penalties).

[*Restoring Science, Protecting the Public: 43 Steps for the Next Presidential Term*](#) also contains recommendations on budgets, whistleblower protections, regulatory processes, and personnel policies that are less relevant to the RFI but that address ways that the federal government can advance scientific integrity.

Several of our organizations also contributed to [agency-specific recommendations](#) that identify top priorities for several agencies (Department of Agriculture, Department of Health and Human Services, Department of the Interior, Environmental Protection Agency, National Oceanic and

Atmospheric Administration Occupational Safety and Health Administration, Mine Safety and Health Administration, National Institute for Occupational Safety and Health, and Office of Science and Technology Policy) to adopt to advance scientific integrity and science-based public policies. Each of these memos begins with a brief overview of the scientific integrity issues that the agency faces and short descriptions of between two and five priority areas, followed by a list of specific actions recommended. As agencies undertake the process of updating their scientific integrity and policy practices, we encourage OSTP and each relevant agency to consider these recommendations.

We commend the efforts of OSTP to seek out public input on scientific integrity. We urge that you make all comments submitted in this comment period publicly available in a public docket or some other format that allows the public to view all submitted comments.

Submitted by:

American Geophysical Union
Climate Science Legal Defense Fund
Free Government Information
Government Accountability Project
Government Information Watch
Jacobs Institute for Women's Health
National Nurses United
Open The Government
Union of Concerned Scientists

Association of Research Libraries Comments on US Office of Science and Technology Policy Request for Information to Improve Federal Scientific Integrity Policies

July 28, 2021

The Association of Research Libraries (ARL) thanks the US Office of Science and Technology Policy (OSTP) for the opportunity to submit comments on improving federal scientific integrity policies. ARL is a nonprofit membership organization of 125 research libraries in the United States and Canada whose mission is to advance research and learning through equitable, enduring, and barrier-free access to information.

Our member libraries, which include academic libraries along with federal and large public libraries, are key stakeholders and infrastructure partners in building a culture of evidence within the US scientific enterprise. With a long-term commitment to equity, data and information curation, discovery, and stewardship, research libraries promote standards and policies for persistence, provenance, and authority necessary to maintain trust in science. These comments mainly address specific data and information management practices that improve discovery, interoperability, and long-term access which contribute to trust in scientific research. They also align with Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities through the Federal Government¹.

ARL represents its membership as stakeholders in engaging with US federal agencies as they develop policies and plans to improve scientific integrity. Our member libraries are often instrumental in engaging their local communities as institutional constituents and partners in research. And within their institutions, research libraries also teach and support practices to advance rigor and reproducibility in scientific research. Research libraries are key infrastructure partners in building a culture of evidence in US scientific research.

I. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science

ARL applauds the work of OSTP and federal agencies in the development and implementation of policies to promote trust in federally funded science. OSTP has been instrumental in promoting policies and practices to advance scientific integrity, including the 2013 memo on *Expanding Public Access to the Results of Federally Funded Research*² and the 2009 presidential memo *Scientific Integrity*.³ These directives have strengthened federal funding policies, ultimately increasing the availability of open data, software, and code. Additionally, the work of OSTP on *Desirable Characteristics of Repositories for Managing and Sharing Data*

¹ Advancing Racial Equity and Support for Underserved Communities through the Federal Government, 86 FR 7009 (Jan. 25, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01753.pdf>.

² "Expanding Public Access to the Results of Federally Funded Research," the website of the White House, President Barack Obama (archived), February 22, 2013, <https://obamawhitehouse.archives.gov/blog/2013/02/22/expanding-public-access-results-federally-funded-research>.

³ "Memorandum for the Heads of Executive Departments and Agencies 3-9-09," the website of the White House, President Barack Obama (archived), March 9, 2009, <https://obamawhitehouse.archives.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09>.

*Resulting from Federally Funded Research*⁴ surfaced critical criteria for ensuring that locations where data is shared are sustainable and reputable.

II. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information

Scientific advancements come from research that is repeatedly tested and made available for further analysis. To accelerate this process, ARL further recommends that federal agencies consider the following practices to expand access, enhance scientific integrity, and increase trust in research. Where practicable, ARL recommends harmonization of policies across agencies to minimize compliance burdens on investigators and research institutions.

Access

- **Making research outputs publicly available as soon as possible:** ARL is pleased to see the Biden-Harris Administration state its commitment⁵ to make the results of federally funded research available and useful for the public, industry, and the scientific community in a timely manner. To demonstrate the utility and necessity of the federal public access plans required by the 2013 OSTP memo, and the role of these plans in the scientific enterprise, OSTP may wish to collaborate with federal agencies to gather data on the budgetary impact of federal public access policies, and how these policies advance research on key challenges such as health, climate change, and social inequality. ARL has recently received funding from the National Science Foundation to work with a group of institutions and disciplines on functional cost models for making research data publicly accessible.

Community engagement

- **Address racial inequity and disparity in science communication:** Work with publishers, scholarly societies, and others pledging to combat racism in science, building on the recognition by OSTP⁶ and the National Academies of Sciences⁷, Engineering, and Medicine that pervasive sexual harassment poses a threat to scientific integrity.
- **Stakeholder engagement:** Stakeholders in developing data access and sharing arrangements should include individuals or groups whose data is being collected.

⁴ Request for Public Comment on Draft Desirable Characteristics of Repositories for Managing and Sharing Data Resulting from Federally Funded Research, 85 FR 3085 (Jan. 17, 2020), <https://www.federalregister.gov/documents/2020/01/17/2020-00689/request-for-public-comment-on-draft-desirable-characteristics-of-repositories-for-managing-and-sharing>.

⁵ "Memorandum on Restoring Trust in Government through Scientific Integrity and Evidence-Based Policymaking," the website of the White House, January 27, 2021, <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/>.

⁶ Testimony of Dr. Kelvin Droegemeier Director, Office of Science and Technology Policy Executive Office of the President of the United States Before the Committee on Science, Space, and Technology United States House of Representatives on "The President's FY 2021 Budget Request for Research & Development" February 27, 2020

<https://science.house.gov/imo/media/doc/Droegemeier%20Testimony1.pdf>

⁷ Sexual Harassment in Academic Science, Engineering, and Medicine (2019) <https://www.nationalacademies.org/our-work/sexual-harassment-in-academia>

Data Management

- **Invest in machine-actionable data management plans (maDMPs) and the broad adoption of persistent identifiers (PIDs).** A recent ARL report on *Implementing Effective Data Practices*⁸ articulated the following considerations for funding agencies:
 - a. Infrastructure:
 - i. Develop systems to generate automatic updates to a DMP using the PID knowledge graph.
 - ii. Provide model maDMPs for researchers that incorporate PID infrastructure as a means of demonstrating the new connections made possible with the addition of identifiers.
 - b. Policies:
 - i. Require researchers and/or research offices to enable appropriate sharing of the content of DMPs. While consideration for sensitive information and/or intellectual property would need to be established, this transparency facilitates compliance and adherence with best practices and could be based on adoption of the Research Data Alliance Recommendations for FAIR DMPs⁹.
 - ii. Require publishers that receive funding and/or article processing charges to declare the funder ID and/or grant ID for the funding organization in all published articles. This connection will ensure that the results from the funding are publicly available.
 - iii. Require and facilitate the use of ORCID iDs, ROR IDs, grant IDs, DOIs, and funder IDs in all grant applications and reporting, as appropriate and to the extent possible.
 - c. Sustainability:
 - i. Implement pilot projects within the funding organization that use the connections made in maDMPs and PIDs. Through these exploratory projects all funders can learn how to build custom implementations and the community can further develop use cases.
 - ii. Invest in continuing support, including through partnerships with institutions and scientific societies, for open PID and DMP infrastructure for sustainability purposes.
 - iii. Join membership-supported organizations providing infrastructure, tools, and services essential to research activity, research data, and researchers themselves. Examples include Crossref, DataCite and ORCID.

Metadata

⁸ John Chodacki et al., *Implementing Effective Data Practices: Stakeholder Recommendations for Collaborative Research Support* (Washington, DC: Association of Research Libraries, September 2020), <https://doi.org/10.29242/report.effectivedatapactices2020>.

⁹ "Draft Recommendations," Research Data Alliance Exposing Data Management Plans Working Group, accessed July 27, 2021, https://docs.google.com/forms/d/e/1FAIpQLSd-FKrKmXP1XZw4SI_kEbVlr2TiXQvKAYnEZTyXC-Csd18q8A/viewform.

- **Promote the creation and adoption of common data elements.** The National Library of Medicine and community organizations have developed or begun developing common data elements to describe and make data variables interoperable.
- **Support the curation of research outputs.** While the sharing of research outputs is a good first step to ensure research integrity, making research output Findable, Accessible, Interoperable, and Reusable (FAIR) is the next step to improve the integrity of research across the board. ARL recommends that OSTP direct federal funding agencies to create new policies and practices to make funded research outputs FAIR.
- **Clearly delineate peer review status in object metadata.** This applies to articles, data, software, and code.
- **Clarify copyright status.** To reduce uncertainty about how US federal government information may be used, label works that are not eligible for copyright protection and are therefore in the public domain according to Section 105(a) of the US Copyright Act with statements on the rights of the authors and the users of these works. Consider the new copyright rights statement by the US Government Publishing Office (GPO) that will be added to the metadata for new and existing content.¹⁰

Rigor and Reproducibility

- **Create more specific funding calls for meta-research, systematic reviews, and/or replication studies.** Health science librarians and library staff often collaborate with faculty to identify relevant citations and studies for inclusion in these types of research.
- **Require registered reports to improve research quality.** Registered reports review the research approach as well as complete a peer review of the research prior to the research outcomes being completed.¹¹ Research has shown the use of registered reports reduces bias and selective reporting in manuscripts.
- **Normalize the creation and sharing of research protocols.** Platforms such as Protocols.io allow the discovery, reuse, and annotation of research methods and workflows. Library staff often provide training and best practices on the use of research tools such as this.

Sustainability and capacity-building

- **Align policies, practices, and funding.** ARL recommends that federal agencies strongly align research integrity policies and practices with sustainable and capacity-building funding mechanisms. Libraries and institutions have invested a significant amount of resources in infrastructure and services to support faculty on academic campuses and in national laboratories to meet existing policies and practices, but any additional federal requirements from federal agencies should include financial support.

¹⁰ "Release Notes: Congressional Serial Set Development, Bibliographic Citation Generator, API USCOURTS Parameter Enhancements, Additional Citation Search Patterns for Congressional Reports," govinfo, July 13, 2021, <https://www.govinfo.gov/features/june-2021-release-notes>.

¹¹ Courtney K. Soderberg et al., "Initial Evidence of Research Quality of Registered Reports Compared with the Standard Publishing Model," *Nature Human Behavior* (2021), <https://doi.org/10.1038/s41562-021-01142-4>.

- **Consider equity among institutions in all new policies and practices.** Any new policies and practices put in place by federal agencies should consider downstream effects on institutions, especially where the requirements may place additional financial or infrastructure burdens. While some institutions may more easily support these new requirements and build infrastructure, for others it will be a considerable burden that will create additional inequities in the scientific enterprise. Policies should include mechanisms for inter-institutional partnerships or networks to build capacity, building consensus around best practices for requirements.

III. Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce

- **Engage universities and the research community around security concerns.** Basic, fundamental research, including emerging technologies such as artificial intelligence, is the engine of scientific innovation, and international collaboration is essential to meet global challenges. OSTP and federal agencies should work with university research officers, IT, and libraries to strengthen existing security practices while promoting expansive and timely access to fundamental research.
- **Further promote the use of ethical research sharing.** Just because data or information can legally be shared, doesn't mean it should be. Libraries and library staff are key partners with research offices and sponsored projects to convey policies and instruct on research practices. ARL recommends that:
 - a. The CARE Principles for Indigenous Data Governance¹² and other similar protocols for ethical partnerships with study groups should be more broadly adopted across federal agencies.
 - b. OSTP develops policies for federal agencies and funding recipients to engage stakeholders in developing data access and sharing arrangements that also include individuals or groups whose data is being collected.
 - c. Stakeholders also be included in developing data governance plans and discussions of which data sets to publish.

Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices

- ARL suggests that OSTP prioritize the upskilling of early career researchers, graduate students, and undergraduates in these areas, with a particular focus on historically underrepresented populations.

Thank you for your consideration of these comments.

Sincerely,
Mary Lee Kennedy
Executive Director
Association of Research Libraries

¹² Research Data Alliance International Indigenous Data Sovereignty Interest Group, *CARE Principles for Indigenous Data Governance* (Global Indigenous Data Alliance, September 2019), <https://www.gida-global.org/care>.

About the Association of Research Libraries

The Association of Research Libraries (ARL) is a nonprofit organization of [125 research libraries in Canada and the US](#) whose mission is to advance research, learning, and scholarly communication. The Association fosters the open exchange of ideas and expertise, promotes equity and diversity, and pursues advocacy and public policy efforts that reflect the values of the library, scholarly, and higher education communities. ARL forges partnerships and catalyzes the collective efforts of research libraries to enable knowledge creation and to achieve enduring and barrier-free access to information. ARL is on the web at [ARL.org](#).

28th July 2021

Scientific Integrity Task Force
White House Office of Science and Technology Policy

My name is Dr Peter Corkeron, and I am filing this comment in my capacity as a private citizen.

I was a Supervisory Research Zoologist in NOAA Fisheries, employed at the Northeast Fisheries Science Center from 2011 to 2019. I led the whale research program in the Protected Species Branch over that time. I am an accomplished scientist, with over 120 refereed publications, see my [Google Scholar page](#), and have been on the editorial board of *Marine Ecology Progress Series* (a leading scientific journal in marine ecology) for over a decade. While at NOAA, I provided the scientific leadership that led to understanding the current plight of North Atlantic right whales. Demonstrating the species' decline went against the prevailing view in NOAA's senior management that right whales were to be lauded as a success. The manner of my treatment from NOAA management, including by members of the Senior Executive Service, was such that my position at NOAA became untenable and I left.

I note the call for comment includes this statement: "We do not seek reports on alleged offenses that are in violation of Federal scientific integrity policies; we ask that you not provide names of individuals who have been or may be accused of engaging in or subjected to such practices, personally identifiable or sensitive information, or specific allegations that should be handled through other appropriate channels, such as law enforcement, Scientific Integrity Officers, or an Office of Inspector General" so I shall not discuss my experiences of violations of these policies. Much of the reason for my departure from service as a Federal scientist can be attributed to failures to uphold the integrity of the scientific work in which I was engaged.

To address the specific points raised in the call for comments:

1. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science:

Some of the trust in Federal science requires the proven demonstration that Federal science is of a high standard. When several highly experienced Federal scientists exit the Federal workforce all within a short time frame, as happened among the scientists working on cetaceans in NOAA over the past couple of years, it indicates a systemic problem. That problem will not necessarily manifest itself in the short term, as several scientists exiting the Federal workforce is not newsworthy. So the public are unaware of this development. Nevertheless, the decline in the quality of Federal science that is likely to flow from this loss of expertise should lead to reduced public trust in Federal science, as that loss of trust will be appropriate.

2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information:

The process of internal review of scientific manuscripts has become problematic for Federal scientific integrity, at least inside NOAA. It requires a reexamination. I give a some examples:

First, when Federal scientists are coauthors on manuscripts, the “policy review” process can create difficulties having appropriate management and policy inferences from data accepted, even when the Federal scientists are not first or final authors on a multi-authored manuscript. I have seen this result in journal reviewers commenting on the lack of discussion of the management implications of scientific findings in a submitted manuscript, leading to requests for revision. This watering-down of management implications goes against NOAA’s scientific integrity policy, but is a common enough occurrence that I am aware of scientists self-censoring the management and policy implications of their work prior to submission for Center review.

Second, the review process can be used against a scientist in a way that can create a difficult working environment for them. Center reviews can stymie a scientist from submission of manuscripts, by being inappropriately slow. There can be an expectation on scientists that all their work - even short working documents to international meetings that other agency scientists are not required to put through Center review – will go through the review process. This can lead to situations where dealing with the Center review process can take longer than writing the original document, and is a clear disincentive to producing publications.

Third, the integrity of the Center review process, as a scientific review, must be maintained. Federal scientists conducting Center review are obliged to keep the work confidential. This does not always happen, particularly with work that includes findings that demonstrate a failure of NOAA’s marine wildlife management processes.

NOAA’s review process requires an overhaul. While the original intent of the review process is laudable, the manner in which it has been misused in recent years should be investigated, and problems rectified.

3. Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce:

At present, the NOAA’s scientific integrity office answers to the NOAA Senior Executive Service. When SES staff are the source of problems for scientific integrity, the only option is to take integrity issues to the Office of Inspector General. That being so, it’s unlikely that the OIG – not being an organization primarily concerned with issues of scientific integrity – will choose to investigate a complaint. What’s needed is an office that oversees scientific integrity across all government agencies engaged in science. Were such an office to be created, it should be staffed by whistleblowers, not by those invested in the current offices for scientific integrity.

Developing written policies and practices in an attempt to resolve issues of scientific integrity in NOAA is necessary but nowhere near sufficient. The scientific culture inside NOAA Fisheries’ Science Centers requires significant overhaul. Center, Division, and Branch Chiefs should have a culture of standing up for the science produced by their scientific staff. This is especially so when the science demonstrates problems that will create difficulties for NOAA staff involved in management. This will require a significant cultural shift from the status quo.

Peter Corkeron



July 28, 2021

White House Office of Science and Technology Policy
ScientificIntegrityRFI@ostp.gov

Re: SI-FTACRFI ¹

Dear Sir or Madam:

The Sugar Association Inc. (SAI) is pleased to submit these comments to Office of Science and Technology Policy (OSTP) concerning the improvement of policies designed to enhance scientific integrity of Federal polices and public trust in science.

Founded in 1943, the Sugar Association represents sugar beet and cane farmers, processors and refiners in the United States. As the scientific voice of the U.S. sugar industry, the Association aims to increase understanding of what real sugar is and instill confidence in consumers around the important supporting role sugar plays in a nutritious and balanced diet. Our efforts include supporting scientific research, consumer education and providing comments on nutrition policies involving sugar. The Sugar Association supports Federal nutrition and food policies that are based on strong scientific evidence and recognize the multifaceted purposes of sugar in the food supply. The Association firmly believes that real sugar is best enjoyed in moderation.

We strongly support this effort by OSTP to request information on improving Federal scientific integrity policies.

- 1) There is an urgent need to standardize methods used by Federal agencies to review scientific evidence.
 - Decision making should be based on best practices for reviewing methodologies and evaluating research.
 - Information communicated to the public should stand the test of time; Federal agencies should refrain from communicating information that may be repudiated in short order.
- 2) There is a pressing need to ensure that agencies, including USDA and HHS attract top talent.

¹ <https://www.regulations.gov/document/OSTP-2021-0002-0001>

- The Federal government should hire and retain the best trained scientific experts in their particular fields.
- Government scientists should be given opportunity to continually improve their knowledge and skills particularly in evaluating large bodies of scientific data.
- Guardrails and processes need to be put in place to ensure that popular opinion and consumer demand do not unduly influence evidence-based policy decisions.

The Dietary Guidelines for Americans (DGAs) serves as an example of the importance of the need to enhance Federal scientific integrity. The DGAs are released by the Departments of Agriculture (USDA) and Health and Human Services (HHS) every 5 years, who rely on a committee of appointed external scientists to review the scientific evidence and provide recommendations for all Americans on what they should eat and what they should limit. While all of us can anecdotally surmise what is “healthy” or what is not good for us, we need robust analyses of high-quality nutrition studies to provide the evidence-basis behind Federal guidance. Absent this science, a recommendation is merely a statement about individual or popular opinions on food—and at times, a mere guess, or a political statement.

It is critical that the DGA be based upon an objective and standardized analysis of nutrition evidence. While these criteria are theoretically how the DGA are developed, the guardrails and oversight ensuring they are in fact developed this way are missing. Several previous DGA cycles have highlighted the substantial gaps in a rigorous development process.

Following the 2015-2020 DGA, Congress raised concerns and, accordingly, mandated that the National Academies of Science, Engineering, and Medicine (NASEM) review the DGA process. The resulting NASEM reports called for a DGA development process that is transparent and developed with the foundation of an objective, standardized review of high-quality nutrition evidence. Included in NASEM’s recommendations were five values to improve the integrity of the process.

1. Enhance transparency
2. Promote diversity of expertise and experience
3. Support a deliberative process
4. Manage biases and conflicts of interest
5. Adopt state-of-the art processes and methods

The DGA must be based on the highest standards of scientific data and analyses to reach the most robust recommendations and instill the public’s trust in Federal dietary recommendations. The accuracy and efficiency of data analyses could be improved by standardizing and validating the processes used, both within and between DGA cycles, and to increase the transparency of the process.

By way of example, the DGA Advisory Committee (DGAC) made recommendations concerning

added sugars consumption without even completing its scientific review of the issue.² At the onset of the 2020-2025 DGA process, the DGAC was tasked with conducting three systematic reviews using the Nutrition Evidence Systematic Review (NESR) process to examine the relationship between added sugars consumption and health outcomes, including risks of cardiovascular disease (CVD), type 2 diabetes and overweight and obesity. However, the DGAC only completed *one* of these three reviews -- risk of CVD. The reviews on the risk of type 2 diabetes and overweight and obesity were scrapped, citing time constraints. Despite completing only 33% of the review of what could be considered the entire body of the evidence, the DGAC went ahead and recommended a significant change to the added sugars guideline. Instead of seeking more time to complete the scientific reviews, as has been done repeatedly by the European Food Safety Authority, which conducted a similar review, the DGAC omitted important work that would have formed the basis for a valid recommendation.

The resulting recommendation from the Committee to lower added sugars to not more than 6% was not supported by the entire body of scientific evidence and was based on unsubstantiated assumptions. Furthermore, the DGAC's recommendation of 6% was merely based on food pattern modeling – an exercise that does not utilize scientific studies nor factor in any health endpoints to reach conclusions. This is a hypothetical modeling exercise lacking the scientific rigor to be the sole methodology used to determine recommended intakes of nutrients. Ultimately USDA and HHS decided not to change recommendations from the DGAC regarding added sugars consumption, but the 2020 DGAC's review process certainly put the scientific integrity of the DGAs into question.

Another example involves the 2020-2025 Committee's review of the relationship between alcohol consumption and all-cause mortality. The Committee used "additional evidence" to support its conclusions, justifying their proposal to change the definition of 'moderate drinking' by referring to cherry picked studies that were outside the scope of the systematic review and supported the opinion of the DCAC member-author of the report chapter on alcohol.

In fact, the DGAC cites just one study to justify its proposal to halve the alcohol consumption guideline for men (from two to one serving/day), describing this single study out of 60 within the NESR systematic review as representing a "preponderance" of evidence. This proposal (not supported by the systematic review) was not reflected in the DGAC's draft conclusion statements and appears to be based on opinion rather than evidence. See, <https://www.dietaryguidelines.gov/about-dietary-guidelines/related-projects/usda-hhs-response-national-academies-sciences-engineering>

There is an urgent need to standardize methods used by Federal agencies to review scientific evidence. Decision making should be based on best practices for reviewing methodologies and

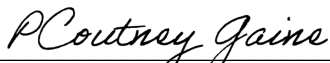
² Scientific Report of the 2020 Dietary Guidelines Advisory Committee, Advisory Report to the Secretary of Agriculture and Secretary of Health and Human Services, July 2020. Part D, Ch. 12, at p. 2. Retrieved from https://www.dietaryguidelines.gov/sites/default/files/2020-07/ScientificReport_of_the_2020DietaryGuidelinesAdvisoryCommittee_first-print.pdf

evaluating research. Information communicated to the public should stand the test of time; Federal agencies should refrain from communicating information that may be repudiated in short order.

Additionally, there is a pressing need to ensure that agencies, including USDA and HHS attract top talent. The Federal government should hire and retain the best trained scientific experts in their particular fields. Government scientists should be given opportunity to continually improve their knowledge and skills particularly in evaluating large bodies of scientific data to derive evidence-based conclusions and recommendations that are not likely to be repudiated in the near future.

In sum, SAI supports this effort by OSTP and we suggest making these efforts as transparent as possible so that the public can participate and follow this important discussion

Respectfully Submitted,

A handwritten signature in cursive script that reads "P. Courtney Gaine".

P. Courtney Gaine, PhD, RD
President and CEO

From: Karen A. Robinson, PhD (Professor, Johns Hopkins University) on behalf of the [Evidence-Based Research Network](#) (an international organization).

Regarding: Request for Information to Improve Federal Scientific Integrity Policies

Response to Prompt #2: Good practices Federal agencies could adopt to improve scientific integrity

In 2014, a group of researchers, journal editors, funders and patients/patient advocates from Canada, USA, UK, Norway, Denmark, and Australia established the Evidence-Based Research Network ([EBRNetwork](#)). This response is provided by the EBR Network.

Evidence-based research is the use of prior research in a systematic and transparent way to inform a new study, so that the new study is answering questions that matter in a valid, efficient, and accessible manner.

Evidence-based research is essential to meeting the policy recommendations included in the Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking (Jan 27, 2021). Namely, the use of evidence-based research is essential to

[It is] the policy of my [the Biden] Administration to make evidence-based decisions guided by the best available science and data,

and, one of the 6 principles,

(2) Agencies should have appropriate rules and procedures to ensure the integrity of the scientific process within the agency.

Meta-research (research on research) suggests that 50% or more of studies are unnecessary and wasteful. More worrisome, such studies put people at unnecessary risk as effective treatment is denied or delayed.

Just as evidence-based healthcare dictates that decisions about treatment be based on evidence, evidence-based research dictates that decisions about research should be based on evidence.

Studies should not be funded or approved to recruit participants without being justified as worthwhile by the explicit consideration of existing evidence. To not do so leads to waste and unnecessary risk for participants.

Results from studies should be presented within the context of what is known. To not do so leads to misleading science communication and lack of transparency.

Ensuring integrity in research, means improving training, bolstering transparency, and protecting science communication. *Federal agencies should endorse and adopt evidence-based research to ensure and improve scientific integrity.*

Example references about evidence-based research

1. Chalmers I, Nylenna M. A new network to promote evidence-based research. *The Lancet*. 2014;384:1903-4.
2. Lund H, Brunnhuber K, Juhl C, Robinson K, Leenaars M, Dorch BF, et al. Towards evidence based research. *BMJ*. 2016;355:i5440.
3. Lund H, Juhl CB, Nørgaard B, Draborg E, Henriksen M, Andreasen J, et al. Using an Evidence-Based Research approach before a new study is conducted to ensure value. *Journal of Clinical Epidemiology*. 2021;129:158-166
4. Lund H, Juhl CB, Nørgaard B, Draborg E, Henriksen M, Andreasen J, et al. Using an Evidence-Based Research approach to place your results into context after the study is performed to ensure usefulness of the conclusion. *Journal of Clinical Epidemiology*. 2021;129:167-171
5. Robinson KA, Brunnhuber K, Ciliska D, Juhl CB, Christensen R, Lund H. What Evidence-Based Research is and why is it important? *Journal of Clinical Epidemiology*. 2021; 129:151-157

Example references about threats to scientific integrity by not practicing evidence-based research (i.e., research waste, harm to people, etc.)

1. Chalmers I. The lethal consequences of failing to make full use of all relevant evidence about the effects of medical treatments: the importance of systematic reviews. In: Rothwell PM, editor. *Treating Individuals - from randomised trials to personalised medicine*. London: The Lancet; 2007. p. 37-58.
2. De Meulemeester J, Fedyk M, Jurkovic L, Reaume M, Dowlathshahi D, Stotts G, et al. Many randomized clinical trials may not be justified: a cross-sectional analysis of the ethics and science of randomized clinical trials. *J Clin Epidemiol*. 2018;97:20-5.
3. Fergusson D, Glass KC, Hutton B, Shapiro S. Randomized controlled trials of aprotinin in cardiac surgery: could clinical equipoise have stopped the bleeding? *Clin Trials*. 2005;2:218-29; discussion 29-32.
4. Greenberg SA. How citation distortions create unfounded authority: analysis of a citation network. *BMJ*. 2009;339:b2680.
5. Jia Y, Wen J, Qureshi R, Ehrhardt S, Celentano DD, Wei X, et al. Effect of redundant clinical trials from mainland China evaluating statins in patients with coronary artery disease: cross sectional study. *BMJ*. 2021;372:n48.
6. Lau J, Antman EM, Jimenez-Silva J, Kupelnick B, Mosteller F, Chalmers TC. Cumulative meta-analysis of therapeutic trials for myocardial infarction. *N Engl J Med*. 1992;327:248-54.
7. Robinson KA, Goodman SN. A systematic examination of the citation of prior research in reports of randomized, controlled trials. *Ann Intern Med*. 2011;154:50-5.
8. Sawin VI, Robinson KA. Biased and inadequate citation of prior research in reports of cardiovascular trials is a continuing source of waste in research. *J Clin Epidemiol*. 2016;69:174-8.

Submitted to: ScientificIntegrityRFI@ostp.eop.gov

Re: SI-FTAC RFI

July 28, 2021

Dear Dr. Ryan Donohue:

Thank you for the opportunity to submit comments on behalf of the Federation of Associations in Behavioral and Brain Sciences. FABBS represents 28 scientific societies and nearly 70 university departments whose scientific members and faculty share a commitment to advancing knowledge in the sciences of mind, brain, and behavior. Our members applaud this Administration's commitment to science and share the goal of developing sound, evidence-based policies guided by rigorous research and data. We also appreciate the inclusive process that OSTP has taken to solicit feedback from the community.

In addition to addressing workforce training issues and potential roadblocks to integrity, such as political interference, it is also important to recognize external forces working against the public confidence in science. It is essential to consider what behavioral and cognitive sciences have taught us about the consumers of information and the ways in which education and personal biases influence individuals' abilities to decipher fact from fiction.

1. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science:

The 2010 OSTP Memo on scientific integrity policies includes the goal to 'strengthen the actual and perceived credibility of government'. Behavioral and cognitive sciences are central to understanding the experience of processing information and determining what – and who – to believe.

Central to achieving trust in Federal science is building a science literate population. Science education must instill an understanding of the scientific process and also provide learners with the tools to reflect on and assess their own judgement and biases, as well as the credibility of scientific sources. Our nation's policymakers speak frequently about the importance of STEM education. However, it is essential to include the behavioral and cognitive sciences in our definition of STEM. Building trust in science requires

empowering individuals to be reliable and discriminating consumers of information; to know how and when to check their own biases and processes. And yet, the behavioral and cognitive sciences are not consistently included in the definition of 'Science' when used in Federal policy about STEM. FABBS member society, the American Psychological Association, has a useful report on the topic.¹ Many of the recommendations from 2010 still hold true today. A few examples:

- Increase resources for the teaching of psychology as a laboratory science at the high school, community college, and college level.
- Include psychological science courses among those required for general STEM education at high school, undergraduate, and post-graduate levels. These courses may emphasize the critical role of psychology within interdisciplinary science, such as behavioral neuroscience, behavioral genetics, or behavioral economics.
- Increase the number of psychological scientists in STEM agencies (e.g., Department of Energy, Department of Transportation) on boards, review panels, and among senior staff, as well as on scientific advisory boards and commissions (such as the President's Council of Advisors on Science and Technology, the Office of Science and Technology Policy, and the upper rungs of management at federal research agencies, such as NSF, NIH, and NASA).

Behavioral research tells us that the messenger can be as important as the message. Research in *Policy Insights from the Behavioral and Brain Sciences* suggests that "children enter kindergarten well-prepared to make judgments about the credibility of their teacher... Thus, an understanding of how young children make trust-based decisions is timely and useful."² This is a humbling finding and underscores just how strong external factors are when trying to avoid bias, even for young children.

2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information:

When considering how to communicate scientific and technological information most effectively, it is essential to start with insights from the behavioral and cognitive sciences that examine this very question.

¹ "Report of the American Psychological Association 2009 Presidential Task Force On the Future of Psychology as a STEM Discipline" <https://www.apa.org/pubs/info/reports/stem-discipline>

² "Trusting Your Teacher: Implications for Policy" <https://journals.sagepub.com/doi/full/10.1177/2372732219862574#>

The Administration can facilitate this across the Federal Government by reinstituting the [Social and Behavioral Sciences Subcommittee](#) of the National Science and Technology Council (NSTC). This subcommittee facilitated collaboration and sharing of information among federal agencies and departments and identified cross-cutting national R&D priorities benefiting from behavioral and social science and recommended action on possible policies.

In addition, OSTP should reconstitute the [Social and Behavioral Sciences Team](#) (SBST) within the White House. Under the Obama administration, the team of applied behavioral scientists considered how people make decisions and act on them to increase effectiveness and efficiency of federal programs. communication, interface, and user experience across federal agencies. By way of example, the 2016 SBST Annual Report highlights responding to climate change, and improving the effectiveness and efficiency of Federal Government operations.

The COVID-19 pandemic has only amplified the importance of the behavioral and social sciences in policy decisions. The National Academies of Sciences, in collaboration with the National Science Foundation, launched the [Societal Experts Action Network \(SEAN\): Facilitating Rapid and Actionable Responses to Social, Behavioral, and Economic-Related COVID-19 Questions](#). This initiative brings researchers together to inform research-based, actionable policy responses. The network has focused on timely questions, such as how best to communicate vaccine efficacy and safety. This integrative approach of science communication would benefit the Administration as a whole as well as the American public.

A report by the American Academy of Arts and Sciences (AAAS)³ includes a call to action with clear opportunities for the Federal Government to support trust in science. Two of the recommendations stand out in relevance to the goal of improving communication about science.

- Connecting research and practice. Federally-funded researchers should work to better connect research and practice through partnerships. Behavioral and cognitive scientists, particularly in areas of education research, have made significant advances and serve as a model for researcher-practitioner partnerships.

³ *The Public Face of Science in America: Priorities for the Future*
<https://www.amacad.org/publication/public-face-science-america-priorities-future>

- Funding. Continued financial support for research in the behavioral and cognitive sciences is particularly critical for understanding impact and exploring how shifts in the communication and engagement landscape influence behavior.

5. Other important aspects of scientific integrity and effective approaches to improving trust in Federal science:

In order to successfully ensure scientific integrity and public trust in federal science, the Administration must prioritize filling key scientific positions within the Federal Government. FABBS members were excited to see the elevation of OSTP Director to a cabinet-level position, but other essential positions remain vacant or inactive.

The Institute of Education Sciences (IES), within the Department of Education, is the premier education research agency of the Federal Government. IES is responsible for informing federal, state, and local education policies and assessing educational progress. It is critical that IES is transparent and clear when communicating priorities to the public, lawmakers, and the scientific community. However, the fifteen-member National Board for Education Sciences (NBES), which oversees IES, has not met since November of 2016. This body is essential for guiding federal research priorities and ensuring the integrity and rigor of research conducted or funded by IES. The Board provides accountability to the American taxpayer and is central to ensuring that IES is able to remain independent and non-partisan, and disseminate the highest quality research to education policymakers around the country. It is imperative that the NBES be comprised of highly qualified candidates with diverse research expertise.

Thank you for the opportunity to respond to this important RFI to improve federal scientific integrity policies. Making progress towards achieving our shared goal, to base federal decisions on rigorous science and enhance public trust in science, requires insights from the behavioral and cognitive sciences. FABBS is eager to serve as a resource in this regard.

Sincerely,



Julianne Baron
Executive Director

Respondent:

Charles J. Rothwell - Affiliation- I am a member of the public; however, before retirement I spent four and a half decades in public health leading health statistics activities at the state and Federal level. My last position was Director of the National Center for Health Statistics one of the 13 principal Federal Statistical Agencies.

Introduction:

I welcome the opportunity to respond to the request for information (RFI) published in the Federal Register (86 FR 34064) in support of the Scientific Integrity Task Force (SI-FTAC), the White House Office of Science and Technology Policy (OSTP) and the White House Office of Management and Budget (OMB) as they collaboratively work with Federal agencies and stakeholders to review the effectiveness of agency scientific integrity policies and practices.

It is a positive step that the Task Force formed a working group to coordinate external engagement in order to gather feedback from a range of stakeholders, including the American public, through a range of interactions and channels for input, including upcoming listening sessions and the RFI. This response addresses the information sought by the Task Force.

In particular, I comment on the second element of the RFI – good practices Federal agencies could adopt to improve scientific integrity including the communication of scientific information, addressing emerging technologies and evolving scientific process, supporting professional development of Federal scientists, and promoting transparency in the implementation of agency scientific integrity policies.

Recommendation 1:

Expansion of *Principles and Practices for a Federal Statistical Agency* as a Framework for Strengthening Scientific Integrity in Federal Agencies

As described in *Principles and Practices for a Federal Statistical Agency* (2021, 7th edition)¹, the Committee on National Statistics of the National Academies of Sciences, Engineering, and Medicine first developed these principles and practices as part of its mission to provide an independent review of federal statistical activities. Acts of Congress and statistical policy directives² issued by OMB have codified many of these

¹National Academies of Sciences, Engineering, and Medicine 2021. *Principles and Practices for a Federal Statistical Agency*: Seventh Edition. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25885>.

² <https://www.whitehouse.gov/omb/information-regulatory-affairs/statistical-programs-standards/>

principles and practices. Most recently, the Foundations of Evidence-Based Policymaking Act of 2018 expanded the role of heads of the principal statistical agencies in their departments and prescribed an enlarged role for federal surveys and administrative records to be used in support of sound policy making. The Committee on National Statistics intends for its principles and practices to assist statistical agencies and units, as well as other agencies engaged in statistical activities, to carry out their responsibilities to provide accurate, timely, relevant, and objective information for public and policy use. It also intends to inform legislative and executive branch decision makers, data users, and others about the characteristics of statistical agencies that enable them to serve the public good.

Principles and Practices for a Federal Statistical Agency, in concert with the OMB statistical policy directives, could serve as the framework for other Federal agencies for training in scientific integrity and transparency. As The National Academies have stated, government data which are collected and presented, based on sound scientific methods “support the invaluable role of widely available, trustworthy, relevant, accurate, and timely government statistics. Such statistics are essential not only for policy makers and program administrators at all governmental levels, but also for individuals, households, businesses, and other organizations to make informed decisions and for scientists to add to knowledge. Even more broadly, the effective operation of a democratic system of government depends on the unhindered flow of impartial, scientifically based statistical information to its citizens on a wide range of issues, including employment, growth in the economy, the cost of living, crime victimization, family structure, physical and mental health, educational attainment, energy use, and the environment.”

As noted in the Statistical Programs of the United States Government³, the Federal Statistical System is composed of 13 principal statistical agencies and units and 96 other statistical programs throughout the Executive Branch. It forms the foundation for evidence building in the U.S. Each agency and program plays a vital role in collecting, producing, and disseminating data that the public, businesses, and governments use to make informed decisions. These stakeholders rely on and bestow trust in the Federal Statistical System to provide accurate, timely, objective, and relevant information. Especially for the 13 principal statistical agencies, they have, over many years, used guidelines developed and published by The National Academies to train their staff on the unique role they play in assuring the data they collect and disseminate are seen by policy makers, researchers and the public as the gold standard for all government data holdings. It is not an easy task to create an environment for staff within an organization to provide timely and relevant data that *informs* the debate of policy making rather than *entering* into that debate. Extending these *Principles and Practices* throughout the Federal government would strengthen scientific integrity, trust and independence.

³ <https://www.whitehouse.gov/wp-content/uploads/2020/12/statistical-programs-20192020.pdf>

Principles and Practices for a Federal Statistical Agency, first published in 1992 and now in its 7th edition, is the flagship publication of the Committee on National Statistics at NAS. The publication covers 5 principles:

- Principle 1: Relevance to Policy Issues and Society;
- Principle 2: Credibility Among Data Users and Stakeholders
- Principle 3: Trust Among the Public and Data Providers;
- Principle 4: Independence from Political and Other Undue External.
- Principle 5: Continual Improvement and Innovation.

In order to fulfill these five principles, there are 10 practices essential for an agency to adopt. These practices represent the ways and means of making the basic principles operational and facilitating an agency's adherence to them. Practices 1 to 4 pertain to an agency's operations, internally and within the federal government; practices 5 to 7 bridge internal operations and external relations with the research communities; and practices 8 to 10 focus externally on an agency's key constituents: data users and data providers. Specifically, the 10 practices are:

1. A Clearly Defined and Well-Accepted Mission
2. Necessary Authority and Procedures to Protect Independence
3. Commitment to Quality and Professional Standards of Practice
4. Professional Advancement of Staff
5. An Active Research Program
6. Strong Internal and External Evaluation Processes for an Agency's Statistical Programs
7. Coordination and Collaboration with Other Statistical Agencies
8. Respect for Data Providers and Protection of Their Data
9. Dissemination of Statistical Products That Meet Users' Needs; and
10. Openness About Sources and Limitations of the Data Provided.

Perhaps equally important the Federal Statistical Agencies could be leaders in the development and implementation of these training activities throughout government. For example, through their Interagency Council on Statistical Policy (ICSP) they have supported a shared mentoring program for their staff to learn new approaches to similar issues from senior staff of other agencies and they have a very successful joint committee (FCSM) taking on similar research issues that challenge all the statistical agencies.

Recommendation 2:

Enhancing Statistical Integrity through OMB's Statistical and Science Policy Office and its Chief Statistician

Although the guidelines specified in *Principles and Practices for a Federal Statistical Agency* have been highly successful for training Federal Statistical System staff and providing assurances to policy makers, researchers and the public that the agencies are doing their best to provide timely and reliable data, many Federal agencies have had great difficulty in instituting the second “practice” --Necessary Authority and Procedures to Protect Independence. Although OMB has published very helpful statistical policy directives to support the independence of these agencies, unfortunately these directives have not been adequate in this specific area.

Scientific integrity in Federal agencies fundamentally must have at its foundation independence, trust, and objectivity. It is fortunate that OMB has the infrastructure to address this issue. At the center of the Federal Statistical System is the Statistical and Science Policy (SSP) Office, which is part of the OMB Office of Information and Regulatory Affairs (OIRA), in OMB. Furthermore, SSP is headed by the Chief Statistician of the United States, which is a senior executive civil service position. This position was created by the Paperwork Reduction Act in 1980 and plays a critical role in coordinating and providing standards, policies, and guidance to our decentralized Federal Statistical System.

Consideration should be given to strengthening the role of the Office of the Chief Statistician. For example, the Chief Statistician could be one of the review officials for developing and assessing the performance of each of the Directors of the 13 Federal Statistical Agencies. And, for those Statistical Director positions not appointed by the President, the Chief Statistician could play a useful role, along with the respective Department’s leadership, in the recruiting and selection of the Statistical Director for that Department’s Statistical Agency. Finally, the Task Force, in concert with OMB, could consider using the *Principals and Practices of a Federal Statistical Agency* as a guide to seek legislation that would assure the autonomy of the Federal Statistical Agencies.

In sum, the work of the Committee on National Statistics to develop and continually update *Principles and Practices of a Federal Statistical Agency* serves as a model framework for addressing and improving scientific integrity across the Federal government. In perhaps a fortunate stroke of serendipity, the Task Force and OSTP have the OMB Chief Statistician and the Statistical and Science Policy Office as a likely ready partner to expand the many sound practices of the principal statistical agencies to other Federal agencies at large. Having a proven framework already in place with the infrastructure to work directly with other agencies should result in greater scientific integrity and public trust in the coming years.



July 28, 2021

Via Electronic Mail

Scientific Integrity Task Force
Office of Science and Technology Policy
Executive Office of the President
1600 Pennsylvania Ave NW
Washington, DC 20500
ScientificIntegrityRFI@ostp.eop.gov

**Re: Comments in Response to Request for Information to Improve
Federal Scientific Integrity Policies**
SI-FTAC RFI
86 Fed. Reg. 34064 (June 28, 2021)

To Whom It May Concern:

Brooklyn Defender Services (“BDS”) submits these comments in response to the Office of Science and Technology Policy (“OSTP”)’s Request for Information to Improve Federal Scientific Integrity Policies, 86 Fed. Reg. 34064, issued on June 28, 2021.

BDS is a full-service public defender organization in Brooklyn, New York, that provides multi-disciplinary and client-centered criminal defense, family defense, immigration, and civil legal services, along with social work and advocacy support. BDS represents low-income people in nearly 30,000 criminal, family, civil, and immigration proceedings each year. We thank President Biden and the OSTP for the opportunity to provide information and feedback about the operation of Federal Scientific Integrity Policies that impact the fields of forensic science and technology.

Since the investments made in law enforcement digitization and infrastructure by the Omnibus Crime Control and Safe Streets Act of 1968¹ and the advent of forensic DNA techniques in the late 1980s, the day-to-day reality of criminal prosecutions in this

¹ The Omnibus Crime Control and Safe Streets Act of 1968 (remarking on the alleged “high incidence of crime in the United States,” establishing a grants program for law enforcement, and encouraging research and development of “methods, devices, facilities and equipment designed to improve and strengthen law enforcement” through the LEAA). *See also* Brian Jefferson, DIGITIZE AND PUNISH: RACIAL CRIMINALIZATION IN THE DIGITAL AGE, 10 (2020) (“Cutting-edge technology looks to have a bright future in criminal justice But this future is actually old. Much of the criminal justice system’s digital repertoire was first envisioned by technocrats and tech corporations in the late 1960s, during the onset of Lyndon Johnson’s War on Crime. Many of the core technologies were initially rolled out in the late 1980s, in the thick of the War on Drugs.”).

country has undergone a steady shift in evidence. Whereas the presentation of complex scientific concepts used to be confined to the most serious of charges—homicides and sexual assaults, the ground has now shifted to a system that sees metrological, scientific, or technical evidence presented in almost *every* case. In response to this development, BDS established a dedicated Forensic Science Practice, as well as a Science & Surveillance Project. These two teams focus on remaining abreast of and responding to developments and issues of data, science, and technology in the criminal legal system.

The fields of forensic science and technology sit uncomfortably at the intersection of science and law enforcement. For almost two decades, independent scientists have grappled with this discomfort, questioning the “science” in a field that is both intrinsically resistant to transparency and stifling of critical analysis, research, and studies.²

Not only does forensics’ status as a scientific field get questioned, the fields of forensics themselves encapsulate a fractiously broad swath of techniques that are used both for investigation and as proof. The umbrella of forensics shades a motley tent. While, classically, forensic methods have largely been metrological (e.g. fingerprinting, hair/bite-fiber analysis, firearms and toolmark examination, etc.), a new space of emerging methods is being presently defined. These new methods capitalize on advances in data science, artificial intelligence, and algorithmic processing and include a broad array of techniques from modern DNA analysis to facial recognition, location tracking and data mining. While these classic and emerging methods may initially appear cut from different cloth, emerging methods are currently following the same unsteady path charted by classic ones: suffering from a lack of transparency and risking abuse, misuse, and misrepresentation.³

The risks posed by emerging methods, however, spread more intrinsically to profound challenges concerning racial justice. The secondary racial justice implications of classic methods’ participation in mass incarceration have been replaced by direct broadsides from the emerging methods against Black, Brown, and other communities that historically have been subjugated by the criminal legal system. Consider, for example, the racial bias in training sets used for facial recognition or the disparate impact of both informational and biometric surveillance techniques.

As set forth below, BDS strongly encourages the Task Force to recognize the chief conclusion of the National Academy of Sciences’ 2009 Report *Strengthening Forensic Science*, which remains salient today: sound forensic science and technology practice requires independence from the Department of Justice (“DOJ”) and law enforcement. No

² See, e.g., Donald Kennedy, *Forensic Science: Oxymoron?* 302 Science 1625 (2003); Paul C. Giannelli, Daubert and Forensic Science: *The Pitfalls of Law Enforcement Control of Scientific Research*, 2011 U. ILL. L. REV. 53, n.85 (2010) (collecting scientific commentaries on “problems in forensic science”).

³ Compare, e.g., Kasmir Hill, “[Wrongfully Accused by an Algorithm](#),” NYTIMES (June 24, 2020) with DOJ Office of the Inspector General, [A Review of the FBI’s Handling of the Brandon Mayfield Case](#) (March 2006).

scientific integrity policy can resolve the conflict inherent in DOJ's role as "the nation's litigator."⁴

A. Independent scientific bodies and scholars have been clear for almost two decades about the conditions necessary for scientific integrity in the forensic science and technology space.

Since, at least, the creation of the Law Enforcement Assistance Administration under DOJ in 1965, both the funding and research agenda for forensic science and technology have been set, almost exclusively, by DOJ.

As Paul C. Giannelli compellingly lays out in *Daubert and Forensic Science: The Pitfalls of Law Enforcement Control of Scientific Research*, beginning with the arrival of DNA evidence in the late 1980s and punctuated by the FBI's misidentification of Brandon Mayfield in 2004, "sectors of the scientific community were becoming interested—and alarmed—about how science was being used in criminal cases."⁵ Between 2003 and 2009, numerous articles and editorials appeared in major scientific publications, including *Science* itself, questioning the scientific integrity of the forensic sciences. These commentaries focused on the pervasive impact of political bias within forensics and the stifling stranglehold that DOJ and the Department of Defense had on research funding, especially given DOJ's penchant for conditioning funding on a right of review.

Giannelli's article is full of examples of DOJ's political interference in the progress of science. These include examples of inappropriate political control of scientific research, direct harassment of independent scientists who voiced dissent, intentional spread of biased interpretations of scientific results, and the outright suppression of independent studies and withholding of critical data.

The steady drumbeat underlying each of these examples and commentaries demanding independence culminated in 2009. On February 18 of that year, a blue-ribbon panel of the National Academy of Sciences published its seminal report—[*Strengthening Forensic Science in the United States: A Path Forward*](#). The central recommendation of that report was that the federal government establish an independent federal agency to oversee funding and research in forensics.

A month later, on March 9, 2009, the Presidential Memorandum on scientific integrity issued requiring all federal agencies to promulgate specific scientific integrity policies. A primary goal of these policies was to prevent the improper political interference in science and the suppression or distortion of scientific findings.

The fear of political interference and suppression was timely. Consistent with the criticisms levelled by those prior scientific publications, it had come to light in 2008 that

⁴ [DOJ Scientific and Research Integrity Policy](#) (published July 19, 2013) (the opening sentence of the policy reads: "The Department of Justice . . . is the Nation's litigator . . .").

⁵ Giannelli, Paul C., *Daubert and Forensic Science*, at 58-65.

DOJ's National Institute of Justice had "attempted to derail" the NAS Report's publication.⁶

Despite the 2009 NAS Report's recommendation that Congress establish an independent oversight and research-funding agency for forensic science, no such body has emerged. The DOJ remains the dominant federal agency in control of both policy and research funding in this area. And time has demonstrated that these are not mere historical threats to scientific integrity. Ultimately, the issuance of DOJ's Scientific and Research Integrity Policy did not end improper political interference in forensic science and technology or the suppression and distortion of scientific findings.

B. No integrity policy can resolve the inherent conflict between scientific values and law enforcement values.

Scientific values are often antithetical to law enforcement values—or at least frequently perceived to be so by prosecutors and police. In particular, the notion of transparency has repeatedly been trumped by an adversarial process that favors trial by ambush. As Sheila Jasanoff has reminded us: "Science and secrecy do not sit comfortably together." The DOJ, the FBI Crime Laboratory, and some prosecutors have attempted to shape science by controlling the research agenda, hiding unwelcomed test results, attacking legitimate studies that were considered unfavorable, harassing scientists who disagreed with them, and "spinning" these issues in the press. . . . This conduct is troubling precisely because it involves the government. Paradoxically, these are the very agencies of government that are entrusted to be "ministers of justice." The problem is exacerbated by the fact that the DOJ and FBI Laboratory control the funding of research in forensic science.⁷

DOJ's Scientific and Research Integrity Policy begins by immediately noting that "[t]he Department of Justice (Department or DOJ) is the Nation's litigator." It is this role—as an interested party to a controversy and an advocate for a particular and consistent litigation position—that creates an irresolvable conflict when it comes to scientific integrity.

Furthermore, this conflict has infected the entire project of forensics. As Maneka Sinha recently noted: "[M]ost forensic methods were not developed in scientific research

⁶ *Id.* at 88 ("As noted earlier, the NAS appointed its forensic science committee in 2006. The appointment of a committee with so many independent scientists was apparently a threat to the DOJ. On April 10, 2008, at a subcommittee hearing, Senator Richard Shelby, Republican of Alabama, stated that individuals at NIJ had 'attempted to derail the [Fiscal Year 2006] report language that [he] requested, directing the National Academy of Sciences to conduct an independent forensics study' and that '[c]urrent and former employees at [NIJ], along with lobbyists and contractors, have attempted to undermine and influence the National Academies study.' The Senator also objected to a NIJ-convened summit designed to undercut the NAS study.").

⁷ *Id.* at 57.

labs, but by law enforcement as tools to pursue suspects and secure convictions without the underpinnings of rigorous science. That early alignment with law enforcement seeped into forensic culture and continues to influence how the forensic community approaches research, training, and practice.”⁸

The DOJ’s Scientific and Research Integrity Policy cannot resolve this conflict. The history of the field(s) since the policy’s issuance demonstrate this clearly.

i. Political or other improper interference in the conduct of scientific research.

DOJ’s scientific integrity policy has been unsuccessful in preventing political interference in the conduct of scientific research.

As Eric Lander noted: “When the [NAS Report] recommended the creation of a federal office separate from law enforcement to ensure the quality of forensic science, the DOJ successfully lobbied for a weaker solution: an outside advisory committee that would make recommendations to the Attorney General. The National Commission on Forensic Sciences was established in 2013 but soon ran into trouble when the DOJ’s efforts to limit the body’s scope caused a federal judge who served on the commission to resign in protest. The DOJ reversed course, and the commissioner returned. The Commission made various recommendations, but only a few were implemented by the Attorney General.”⁹

Shortly thereafter, efforts to liberate the forensic research agenda and reform forensic methods ran aground on the Trump Administration’s broadside assault on science. Trump’s DOJ effectively disbanded the National Commission on Forensic Sciences by allowing the Commission to lapse in April 2017. As Lander explained: “The DOJ instead chose to rely solely on its own internal Senior Advisor on Forensics. Whereas the previous incumbent had been a forensic scientist, the DOJ in August 2017 tapped as its new advisor a prosecutor without scientific training who had served as a law enforcement representative on the NCFS. The new advisor has employed tactics often used to resist scientific consensus, such as characterizing basic scientific statements as extreme and alleging substantial disagreement within the scientific community.”¹⁰

Simultaneously, as Sinha has detailed in a forthcoming article, DOJ set its suppressive sights on the President’s Council of Advisors on Science and Technology (PCAST)’s 2016 Report *Forensic Science in Criminal Courts: Ensuring Scientific Validity of Feature-Comparison Methods*:¹¹

⁸ Maneka Sinha, “[The Entrenched Carceralism of Forensics](#),” *Inquest* (July 26, 2021).

⁹ Eric Lander, *Fixing Rule 702: The PCAST Report and Steps to Ensure the Reliability of Forensic Feature-Comparison Methods in the Reliability of Forensic Feature-Comparison Methods in the Criminal Courts Criminal Courts*, 86 *Fordham L. Rev.* 1661, 1664 (2018).

¹⁰ *Id.* at 1675-76.

¹¹ Maneka Sinha, *Radically Reimagining Forensic Evidence*, *Forthcoming Alabama Law Review*, 73 *Ala. L. Rev.* ____ (2022).

As the PCAST Working Group came close to releasing its findings, it met with DOJ representatives. According to Eric Lander, Chair of the PCAST Working Group and co-chair of the entire PCAST, DOJ officials immediately, upon learning of the group's findings, became concerned that its conclusions would threaten prosecutors' ability to present forensic science evidence against criminal defendants and could undermine convictions that had already been secured. Citing such concerns, DOJ officials pressed to prevent or delay release of the report and argued that the report's conclusions should not be applied to closed cases. The Working Group declined to delay release, concluding that such a move would be inconsistent with its role as an independent, scientific research panel and declined to limit its findings to future cases, as there was no scientific justification to distinguish between closed and open cases. DOJ still did not abandon its efforts to block publication of the report, going so far as to (unsuccessfully) lobby the White House to prevent its release. When these initial efforts failed, DOJ continued to strike at the PCAST. On the day the PCAST report was published, the country's top prosecutor, then-Attorney General Loretta Lynch, swiftly denounced it.¹²

The substance of these broader institutional battles between empaneled commissions of scientists and DOJ are not unique to birds-eye policy research. The same dynamics have played out within cases and individual forensic disciplines.¹³

ii. Political or other improper interference in the utilization of science in decision-making.

DOJ's scientific integrity policy has also been unsuccessful in preventing political interference in the *evaluation* of scientific validity. In the forensic science and technology space, the primary decision-making utilizing science revolves around either criminal charging decisions or the sponsorship of evidence at a hearing or trial.

As the NAS Report noted, "The simple reality is that the interpretation of forensic evidence is not always based on scientific studies to determine its validity. This is a serious problem. Although research has been done in some disciplines, there is a notable dearth of peer-reviewed, published studies establishing the scientific bases and validity of many forensic methods."¹⁴ This reality—that DOJ interpretation of forensic evidence is often based on considerations other than empirical support for method validity—has been historically reemphasized by DOJ concern over the impact of scientific truth on past and

¹² *Id.* at 37-38.

¹³ Examples include efforts to influence discipline-specific research by funding research that is aligned with DOJ's political agenda and bias. Giannelli, at 65; *see also* Itiel E. Dror and Nicholas Scurich, [*\(Mis\)use of scientific measurements in forensic science*](#), FSI: Synergy (September 6, 2020) (discussing the strange life of the "inconclusive" result in forensic science error rate studies).

¹⁴ NAS Report, at 8.

future convictions. Take, for example, the DOJ's first reaction to the PCAST Report: "DOJ officials acknowledged the lack of empirical studies establishing reliability for some disciplines but expressed concerns that the report could affect past convictions and ongoing cases."¹⁵

DOJ prosecutors often determine whether to rely on or present forensic evidence not by evaluating scientific validity and empirical evidence, but instead with an eye on convictions. The discussion of the PCAST Report response above is a perfect example of this. However, the impact of this lack of scientific rigor and care is felt most directly in individual cases. For example, DOJ prosecutors still routinely sponsor firearms and toolmarks (FATM) evidence in criminal trials, and do not concede the need for limitations on such testimony. FATM has been roundly criticized by the NAS Report in 2009 and PCAST in 2016. The major criticism of the discipline revolves around the lack of direct empirical testing of the method. Amidst courts across the country ruling to limit FATM examiner claims to that which is scientifically defensible, DOJ has continued to oppose limitations on the presentation of FATM evidence in individual cases and has issued an unsigned DOJ statement that is nothing more than advocacy disguised as a scientific pronouncement.¹⁶

C. Trust cannot be established in forensic science if the Department of Justice remains in control of the field's funding, oversight, and research.

BDS strongly encourages the Task Force to seriously grapple with the now decades-old appeal of independent scientists. Abandon the project of internal reform. Move the responsibility for oversight and research funding of forensic science and technology out of law enforcement's control. Integrity demands nothing less.

Please do not hesitate to contact us if you have questions regarding our comments. Thank you for your attention and considering our concerns.

Sincerely,

/s/ Elizabeth Daniel Vasquez

Elizabeth Daniel Vasquez

Director, Science & Surveillance Project

/s/ Clinton Hughes

Clinton Hughes

Forensic DNA Attorney, Criminal Practice

¹⁵ Lander, at 1674.

¹⁶ See [United States Department of Justice Statement on the PCAST Report: Forensic Science in Criminal Courts: Ensuring Scientific Validity of Feature-Comparison Methods](#) (published Jan. 13, 2021); Thomas D. Albright, [The US Department of Justice stumbles on visual perception](#), 118 PNAS 24 (2021).

**American Society for Microbiology Response to
White House Office of Science and Technology Policy
Request for Information to Improve Federal Scientific Integrity Policies
FR Doc. 2021–13640
June 28, 2021**

The American Society for Microbiology (ASM) is one of the oldest and largest life science societies with 30,000 members in the U.S. and around the world. Our mission is to promote and advance the microbial sciences. We appreciate this opportunity to weigh in on actions the federal government, in partnership with stakeholders, can take to improve scientific integrity policies.

ASM is fully invested in the highest standards of rigor and reproducibility in experimental design, interpretation, and reporting. In recognition that scientific advancement is a global pursuit, we support policies that balance the spirit of international collaboration and preservation of scientific freedom with the protection of national security and economic interests. As a global and diverse scientific society, ASM also recognizes the importance of ensuring a safe and inclusive research environment.

ASM's honorific branch, the American Academy of Microbiology, addressed the topic of responsible scientific research in a 2016 colloquium in which participants considered issues related to reproducibility, the ethical conduct of scientific research, and good practices. The Academy's discussions focused on several areas where Federal policies may impact scientific integrity both directly and indirectly, including funding uncertainties. These recommendations remain relevant today and our responses to the Scientific Integrity Fast Track Action Committee (SI-FTAC) RFI are drawn in large part from this report.

ASM encourages the Office of Science and Technology Policy to develop and implement uniform scientific integrity policies and training across the federal research enterprise. Congress should ensure that funding is provided for this work.

Scientific advancement is incremental and requires a solid foundation of rigorous and reproducible information to translate fundamental discoveries into real world applications. Poorly designed experiments, reporting bias, and misconduct all contribute to the publication of erroneous and non-reproducible information and hinder scientific inquiry. However, it is important to avoid conflating lack of reproducibility or replicability, which are key to sound science, with ethical and academic transgressions; there are many scientifically valid reasons that findings may be unable to be reproduced or are difficult to reproduce.

All stakeholders, including funding agencies, research and academic institutions, journals, professional associations, individual investigators, private sector and industry partners and research groups, have a role to play in ensuring rigor and integrity in scientific practice. This premise is supported by the San Francisco Declaration on Research Assessment (DORA), which set forth recommendations to improve the ways in which scientific research output is evaluated by funding agencies, academic institutions, and other parties to avoid incentives that inadvertently undermine rigor and integrity.

ASM commends federal agencies for taking numerous steps to enhance scientific integrity and transparency over the past several years. OSTP should work toward harmonization of these policies and engage with federal scientific agencies and the scientific community to develop uniform underlying principles for scientific integrity policies.

ASM recommends that federal agencies, with OSTP coordination and stakeholder input, publish clear guidelines governing data stewardship and open access, and that Congress provide funds for data management and data infrastructure. SI-FTAC can lead in this area by taking thoughtful steps toward requiring open data but must do so with input from the nonprofit scientific publishers and the research community. Additionally, federal agencies should uniformly encourage adoption of FAIR data standards in federally funded science, as well consider incentivizing private companies to harmonize approaches to metadata underlying experiments.

Data availability and sharing are critical to ASM's mission to advance the microbial sciences. Without access to data, it is virtually impossible to evaluate reproducibility and potential causes or explanations for any lack of reproducibility. A critical component of peer review is to piece together what the authors did to ensure results are both understandable and interpreted correctly. Better data management with metadata that provides crucial insight into exactly what was done and when would alleviate much of the guess work in peer review, and in turn enhance the quality of the science that is published. Better and more rigorous requirements for data management solutions will lead to more rigorous peer review.

In 2019, ASM expanded our own data policy to be more comprehensive and to apply across all our journals, not just those that are open access. As of October 2019, to publish in any ASM journal authors need to make their data publicly available except in rare circumstances, preferably by depositing it in publicly accessible, curated, and sustainable data repositories. While this policy is not without challenges, we believe the open data policy benefits both authors and readers. Data receive persistent, unique identifiers when they are deposited in these repositories, making them findable and citable. Readers have access to the original underlying data described in a paper, enabling the reuse of that data either for reproducibility purposes or for entirely new analyses. In return, the original data generators will receive credit for their work in the form of data citations. Formal data citations promote reproducibility and help identify how data are reused. We also recognize that many scientists are hesitant to share data in advance of publication due to unscrupulous actors who seek to exploit this information. Efforts to encourage data sharing should also seek to address these unfortunate and detrimental circumstances.

Specific requirements for data availability would vary by discipline. Therefore, scientists, institutions, funding agencies, and scientific societies encompassing specific fields should develop best practices and guidelines to address the following: the types or levels of data to be shared (e.g., raw vs. processed), designating responsibility for the storing and sharing of data, and the appropriate centralization of data. Examples of well-established standards for data sharing include those developed by the Genomic Standards Consortium and various repositories of "omics data."

Creating a peer review process that allows for open data sharing will require investment and technological development by the vendors that create the systems journals use for peer review. It also will require investments by companies that create the tools that scientists use to collect their data (e.g., to enable conversion of proprietary file types into open file types while retaining any underlying

metadata). There may be a role for the federal government in facilitating or encouraging these investments.

Publishing both positive and negative data are valuable to the scientific community and reporting of negative results should be encouraged in respected venues. ASM encourage SI-FTAC to consider how this practice might be implemented in federal science agencies.

ASM is committed to providing an outlet for the publication of sound, scientific information that is important to the overall body of research, including null or negative data and results. For example, ASM Journals recently relaunched Microbiology Spectrum¹, which is aimed at publishing all good quality research, including replication studies, negative results, and re-analyses. Scientific societies also provide a multitude of forums for scientists to discuss research outcomes, including but not limited to annual conferences.

ASM encourages SI-FTAC to harmonize anti-harassment and anti-discrimination policies across science agencies, to support and serve as convener for the various entities that are responsible for implementing those policies, and to collect data on an ongoing basis to inform anti-harassment and anti-discrimination policies. Federal support also is needed for the development of infrastructural resources, such as effective training programs to address harassment in science.

Harassment in any form or for any reason undermines the facilitation of good science. As a global and diverse professional scientific society, ASM recognizes the significant role that we can play in ensuring a safe and inclusive environment.² We are committed to promoting an environment that both allows for the free expression and exchange of scientific ideas and promotes equal opportunities and respectful treatment for all. However, the responsibility of the federal science agencies in addressing and eradicating discrimination and harassment cannot be overlooked.

The best science is conducted when research environments are diverse and inclusive, regardless of gender, race or ethnicity, religious affiliation, or sexual orientation. Congress has recognized the need to address these issues through legislation such as the Combatting Sexual Harassment in Science Act. If enacted, this legislation would clarify and strengthen the federal government's role in addressing this by convening stakeholders, authorizing data collection, and funding research to better understand how to address harassment in STEM. ASM supports this legislation and encourages these efforts to expand beyond sexual harassment to address racism and other forms of bias in the scientific enterprise.

ASM commends the NIH leadership for establishing a working group, which has now issued a report making recommendations for changing the culture to end sexual harassment. The report includes recommendations for scientific societies regarding conferences, meetings, and events. ASM also commends the leadership of the National Science Foundation for efforts to directly address harassment among grantees. These efforts are critical to changing the culture and such efforts should be required for all federal science agencies.

¹ Microbiology Spectrum: <https://journals.asm.org/journal/spectrum/about>

² ASM expanded its Member Code of Ethics to capture conduct component. See "Code of Ethics and Conduct" (<https://asm.org/Articles/Ethics/COEs/ASM-Code-of-Ethics-and-Conduct>).

SI-FTAC should consider recommending that federal agencies expand their efforts to educate scientists on fundamental best practices in both conducting and reporting research at all research institutions and across the career spectrum.

Scientific training is, by its very nature, individualized to fields of study, institutions, and laboratories. Such training typically focuses on STEM students and postdocs, though there are data showing that the problem of misconduct spans generations and includes senior scientists ([Fang et al. 2013](#)).

An important way to instill principles of integrity in the research enterprise is to strengthen oversight. This can be done by establishing a comprehensive, consistent, and transparent system to report problems to both research institutions and federal oversight entities (e.g., HHS's Office of Research Integrity) to enforce integrity at all levels. This is certainly an area where collaboration will be needed between federal science funding agencies and the stakeholder community. We appreciate that ORI offers grants that are open to scientific societies. We also support the requirement that every four years, NIH grantees must participate in a Responsible Conduct in Research training; such training should be required of all federally funded scientists, regardless of career stage.

While the scientific enterprise would benefit from federal scientific integrity policies that create a clear set of standards and mechanisms for enforcement across agencies, the SI-FTAC should also consider the underlying factors that drive mistrust, misunderstanding, and misconduct in science. These include inconsistent federal funding, misunderstanding of science among the public, and rhetoric that fuels mistrust.

The members of the American Academy of Microbiology who participated in our 2016 colloquium noted that scarcity of funding can fuel sloppy and dishonest science where it exists. Congress and the federal government can support scientific integrity by providing consistent funding levels for scientific research. Colloquium participants acknowledged that the double-edged sword of competition and scarcity could persist as a complication in resolving problems with reproducibility. Positive forms of competition incentivize the quest for new knowledge or the creation of a particular product. Negative competition—where competition dictates job security or the ability to continue practicing science—can impair creativity and spawn undesirable research practices. Sustainable, predictable funding for research and training is a means by which many of these problems can be addressed.

Concurrent with the pressures induced by decreased funding availability is the rapidly expanding size of today's scientific enterprise—in both numbers of projects and the personnel and resources required—that creates huge pressures on institutions to hit regular home runs with research results. Colloquium participants expressed concern that the focus on “high-impact” science might distort the course of science, such that some important questions are no longer pursued. Publication in high-impact journals has disproportionate rewards for those who succeed. Coupled with the expectation of these journals to publish innovative, flashy, and newsworthy science, these academic and financial rewards might tempt scientists to decrease rigor, artificially tidy up results, and inflate import to submit the “perfect story,” which is, frankly, rare.

Finally, primary, secondary, and university curricula must be based on sound, rigorous science, as opposed to politics or personal beliefs. Curricula must also provide students with a deep understanding

of the role of science in the global challenges they face and prepare them to solve problems creatively, ethically, and innovatively at all levels.

We urge SI-FTAC to continue an open dialogue with the scientific community and research institutions, with the goal of finding an appropriate balance between our nation's security and an open, collaborative, scientific environment.

Scientific advancement is a global pursuit, and it is critical that public policies allow and encourage formal and informal scientific collaboration regardless of national boundaries. At the same time, ASM recognizes that vigilance is required to protect integrity of the publicly funded research enterprise.

The American Society for Microbiology thanks the White House Office of Science and Technology Policy and for making research and development a key priority. ASM and its members look forward to next steps in this endeavor and stand ready to assist you. For more information, please contact Allen Segal, ASM Director of Public Policy and Advocacy, at asegal@asmusa.org or 202-942-9294.

Sincerely,

A handwritten signature in black ink that reads "Stacey Schultz-Cherry". The signature is written in a cursive, flowing style.

Stacey Schultz-Cherry, PhD
Chair, ASM Public and Scientific Affairs Committee

July 28, 2021

ATTN: White House Office of Science and Technology Policy and Scientific Integrity Task Force

RE: Request for Information to Improve Federal Scientific Integrity Policies

To whom it may concern,

Please accept these comments from the [Gulf of Mexico Reef Fish Shareholders' Alliance](#) (Shareholders' Alliance) in response to the Request for Information to Improve Federal Scientific Integrity Policies.

The Shareholders' Alliance is the largest organization of commercial snapper and grouper fishermen in the Gulf of Mexico, with membership in every Gulf state. We work hard to ensure that our fisheries are sustainably managed so our fishing businesses can thrive and our fishing communities can exist for future generations. We are the harvesters that provide much of the American public with a reliable source of domestically-caught wild Gulf seafood, and we do this through a philosophy that sustainable seafood and profitable fishing businesses depend on healthy fish populations.

Our organization and our members believe the best policies that lead to robust fish stocks, and therefore healthy seafood businesses, are based in rigorous and sound science. We value cooperative research opportunities, and our organization has actively participated with National Oceanic and Atmospheric Administration (NOAA) and academic institutions on research since our foundation in 2006. We know that science evolves, and that better data lead to better management and ultimately healthy marine environments.

For the last thirty years, we have seen populations of iconic species like American red snapper rebuild, in part, because our Regional Management Council, the Gulf of Mexico Fishery Management Council (Gulf Council), has set catch levels and fishing quotas based on stock assessments that are peer reviewed and go through a standard, rigorous process called the [Southeastern Data, Assessment and Review](#) (SEDAR). One of the biggest challenges in Gulf fisheries management is private angler data. Commercial fishermen participate in mandatory reporting, which is subsequently verified. Private anglers participate in voluntary reporting through surveys with low response rates. As a result, commercial landings estimates are much more certain than those in the private angler sector. Collaborative research by private anglers, as commercial fishermen have done, could lead to more accurate data, so long as it goes through a

rigorous peer review process, and we see value in such collaborations and independent studies occurring.

However, we are concerned with the recent trend in fisheries research projects being funded by Congress, leveraged by radical private angling lobbying groups, and used to direct management and policy. In 2016, Congress determined there was need for a large scale research project with the intent of generating an estimate of how many red snapper are in the Gulf of Mexico. This information could be used to potentially confirm reports from both recreational and commercial anglers that red snapper populations are in better shape than they have been historically, and generate data that could inform a sustainable increase in quotas and access for all stakeholders. The result of these appropriated funds is the Great Red Snapper Count (GRSC), which had a price tag of around \$10 million.

The final report of the GRSC is still being revised based on input from independent reviewers and the Gulf of Mexico Science and Statistical Committee (SSC). The GRSC preliminarily suggests there are three times more red snapper in the Gulf than estimated by NOAA.^{1,2} This should be good news for commercial and recreational fishermen alike. However, the NOAA Bottom Longline Survey, which includes thirty years of data, shows a declining trend in red snapper.³ On top of that, commercial reef fish fishermen are seeing localized depletion on well-known fishing spots during the height of the private angling seasons. The results of the GRSC and the process for utilizing its results for management advice has also brought to the forefront the need for a clearer process for integrating independent research outside of the SEDAR process into management.

Information generated by the GRSC created immense pressure on the SSC and the Gulf Council to recommend and implement catch levels higher than have ever existed for red snapper – **up to 263% higher**.⁴ At the April 2021 Gulf Council meeting, the acting chair of the SSC, made note of this on the record:

“I think there was a lot of pressure on the SSC, and not only to undertake this in a very expedited fashion, but it was also clear that there were very strong expectations that this would result in a substantial increase in catch.”⁵

¹ Mississippi-Alabama Sea Grant. March 2021. [Great Snapper Count finds 110 million red snapper in Gulf, three times more than previous estimates.](#)

² Stunz, G. W. et al. 2021. [Estimating the Absolute Abundance of Age 2+ Red Snapper \(*Lutjanus campechanus*\) in the U.S. Gulf of Mexico.](#) Mississippi-Alabama Sea grant Consortium, NOAA Sea Grant.

³ Pollack, A.G. March 2021. [Additional Analysis of Relative Abundance for Red Snapper Captured During Fishery Independent Bottom Longline Surveys in the Northern Gulf of Mexico.](#) NOAA Fisheries, Southeast fisheries science Center. Mississippi Laboratories, Pascagoula, MS.

⁴ NOAA Fisheries. Southeast Fisheries Science Center April 2021. [Catch Advice for the Gulf of Mexico Red Snapper Stock Derived from Estimates of Absolute Abundance Produced as Part of the Great Red Snapper Count.](#) p 21

⁵ April 2021. [Gulf Council Meeting Minutes.](#) p 34

For now, the Acceptable Biological Catch (ABC) remains close to the level set prior to the GRSC (increased to 15.4 million pounds from 15.1 million pounds). But the Overfishing Limit (OFL) was increased from 15.5 million pounds to 25.6 million pounds,⁶ despite concerns raised by members of the SSC⁷ and the independent reviewers.^{8,9,10} This is a larger catch limit than when the fishery was declared overfished in the 1990s. A 10-million-pound disparity between the ABC and OFL creates opportunity for unsustainable harvest of red snapper without triggering an official overfishing declaration. This could unravel the great progress we have made rebuilding the fishery.

A similar study to the GRSC has been initiated in the Gulf for Greater Amberjack. The Greater Amberjack stock is currently overfished, undergoing overfishing, and has missed several rebuilding timelines. Commercial fishermen are concerned that, should the trajectory of [Greater Amberjack Research Program](#) (GARP) be the same as GRSC, it will further damage a sensitive stock that hasn't been at healthy levels since the 1980s.¹¹

Congress appropriated \$9 million for the GARP, and the final award to the academic institution that will conduct the research has yet to be announced. Mississippi-Alabama Sea Grant (MASG) is distributing these funds and leading the process for selecting an awardee. MASG had the same role for the GRSC.

Our concerns and suggestions for scientific integrity in Gulf of Mexico fisheries are as follows:

1. A policy should be developed for reviewing and evaluating independent research funded by Congress. The GRSC was an unprecedented and groundbreaking study, but as the project came to an end and preliminary results communicated, it became clear that there was no pre-existing process for evaluating and reviewing the results before they were distributed to the public and incorporated into management. Commercial fishermen were immediately concerned about the public perception around the GRSC results; we knew that there were fish on what the GRSC called “uncharacterized bottom,” and had been saying so for years,¹² yet based on the countless hours commercial fishermen spend on the water, we knew the stock could not handle the kind of pressure that would come from the public thinking there were 110 million red snapper in the Gulf..

⁶ June 2021. Gulf Council. [Modification of Annual Catch Limits for Gulf of Mexico Red Snapper.](#)

⁷ March 30-April 2, 2021. Standing, Reef Fish, and Socioeconomic SSC. [Meeting Summary.](#)

⁸ Christman, M. March 2021. [Draft Review of GRSC Report by Christman, 23 March 2021](#)

⁹ Cadrin, S. March 2021. [Peer Review of “The Great Red Snapper Count: Estimating the Absolute Abundance of Red Snapper in the U.S. Gulf of Mexico.”](#)

¹⁰ Eggleston, D. March 2021. Peer Review of [“The Great Red Snapper Count: Estimating the Absolute Abundance of Red Snapper in the U.S. Gulf of Mexico.”](#)

¹¹ SEDAR 70. [Stock Assessment Report. Gulf of Mexico Greater Amberjack.](#)

¹² Gulf of Mexico Reef Fish Shareholders' Alliance. March 2021. [Gulf of Mexico Reef Fish Shareholders' Alliance Statement on the Great Red Snapper Count.](#)

The interest generated from the publication of the preliminary results, and the expectation that this “new” estimate of red snapper abundance would mean large quota increases, highlighted the lack of process to formally review the GRSC before its results would be used for setting catch levels. SSC members voiced their concern about the process around the GRSC, the timeline in which it was occurring, and the preliminary presentation on the study they received in January 2021.^{13,14} The SSC ultimately passed a motion to “*request an expedited review of the Great Red Snapper Count results by an independent panel including SSC representatives and CIE or other independent reviewers with expertise in the methodologies used.*”¹⁵ This was the first time a formal review process had been suggested. With the GARP underway, and the potential for more Congressionally funded independent research, NOAA must develop a clear, transparent policy directing how these studies are independently peer reviewed.

2. There must be a standardized methodology for incorporating independent research into catch advice and management decisions. Usually, catch advice is generated from a research track or benchmark assessment through SEDAR, or an interim assessment by a NOAA Science Center. SEDAR is a public process and can incorporate both federal and independent research. The GRSC is the first instance, to our knowledge, of a single study being used to generate catch advice without going through SEDAR. This sets precedent for any research to generate catch advice outside of the standard SEDAR. Our marine resources and fish populations are too important to base management advice on one study that isn’t consistent with the stock assessment process.
3. There needs to be a well-defined, quantitative, transparent process for awarding public funds for independent research. The Request for Proposals (RFP) for the GARP gives the director of MASG the sole authority to determine what academic institution receives the funds. While there is a Steering Committee and a review process for proposals, there are no clear guidelines on selecting a project award. “The MASGC director, in consultation with the steering committee, has final discretion to recommend proposal(s) for funding.”¹⁶ Award of public money should not lie in the hands of a single individual, and the process for awarding such funds should have clear, transparent guidelines that are quantitative and available to the public.
4. Deliberations by the Regional Fishery Management Councils on selected SSC members should be open to the public. The selection of SSC members at the Gulf Council currently occurs in closed session and minutes are not taken or recorded. This leaves the public in the dark about what qualifications or characteristics were considered when selecting or

¹³ Gulf Council SSC. January 2021. [Meeting Minutes](#). p 194.

¹⁴ Stunz, G. January 2021. [The Great Red Snapper Count. Estimating the absolute abundance of Red Snapper in the U.S. Gulf of Mexico.](#)

¹⁵ Gulf Council SSC. January 2021. [Meeting Minutes](#). p 194.

¹⁶ MASG. January 2021. [Greater Amberjack Research Program Request for Proposals.](#)

omitting someone from the SSC. Commercial fishermen rely on the SSC to be composed of the best and impartial scientific minds in the region so that recommendations on catch levels to the Gulf Council are precautionary and ensure populations continue to grow and support our businesses. Publicly selecting SSC members would defend against political motivations bleeding into the science that is crucial to informing management and keeping the Gulf of Mexico healthy.

We appreciate the opportunity to bring these suggestions to the White House Office of Science and Technology Policy and urge the Task Force to consider them. We firmly believe that good science leads to healthy ecosystems, abundant fish stocks, and better access to fish and seafood for all stakeholders.

Thank you,

A handwritten signature in black ink, reading "Eric Brazer". The signature is written in a cursive, flowing style with a prominent "E" and "B".

Eric Brazer
Deputy Director, Gulf of Mexico Reef Fish Shareholders' Alliance



Request for Information Response

To: White House Office of Science and Technology Policy
From: University Corporation for Atmospheric Research
Date: July 28, 2021
Re: Request for Information to Improve Federal Scientific Integrity Policies

The University Corporation for Atmospheric Research (UCAR) is a nonprofit consortium of 120 North American colleges and universities focused on research and training in the Earth sciences. The responses provided here represent a consolidation of views solicited from UCAR, the National Center for Atmospheric Research (NCAR), and UCAR Community Programs (UCP). The responses reflect our collective input and not a consensus position of all communities, entities, or individuals within UCAR, NCAR, and UCP.

The White House Office of Science and Technology Policy sought input on the following topics:

1. The effectiveness of Federal scientific integrity policies in promoting trust in federal science
2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information
3. Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce
4. Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices
5. Other important aspects of scientific integrity and effective approaches to improving trust in federal science.

As a general principle, UCAR supports efforts to strengthen scientific integrity policies across the federal government. As the steward of the National Science Foundation's premiere Earth system science research and development center, the protection of scientists from undue political interference, and the protection of scientist's rights to safeguard their work from such interference is of utmost importance. Please find below responses to the prompts presented in the request for information.

Prompt 1: The effectiveness of Federal scientific integrity policies in promoting trust in federal science

The presence of scientific integrity policies provide a recognizable construct in which scientists and the general public operate; whereas the absence of such policies lead to uncertainty, confusion, and significant risks to the public. Such policies must themselves be transparent, to allow for the public to understand how they function, and applied consistently across the government. Strong policies should make clear what political interference is taking place, the potential or actual harm that results from such interference, the remedy for halting and reversing

such interference, the penalties for engaging in such interference, and a mechanism for scientists and science agencies to correct the record.

Some suggest that increasing the independence between agency scientists and political appointees may be a necessary step to avoid violations of scientific integrity, or, to have leadership in science agencies be driven by merit as opposed to political appointment. What is evident in these perspectives is a desire to ensure that science carried about by federal scientists are allowed to continue unmolested by the political whims of the day. Note that not all political interference may occur between political appointees and career scientists, making it that much more important to ensure that policies are broadly applicable and enforced consistently irrespective of the source of interference.

Prompt 2: Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information

There is a recognized need for the use of media professionals in the communication of federal science to the general public. Such media may inadvertently, or deliberately, misinterpret or misrepresent findings in the course of their reporting. However, there are mechanisms in the media to correct mistakes after they occur, and systems in place to prevent mistakes from occurring. Such mechanisms should exist within the federal government to allow scientists to correct the record if misinformation is disseminated by an Agency. In addition to corrective measures, federal agencies may consider developing policies the involve the authors of scientific work in the creation and review of any media about their specific work, or their area of expertise. Such consultation could alleviate the possibility of incorrect information being shared to the public, clearly highlight instances of more deliberate misrepresentations, create opportunities for professional growth by both media professionals and scientists, and if done transparently, strengthen the trust an agency has with the general public.

Prompt 3: Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce

The expertise that exists within the greater scientific workforce, both in and out of the Federal government, must be recognized and promoted. Such efforts are needed to provide confidence to the scientific workforce that their work will not be marginalized or viewed as driven by an external agenda. Better, more effective, more efficient, and more inclusive methods of communicating science to the general public is an essential step in addressing such issues.

The disagreements between scientists, and the challenges of communicating uncertainty, are equally important to address. Federal science agencies should consider developing transparent dissenting views policies, as well as educating the general public on how disagreements in the scientific community arise, resolve, and inform continued research on any topic.

In addition, Agency leadership should continue to promote the interaction between federal scientists and the greater scientific community. Top-down policies that reward such interactions, and the communication of the benefits of such interactions, may prove to be more effective than bottom-up efforts that arise on an individual basis.

Lastly, but critically, Federal agencies must develop policies that protect the peer review process from interference, political or otherwise. The peer review process is an essential and necessary part of the scientific process, widely considered to be the gold standard of review. Protecting the integrity of peer review provides credibility to scientific works published and relied upon by Federal agencies. Policies that strengthen, protect, and demystify peer review to the general public will likely serve to build greater confidence in decisions reached by the Government that are based on science.

Prompt 4: Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices

No amount of training will provide the degree of confidence in a system than consistent and transparent application of the policy. Making scientists more aware of their rights will not necessarily lead to a greater number of scientists exercising such rights. To the extent that scientific integrity officials can communicate out the results of their investigations, such information would be the basis for improving the awareness of scientific integrity practices and in turn make any trainings for staff more effective.

Prompt 5: Other important aspects of scientific integrity and effective approaches to improving trust in federal science

As stated above, Federal agencies can improve upon the methods used to communicate uncertainty and risk in scientific findings that underpin policy decisions. Such improvements would likely lead to greater trust between Federal scientists and the public.

To the White House Office of Science and Technology Policy Scientific Integrity Fast-Track Action Committee

Contributed on behalf of the [Pennsylvania State University Science Policy Society](#)

Respondent type: academic and advocacy

Tara L. Pickens, MSc, PhD Candidate, Pennsylvania State University, Department of Food Science and President of PSU Science Policy Society

Part 1: Towards improving the engagement of Federal scientists working on scientific matters with news media and on social media.

Sierra M. Hicks, Master's student, Pennsylvania State University, The School of Engineering Design, Technology, and Professional Programs

Part 2: Towards addressing gaps in current scientific integrity policies related evolving scientific practices, such as citizen science and community-engaged research, in addition to scientific integrity policies related to emerging technologies.

Part 1: Towards improving the engagement of Federal scientists working on scientific matters with news media and on social media.

The following analysis and recommendations in Part 1 are based upon the publicly available USDA Departmental Regulation on Scientific Integrity, DR 1074-001, and USDA's Office of Communications organization chart, although these recommendations could potentially be extrapolated to other Federal Agencies' Scientific Integrity Protocol.

The relationship between the scientific community, politics, journalism, and public trust has long been tenuous but the COVID-19 pandemic placed a spotlight on the interplay. From the misinformation surrounding effective treatments for COVID-19^{1,2} and the politicization of vaccine safety^{3,4} to the media and [political](#) portrayal of uncertainty regarding the anthropogenic effects exacerbating climate change^{5,6}, current events are placing a further strain on these relationships. Politics and journalism move at a much faster pace than science and this creates dissonance that is often then translated to the public^{7,8}.

Transparency, uncertainty, and self-correction are central to the scientific endeavor and can often be miscommunicated by the media as "science has failed." According to [findings](#) by researchers at the Annenberg Public Policy Center and the University of Buffalo, the media's narrative surrounding the self-correcting nature of science plays a tremendous role in the public's trust and support for science and science-based policy. The [relationship](#) between scientists and journalists is one of the central pillars of science communication and has undergone a rapid shift as our digital landscape has evolved to include new media outlets such as blogs, social media, and online video-sharing platforms. This has created many opportunities for scientists to communicate with the public directly^{9,10}, but [journalists](#) will remain key players in the transfer of scientific knowledge from governmental agencies to stakeholders. A recent Nature interview¹¹ with five journalists who covered science during the COVID-19 pandemic revealed Journalists feel that: 1) Scientists often

do not communicate scientific information in a way that is accessible to the average Reader or Listener; and 2) Institutions do not support scientists in speaking with journalists. Science is like a second language, and this builds a wall of inaccessibility to outsiders who need a translator to properly interpret and communicate the findings to various stakeholders, and most often, journalists are filling the role of translator^{12,13}. We must ensure that Federal scientific information, along with its' inherent uncertainties, is communicated freely, clearly and effectively to journalists who then translate this to the public and decisionmakers and we must ensure that Federal scientists may speak freely about their work and are able to express their expert opinion on important scientific matters without fear of repercussion.

While most scientists consider visibility in the media and engagement with journalists a professional duty and an indicator of the Broader Impacts of their work, there is some separation in how they distinguish between the arenas of internal scientific and public communication. Different sectors prefer different modes of information transfer and use knowledge in different ways. There is a need for investment into improving the skillsets and communication skills of Federal scientists to ensure that knowledge transfer can be achieved across varied audiences. Review of the current policy (DR 1074-001 §6e) indicates that while USDA scientists are encouraged to engage in communications with the media and are advised by the Office of Communications, Federal scientists receive no formalized training in communicating science to the media or other non-scientist stakeholders. Further, Federal scientists are not permitted to speak with media without prior approval and routing through the Office of Communications, which does not employ a Scientist to make calls on scientific accuracy. To address these issues, I recommend the following:

1) Improve the communication skills of Federal scientists:

While the USDA's Science Integrity Policy notes that scientists are encouraged, but not expected, to engage with the media, there is no mention of any skill development that may improve their science communication skills for non-scientist audiences. These skills can be developed through practice and professional development opportunities. There are many science communication-focused workshops that explore the interplay between knowledge transfer and audience motivation. I recommend providing a workshop such as the Alan Alda Science Communication Workshop to Federal scientists who express interest in communicating with the media and/or directly to the public or other non-scientist stakeholders.

2) Declare the right of scientists to maintain accuracy as the final reviewers of content:

The USDA Office of Communications organizational schema does not include a scientist to ultimately make the calls about scientific accuracy of press releases, blogs, or other information outlets. I recommend to:

- a) Declare the right of each Federal scientist to take ownership of their content and act as the final reviewer. Their name will be released publicly.
- b) Add a Science Communication Specialist to the Office of Communications with at least a Master's level science education and expertise in science communication who will

act as the final scientific reviewer when the original scientist is unable to do so. This role will serve both branches of the Office of Communications.

3) *Ensure a sustainable pipeline of incoming scientists with honed science communication skills:*

Federally funded research should more highly reward scientists engaged in Broader Impacts with an emphasis on science communication. One might argue that the ability of a scientist to transfer knowledge across different audiences is as important as the ability to contribute to research. Ultimately, if policy-decisions are to be made based upon the best available science, it is integral to clearly communicate the strengths and weaknesses of that science to the public and decision makers. Through more highly rewarding science communication efforts, we can build a stronger scientific community and improve scientific integrity and public trust. I recommend two things:

- a) Ensure that early career scientists with a passion and acumen for science communication are more highly rewarded through their Broader Impacts section of Federally funded research expenditures by allocating at least 5% of funding towards projects with a strong science communication component.
- b) Offer remote summer internships to undergraduate and graduate students within the Office of Communications who can get experience writing on relevant topics to a variety of stakeholders. Remote internships would be less costly than in-person and assure the burgeoning scientist is still able to make progress on their research project at their home university. These interns would be overseen by the Science Communication Specialist as recommended above.

Part 2: Towards addressing gaps in current scientific integrity policies related evolving scientific practices, such as citizen science and community-engaged research, in addition to scientific integrity policies related to emerging technologies. to emerging technologies.

Collaboration, specifically collaboration among various perspectives, is perhaps one of the most critical tools of human achievement. A film, *The Professor and the Madman*, made its recent Netflix debut, popularizing the narrative of a Sir James Murray who brought the Oxford English Dictionary into our world. His method amassed the support of ordinary people in the order of thousands, who sent postcards of quotes demonstrating the use of words found in literature, beginning in the 1500's¹.

Alliances among ordinary people produce results otherwise not achievable by limitation of time, resource, access, etc. The International Science Council views citizen science (CS) as “An important vehicle for democratizing science and promoting the goal of universal and equitable access to scientific data and information.” CS data, in particular, is highly valuable to scientists, and anyone invested in the pursuit of crucial sustainable development, given its valuable and extensive use in studies of biodiversity and pollution². CS is also found effective in triggering behavior change and building social capital around environmental issues, which are abundant³.

Our environment is rapidly changing, and capturing such changes requires observation spanning large quantities of time and space. Perhaps in the most authentic spirit of CS, a study in Australia suggests that in its marine space, leveraging the activities of millions of resource users, such as divers, beachcombers and Indigenous, commercial and recreational fishers is beneficial⁴.

While CS is becoming more popular and accepted, it comes with its own set of challenges which have been identified by various scholars. Those challenges, however, have not been recognized without valuable thought toward solutions, both tested and hypothesized. Further discussed herein are important additions to an existent government supported CS website, and key focus areas for further policy/procedural development.

Citizenscience.gov appears to serve as the United States Government's supportive resource for ambitions pertaining to CS. Included therein are use cases of CS, general overview materials, toolkits and guides. A critique of this outlet is the lack of scholarly materials dated 2015 or later, which would be necessary in a field where so much knowledge concerning best practices is being rapidly generated. The following additions to the website demonstrate the depth that guidance materials must achieve, and highlight specific focus areas that are found to be most important in up-to-date scholarly literature.

Different considerations for flexibility must be made with regard to shorter and longer-term CS studies. Operational and structural aspects, such as an online platform, must be easily upscaled or downscaled depending on what is required, mostly when a project is developing beyond its 5-year point⁵.

Considerations must be made for the circumstance where privacy meets contributor interests. Potential participants may be likely to decline engagement if they feel their go-to fishing spot might be discovered, for example. A study found it helpful when they gave participants control and discretion to select a range of spatial scales to record observations, and when a contributor submitted an observation, their permission was sought for use of the photo on the website “for promotional not-for-profit purposes⁶.”

Specific ways to keep contributors engaged and motivated include (1) Provide instantaneous feedback once a person logs an observation, informing them of the next steps, (2) Celebrate and provide feedback at the group-level to contributors, (3) Provide updates via social and online media, in addition to newsletters, (4) Maintain a platform that displays the most recent observations and (5) Push for use of project data in scientific publications or policy actions, which leads to contributors feeling they're participating in something of value. These supportive measures help achieve engagement objectives and ensure on-going funding streams, in addition to maintaining flow of contributions⁷.

Leverage the use of wireless technologies to maximize reach, streamline workloads and processes and facilitate collaboration among contributors. Integration of websites, smartphone applications and social media (Facebook, Instagram, and Twitter) have proved beneficial. However, project administrators should be aware of challenges associated with using websites and apps such as developer software updates which require further resources to manage, and should be planned for in advance⁸.

‘Contributory’ CS projects can also include elements of a ‘Collaborative’ model where contributors are not limited to data collection, but can also formulate research findings and disseminate information⁹.

New projects should consider existent, tested infrastructure throughout the lifecycle of project data. To whatever degree achievable, a project should avoid use of new and distinct platforms¹⁰.

An archiving strategy should involve more than one copy, use different media technologies, and preserve the datasets at different locations¹¹.

Available within any CS guidance resource should be an increased amount of material supporting data documentation, as this encourages reuse. Other ways to increase reuse of data include providing (1) Easy access to data in standardized formats, (2) Multiple download options such as raw and cleaned data, temporal and spatial subsets, and (3) Multiple format options such as spreadsheets, geographic formats, and API access¹².

Scientists/administrators should be made aware when exploring any CS guidance resource that broader open science efforts are required to promote open science access to citizen science data¹³.

Section 402 of Public Law 114-329 pertains to crowdsourcing and CS regulation, but only appears to oversee the affairs of Federal agencies. No explicit language in section 402 regulates the CS affairs of private industry, though private industry and its scientific results influence public opinion of scientific integrity. More regulation is needed and called for by scholars in this regard. Henceforth discussed are focus areas for policy development across Federal and private CS.

For projects that collect and process CS observational data at national scales, governing projects can be especially challenging given the multi-jurisdictional environment. An agency which serves as a liaison between these jurisdictional environments and scientists might assist to streamline these larger-scale projects and aid in the timely management of observations submitted by the public. The agency could also work alongside or, in some cases, replace a project’s National Steering Committee and National Coordinator (Supported by Regional Administrators in each jurisdiction). This agency could also help

develop memorandum of understanding among multiple organizations, particularly handling the governance of data across jurisdictions¹⁴.

In addition to contributor training, sensor calibration checks, flagging outliers for further checks, incorporating uncertainty metrics into devices, volunteers and individual measurements, requirements for the initial analysis of the quality of collection, sampling approaches, and triangulation against other data sets might help to increase the credibility of CS data in the scientific community¹⁵.

Policies pertaining to privacy should balance privacy against openness. Concerns around the safety of endangered or threatened species in addition to citizen scientists in sensitive locations are legitimate. “Any regulation regarding privacy should ensure data ownership and data use rights are clearly stated and reflect the priorities of the volunteers¹⁶.”

Preventative regulatory measures should be taken to ensure that licensing doesn’t prevent third parties from providing value-added data and services, such as with Creative Commons licenses commonly used in the CS field (CC BY-NC 2.0 & CC BY-SA 3.0). A study suggests other licenses, such as the Open Data Commons Open DataBase License may be appropriate for maximizing project data reuse¹⁷.

Regulatory oversight must remove the limitations of sticking to absolute and fixed measures of impact, which are typically quantified. Progress must be measured against project-specific objectives and take into account a variety of contextual factors. Comparisons must also be made to different citizen science projects, a non-citizen science project, or a lack of project¹⁸.

Quality assurance/quality control (QA/QC) checks must be required to be documented in a standardized way. QA/QC practices can be documented on project websites or through formal QA/QC plans. Controlled vocabularies for articulating common data-quality practices can be developed by researchers seeking to advance the field of CS¹⁹.

Standard data policies should be developed that include privacy policies and terms of use, and which clearly outline data governance practices²⁰.

Wildlife laws should be explicitly expressed in their relation to citizen science regulation or developed to protect species from potential harm of increased proximity to human observers. Systems to check on animal welfare should be a requirement. Where formal regulations are undesirable or impractical, informal regulations as alternatives or additions should be considered²¹.

A word on citizen science, a global digital ecosystem and Indigenous Communities:

An emerging trend in technology is the global digital ecosystem, called into use especially for enhancing precautionary, predictive, and adaptive environmental governance. The ecosystem, in theory, includes a fully integrated global environmental monitoring, data-sharing, and decision-support systems, meant to build support for constructive action toward sustainability. Primary targets for initial publications and discussions of such an ecosystem include citizen scientists alongside the likes of environmental scientists and conservation tech-innovators. Specific citizen scientists, Indigenous communities, deserve and require special considerations and protections. Although Indigenous peoples make up less than 5% of the world's population, their traditional lands are home to 80% of the world's biodiversity. Indigenous and Tribal Peoples are protectors and managers of natural resources and biodiversity. Key issues requiring attention are Indigenous data sovereignty and data rights. In other words, Indigenous people must have control of Indigenous data by law. Regulatory action should be taken regarding the compliance to [CARE](#) principles for Indigenous Data Governance, which complement existing FAIR standards. Regulation must be consistent with the UN Declaration on the rights on Indigenous Peoples²².



SPARC Response to OSTP Request for Information to Improve Scientific Integrity Policies (86 FR 34064)

Submitted on behalf of SPARC (The Scholarly Publishing and Academic Resources Coalition) by Heather Joseph, Katie Steen, and Nick Shockey, July 28, 2021.

[SPARC](#) (the Scholarly Publishing and Academic Resources Coalition) is an advocacy organization working on behalf of more than 240 academic and research library members to make research and education open and equitable by design. We believe that sharing knowledge is a fundamental human right, and that strong open science policies that reflect this right will simultaneously increase scientific integrity while also increasing and diversifying participation in the scientific enterprise.

We thank OSTP for the opportunity to provide comments on federal scientific integrity policies and to make suggestions for their improvement.

Open Science is Foundational to Ensuring Integrity and Equity in the Scientific Enterprise

A strong open science policy should be a cornerstone of the Biden Administration's approach to improving scientific integrity. Open science can significantly advance numerous areas that impact public trust in research—including reproducibility, error and fraud detection, prevention of the suppression or distortion of scientific findings, and the advancement of equity in research.

The open communication of research outputs (including articles, data, software, code, and algorithms) can significantly boost scientific integrity by dramatically increasing the number of reviewers and enabling the use of new automated tools for detecting errors often missed by human readers.

While there are numerous examples of openness enabling a more powerful review of research results, a specific example is instructive. Researchers Michèle Nuijten and Sacha Epskamp developed a tool called *statcheck* that *Nature* described as “a spellchecker for statistics.”¹ The program automatically scans articles for statistical

¹https://www.nature.com/news/polopoly_fs/1.21049!/menu/main/topColumns/topLeftColumn/pdf/540151a.pdf?origin=ppub

results, recomputes the calculations and checks that the numbers match. In reviewing 30,717 Psychology papers to identify 16,695 that tested hypotheses using statistics, statcheck found at least one potential error in half,² demonstrating both the magnitude of the challenge and the utility of automated tools in meeting this challenge.

Nuijten and Epskamp's collaborator, Chris Hartgerink, extended the tool to automatically notify both the authors and readers of the potential error in papers analyzed by statcheck. When a statistical inconsistency was detected, Hartgerink's script automatically posted a message on [PubPeer](#), an open, non-profit platform where people share and discuss scientific articles.³ This extension of the statcheck script demonstrates how these tools can be applied not only to detect errors but also to begin to correct the scientific record through communication on open platforms.

Open science can be a powerful counter to the suppression and distortion of scientific findings. Openly licensing articles and data allows them to be distributed, shared widely, and mirrored in different repositories, avoiding a single point of failure where important results may be removed from a website or repository. Opening up the scientific evidence underlying government policies and recommendations can boost public confidence, particularly in difficult or politically-charged decisions. In a Joint Appeal for Open Science by CERN, OHCHR, UNESCO and WHO, the UN High Commissioner for Human Rights, Michelle Bachelet, specifically highlighted the importance of opening up research results to bolster public support for the measures necessary to combat both COVID-19 and climate change effectively.⁴

In the same statement, Commissioner Bachelet raises the opportunity that open science presents to “promote the inclusion of scholarship by people whose contributions and needs are too often overlooked.”⁵ Well-constructed policies that support both open participation in and access to the results of science can boost public confidence in research by making it more representative of the public it seeks to serve.

By limiting participation to the select few who can afford to pay, the legacy, subscription-based model of distributing research findings is fundamentally at odds with the advancement of equity in research. The exorbitantly expensive “open” options now presented by the largest commercial publishers simply flip restrictions on access to restrictions on participation, locking out authors who cannot afford to pay to publish by

² <https://link.springer.com/content/pdf/10.3758/s13428-015-0664-2.pdf>

³ <https://www.vox.com/science-and-health/2016/9/30/13077658/statcheck-psychology-replication>

⁴ <https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26433&LangID=E>

⁵ Ibid

charging fees that can exceed \$11,000 per article.⁶ To address the barriers presented by both paywalls and prohibitively expensive publication fees, OSTP should strengthen the 2013 Memorandum on [Increasing Access to the Results of Federally Funded Scientific Research](#) in the key areas described below that can put equity and the public interest at the core of U.S. open science policy.

Effectiveness of current agency policies

The [2010 OSTP Memorandum](#) on Scientific Integrity identifies “facilitating the free flow of scientific and technical information” and “establishing principles for conveying scientific and technical information to the public” as foundational to scientific integrity in government, but we have largely fallen short in implementing effective policies that build on these key principles. The 2013 OSTP memorandum on [Increasing Access to the Results of Federally Funded Scientific Research](#) was designed to address that gap, and directed federal science agencies to develop plans to improve public access to the results of their funded research.

While this Memorandum resulted in federally-funded research being made available more rapidly and broadly than before, as we saw during the COVID-19 crisis, it has fallen far short of providing scientists and the public with what is needed: a free, immediately accessible, fully machine-readable collection of articles reporting on taxpayer-funded research.

Eight years after the issuance of the 2013 Memorandum, many articles reporting on taxpayer-funded research are not readily available to most scientists (or to the public) for a full year after publication. They are still difficult to locate, housed on publisher’s proprietary websites, and published in formats and under licensing terms that make them impossible to use fully through text and data mining.

In fact, in November 2019, the Government Accountability Office (GAO) released a report on [Additional Actions Needed to Improve Public Access to Research Results](#) which reviewed the progress of 19 federal agencies on the implementation of their public access plans as directed by the memorandum. According to the report, 11 agencies still do not fully ensure that researchers comply with public access policies, and 7 agencies have not taken steps to make data underlying publications findable and accessible.

Rather than focusing on these compliance challenges, we have the opportunity—and the imperative—to revamp the 2013 Memorandum to establish a strong, uniform policy

⁶<https://www.forbes.com/sites/madhukarpai/2020/11/30/how-prestige-journals-remain-elite-exclusive-and-exclusionary/?sh=af9deb94d48f>

that ensures equitable open access to and participation in U.S. federally-funded scientific research. We encourage OSTP to consider the following recommendations:

Recommendation 1: Update the 2013 Memorandum on Public Access to Federally-funded Research Outputs

To boost scientific integrity, improve research assessment, and increase equity, we recommend the federal government update OSTP's 2013 Memorandum to require a consistent policy across federal agencies that ensures articles reporting on all basic and applied federally-funded research and the data, software, code, and algorithms needed to validate and/or reproduce their results are made immediately available with no embargo period to the public, at no cost, under an open license, and in an AI-ready, machine-readable format.

Specifically, the policy memorandum should be updated to require that:

1. All articles reporting on federally-funded research and the underlying data and tools needed to validate their conclusions (including software, code, and algorithms) should be made freely available online to the public immediately upon publication.
2. Articles should be made available in open and machine-readable formats that fully enable productive reuse including text/data mining and computational analysis. Title II of the Foundations for Evidence-Based Decision Making Act provides guidance on this.
3. Articles and underlying data should be made available under an open license or be published as part of the public domain, specifically a Creative Commons Attribution 4.0 International (CC BY) license or similar for articles and CC0 for data.
4. To minimize the cost to researchers and increase contributions from more diverse voices, a copy of a researcher's final accepted manuscript or final published article should be made available via a digital repository maintained by a U.S. federal agency or in an open, nonproprietary repository designated by the agency that ensures long-term open access to and preservation of these articles.
5. Underlying data, software, and code should be made available via digital repositories maintained or approved by a U.S. federal agency. (Further details on the desirable characteristics of data repositories were submitted by SPARC to OSTP in an earlier submission to this RFI available [here](#).)
6. All other non-classified data not directly attributable to a publication, including associated metadata, should be made available to the public as soon as possible and adhere to findable, accessible, interoperable, and reusable ([FAIR](#)) principles.

Recommendation 2: Support the policy update with federal funding for the development and ongoing sustainability of critical research infrastructure

Any policy update should be supported by federal investment in research infrastructure so that scientists can quickly and openly disseminate knowledge and engage with other researchers and the public on their findings. OSTP should direct agencies to establish new and leverage existing funding mechanisms, such as partnerships with philanthropies, research institutions, and scholarly societies to support critical community-driven, open infrastructure—including article, data, software, and code repositories.

Recommendation 3: Engage with the academy on transitioning to open access models that center equity and inclusion

Perpetuating a system that does not welcome voices from historically underrepresented populations has consequences that endanger long-term trust and integrity in science. Incentivising (intentionally or unintentionally) existing power dynamics in the scientific community hinders the sharing of research results and favors exclusivity in science. Current subscription and APC-based pay-to-publish approaches restrict researchers at less-resourced institutions from reading the latest research or publishing their own research because fees to access or publish are too high. More equitable open science practices (including use of open repositories) invite a greater diversity of voices into scientific discussions from the scientists that conduct the research, to the research participants, to the public consumers of research outputs.⁷ We recommend that OSTP support compliance solutions that center equity of participation in scientific communication, and encourage the research community to develop business models that better support open and equitable access to and participation in science.

Recommendation 4: Ensure full reuse through consistent data practices and licensing

Strong reproducibility and replicability practices are key to addressing any improper interference or errors in research and data collection. Underpinning these practices is the ability to access and reuse the data, software, code, and algorithms of a scientific finding so researchers may analyze each other's work to validate the results. Full reuse requires both the article and data to be machine-actionable. This will differ by scientific discipline, but it is imperative that implementation at the agency level incentivize the incorporation of data experts in research design and require an open license for final manuscripts and the underlying data needed to reproduce the results.

Recommendation 5: Re-think research assessment metrics and practices

⁷ <https://journals.sagepub.com/doi/10.1177/1475725719869164>

The current research incentive system is overwhelmingly skewed to reward a single research output: publication of articles in high impact factor journals. Reliance on publications as the sole proxy for quality erodes trust in science and further entrenches inequities in the scientific communication system. We recommend that OSTP support the expansion of incentives to include outputs beyond the journal article (e.g. data, code, preprints, etc.) and encourage the use of more qualitative factors for impact such as influence on policy and practice by inviting supporting language on research output sharing in all Federal calls for applications, grant evaluation guidelines, and grant reporting systems. For example, the Howard Hughes Medical Institute (HHMI) [asks researchers](#) to provide a written impact statement for each journal article they reference and an overview of their training and service activities.

Recommendation 6: Expand the practice of preregistration

The practice of preregistration of a research study design, before data is collected, has been demonstrably successful in the clinical trials environment and should be considered for expansion to other disciplines. The routine practice of preregistration improves research rigor and integrity by including unpublished studies in the scholarly record, and helps to address potential biases that interpretation of data so often has on a study's stated objectives. Similarly, protocol registrations allow researchers to publish research procedures and methods, often in a machine-readable format. We recommend that OSTP consider endorsing practices such as preregistration and protocol registration as critical aspects of research communication, which facilitate reuse and replication of research and reduce inefficiencies in the research ecosystem.

Recommendation 7: Agency workforce development

Training the workforce at federal science agencies on open science practices that improve both rigor and transparency is central to ensuring scientific integrity and specifically, the open sharing of research with the public. For example, many scientists hold onto data for years without sharing it while they wait for papers to be published. Part of this problem is driven by an outmoded incentive system, but part is also driven by the lack of consistent standards for research sharing. Agency staff and, particularly, grant officers have the potential to standardize when and how scientists share their results from federally-funded research. They can also be helpful in ensuring the results are shared in a way that maximizes reuse to allow for reanalysis and collaboration.

SPARC appreciates the opportunity to provide our feedback on this critical issue, and stands ready to work with the White House Office of Science and Technology Policy in its laudable efforts to improve federal scientific integrity policies.

Please contact Katie Steen (katie@sparcopen.org) with any questions.

This response to the Scientific Integrity RFI is submitted by David T. Ozar, PhD, and Donald E. Patthoff, DDS, as Members of the Public. Ozar is Emeritus Professor of Philosophy, Loyola University Chicago, and Patthoff is semi-retired from private dental practice in Martinsburg WV. Ozar has taught and the two of us have lectured and written extensively, both together and as individuals and in both academic and professional settings, on professionalism and professional ethics, including professional ethics and integrity in the sciences. Both of us have also served on hospital ethics committees for more than 20 years. The corresponding author for this response is: David Ozar; email: dozar@luc.edu and cell phone: 847-404-1431.

Introduction

We offer here three sets of ideas that are crucial to responding effectively to the needs that have prompted the Office of Science and Technology Policy (OSTP) to create the Scientific Integrity Fast-Track Action Committee (SI-FTAC). These ideas concern, respectively, Trust, Profession and Professional Ethics, and Two Challenges For Science Today. We believe these three sets of ideas are relevant to every aspect of the tasks named in the RIF, but especially to the themes of “*promoting trust in Federal science*” in Topic #1, “*improve the communication of scientific and technological information*” in Topic #2, and “*improve training of scientific staff*” in Topic #4.

Part One: Trust

The first set of ideas we want to offer concerns the theme of trust on the part of the public since this is the desired goal of federal scientists and OSTP and the proposed SI-FTAC. There are three different kinds of trust that are relevant¹; and it is difficult, if not impossible, to support or enhance public trust in the work of federal scientists effectively without a clear understanding of all three and especially a clear emphasis on the third, *Trusting the Person*. We call these three kinds of trust “*Trusting That*,” “*Trusting What*,” and “*Trusting the Person*.”

Trusting That is directly related to reliability based on evidence. When we *Trust That* such-and-such a thing will happen or someone will act in the expected way, our trusting is, if well-founded, based on our having received (and understood) sufficient evidence that we can reliably expect that thing to happen in the future and can therefore act accordingly with confidence. The second kind of trust, *Trusting What*, is about trusting what another person says. It too depends on evidence, evidence that the person is well-informed and is speaking truthfully. The third kind of trust is *Trusting the Person*. It also depends on evidence, but a person’s evidence for *Trusting the Person* needs to be evidence that the person to be trusted is committed to the well-being of the person whose *Trusting the Person* is being asked for, and evidence of such commitment is not scientific evidence, but rather sincere articulations of such commitment supported by consistent behavior that is consistent with this commitment. This third kind of trust is one of the hallmarks of, for example, a well-respected profession and a well-lived professional life. That is, professionalism as an ideal is being achieved, or nearly so, when both the profession as a whole and the members of and

organizations within that profession are in fact widely trusted in this third way by those whom they serve. The theme of Profession and Professional Ethics will be discussed more fully in Part Two.

Although it may seem counter-intuitive, if SI-FTAC does not pay serious attention to *Trusting the Person*, if it focuses only on *Trusting That* and *Trusting What*, i.e. only on ways of securing Scientific Integrity as these are usually understood, the OSTP's efforts to enhance public trust in the work of federal scientists will not be very effective. *Trusting the Person* is therefore the most important kind of trust for SI-FTAC to focus on.

One reason that *Trusting the Person* is the most important kind of trust for SI-FTAC to focus on is that, with the exception of relevant scientists themselves, the public who receive medical and other scientific information from federal scientists (or any other source) are not expert enough in the relevant sciences to evaluate the evidence in ways that could support their *Trusting That* what they are told is true. On most matters, in fact, most of the public lack sufficient expertise to understand what the evidence is (e.g. various computer readouts or statistical conclusions interpreted on the basis of complex scientific theorizing) or how it has been obtained. That is, *Trusting That on the part of the public* is not something that federal scientists can reasonably aim at, even if published methods and evidence are fully accepted by other scientists. Of course, whenever reports of violations of Scientific Integrity within the federal scientific community, e.g. transmission of incorrect claims, improperly done research, etc., reach the public, this will obviously not help the public to trust in the work of federal scientists, although appropriate transparency about correcting such events will be important. But our point is that, even if all the research done by federal scientists is carried out perfectly and reported correctly, this will not enable the public to evaluate what they are told on the basis of the relevant evidence because they would need to be experts themselves to do so. Making sure of these things is necessary, but enhancing *Trusting That* it is not the most important thing when enhancing public trust in the work of federal scientists is the goal.

A second reason that *Trusting the Person* is the most important kind of trust for SI-FTAC to focus on is that the relevant evidence for *Trusting What* someone says is evidence that they speak truthfully and that they are well-informed. But even if the public is willing to believe that federal scientists are speaking truthfully (see Part Two and Part Three below), *Trusting What* on the part of the public depends on the public understanding what counts as evidence that federal scientists are well-informed. But only a small percentage of the public understand how scientific skills are vetted and certified or the difference between genuine certification of skills and public relations tools that appear to certify but do not, etc. Most people see the federal bureaucracy as a huge unfathomable apparatus rather than, when it is at its best, an efficient certification system for relevant skills. Someone might reply, of course, that the public should take this on trust, but that brings us back to the question of what kind of trust? The answer is *Trusting the Person*.

Evidence of truthfulness on the part of federal scientists and evidence of effective certification of federal scientists' expertise, on which the public's *Trusting What* those scientists say both rely unavoidably on the public's belief that they have evidence for *Trusting the Person* in each of these

cases. But for many complex reasons – the size of the federal bureaucracy, its distance from people’s ordinary lives, political differences of many sorts, as well as the esoteric nature of much of the work that federal scientists do etc. – the public do not receive much dependable evidence that *Trusting the Person* of federal scientists or those who certify their expertise is justified; that is, that these persons are primarily committed to the well-being of the persons who make up the public. Commitment of this sort may be regularly articulated by political leaders in the name of the federal government; but opposing political leaders are just as likely to deny it, and in any case many members of the public find it hard to grasp how an organization of this size could possibly function with such an altruistic commitment at the heart of its work (and for too many, taxes and regulations are evidence that their wellbeing is not the primary interest of the federal government). So while the key to enhancing the public’s trust in the work of federal scientists lies in enhancing their *Trusting the Person*, reaching them effectively in this respect will not be easy.

Part Two: Profession and Professional Ethics

The best way we know of to explain how *Trusting the Person* can be achieved is via the theme of Profession and Professional Ethics.² Each of our society’s professions has a distinctive set of aspirational ethical standards (much more complex than the summaries in most professions’ Codes of Ethics). But there is one ethical standard that is common to every profession; namely, that the profession as a whole and each of its members and each of its professional organizations will dependably act on the basis of a primary commitment to the well-being of those whom that profession serves. This commitment is regularly articulated by the profession’s professional organizations and, more importantly, in the conduct of the profession’s members and the actions of its professional organizations. Admittedly that are always exceptions, individuals who place other motives ahead of this one and organizations that act more like trade organizations than groups of professionals. Admittedly our society’s professions’ reputations have been damaged by the impact of our society’s commercialism on many aspects of professional practice. But the ideals to which professions aspire are still well known to large segments of the public and are widely sought by the public with these ideals in mind, especially when their own interests are at stake.

Therefore the theme of profession has more potential than any other to highlight the reality, if it is a reality, that the public has good evidence to support *Trusting the Person* of federal scientists and those who certify their expertise. For the scientists who work in the federal government are already members of one or more scientific professions and presumably those who certify their expertise as well. Each of them therefore has made a commitment in becoming a professional to give priority to the wellbeing of those whom their profession’s practice serves; and it is likely that many of these are not only aware of this, but personally committed to practicing their professions accordingly. In addition, even if some lack this awareness, they have very good reason to practice and to describe their practice and to view themselves in accordance with this commitment, i.e. to give priority to the wellbeing of those whom they serve who are, on the one hand, the public in general and, on the other, any persons who happen to be the specific recipients of the benefits of their work.³

An important question that SI-FTAC should be asking is therefore, first, whether this is how federal scientists see themselves and whether seeing oneself in this way is one entry criterion for federal scientific service. If not, there is something very important here that needs rectification. Second, if federal scientists do generally see themselves as committed professionals in this way, then finding more effective ways to communicate this fact to the public can contribute to the enhancement of public trust in the work of federal scientists.

That is, if the public genuinely believed that federal scientists and those who certify them are primarily committed to the well-being of everyone in our country (rather than to their own or other persons' well-being or that of the federal government, or something else), i.e. that they can *Trust the Person* of these scientists and therefore believe that federal scientists will speak truthfully to them, and similarly *Trust the Person* of those professionals who certify federal scientists' skills so that they have that as evidence that federal scientists are well-informed, then the public would have better evidence than they now have to *Trust What* federal scientists say. But without the public having greater evidence that they can *Trust the Person* of federal scientists and those who certify their skills, it seems unlikely, no matter how the focus on Scientific Integrity is advanced in other ways, that the public's ability to *Trust What* federal scientists say will be significantly affected.

One additional comment on this topic: There is published literature on the ethics of persons in public service which also stresses serving the whole community.⁴ and there are handbooks and codes of ethics for federal employees and office holders that are no doubt well-known to SI-FTAC that probably also stress the obligation to place the public's wellbeing ahead of other goals. But the literature on ethical standards for persons in public service and the handbooks and codes of ethics internal to the federal government are almost unknown to the general public. By contrast, most people have expectations of health professionals, lawyers, and other professionals that have been shaped by their awareness that professionals typically undertake special obligations, including the commitment to give priority to the wellbeing of those they serve. Therefore, since federal scientists and their certifiers are members of various professions, making the case that they have undertaken this sort of commitment is more likely to be effective in enhancing the public's trust than stressing the other sources of ethical standards for federal employees.

Part Three: Two Challenges For Science Today

Unfortunately, even though federal scientists and their certifiers are members of professions and their practicing in accord with those professions' commitments could be more effectively communicated to the public, the public sees far too much evidence that appears to say that science is principally done for profit in our society for the public to automatically accept that federal scientists and their certifiers are different from the many employed scientists who work in the commercial marketplace. In healthcare advertising and especially in pharmaceutical advertising, for example, but also in advertising generally whenever scientific claims are used for clearly commercial ends, the public sees what it can easily interpret as clear evidence that science is primarily done for the benefit of commercial entities, i.e. for the seller's profit.. This

apparent evidence that science not being done primarily for the benefit of the public is further reinforced by the presence in so much advertising of the fine print that appears at the bottom of the screen for too few seconds to read it carefully or in a rapid voice-over that few can understand. For these “communications,” when examined, routinely explain that what is been said or shown in the ad is only true some of the time or under certain conditions, or that the product involves otherwise unstated risks to the user, etc. Since this information is deliberately made hard to obtain, this advertising practice strongly suggests that truth-telling is not the primary intention of the seller, and this in turn weakens any conviction that the scientists working for the seller should be accorded *Trust What* by the audience. Efforts to demonstrate that federal scientists are well-informed and can be depended on to speak truthfully, which are preconditions of the public’s having evidence that they should *Trust What* federal scientists say, may not be able to eliminate this challenge to the public’s understanding of science, but they should not be designed as if it did not exist.

In addition, though recent years have seen some changes, science education at the elementary and secondary levels for many members of the public, as well as most journalistic coverage of science, have routinely presented scientific conclusions as simply true, rather than with the correct qualifications. For science at its best can only tell us things that are statistically reliable, and that does not mean that exceptions will never occur, but in fact that there is some likelihood of their occurrence. Consequently, large segments of the public view exceptions to scientists’ statements as evidence that the scientist’s statements are untrue (and independently of whether the scientist was speaking truthfully or was certified to be well-informed).. Advice from professionally committed scientists that is based on well evidenced scientific work is certainly action-worthy for the most part, but only if it is kept in mind that there will always be a known (or unknown) percentage of outliers or contexts in which what is advised won’t work out as predicted.

Physicians, dentists, and other health professionals, for example, know from daily experience that many members of the public believe that science is capable of making practical claims that are without exceptions and therefore that, if exceptions or outliers occur and in spite of careful explanations about their relative likelihood, many members of the public will conclude that the scientific work involved must have been unreliable. Many who are refusing Covid vaccination today explain themselves by noting that outliers occur and imply that, because they do, the science-based advice that the odds highly favor vaccination is not to be trusted. In the case of Covid, even saying clearly that what we know is that vaccination is 97% effective in preventing death and serious illness is nevertheless taken by far too many people, if they are capable of hearing this statistic as scientifically relevant at all, as proof that the vaccination does not work, evidence of a view of science in which genuine science is exceptionless and statistical reliability is no reliability at all. Perhaps how federal science-based recommendations are presented could be adjusted somehow to begin to reeducate such persons about what science can actually do, but it will be difficult, and such efforts will be in vain, we believe, if significant segments of the

public cannot come to actively believe that their wellbeing is the priority of federal scientists; and to do that, we believe the central focus of SI-FTAC's efforts needs to be on *Trusting the Person* above all.

¹ The account of trust employed here is drawn from: Anne C. Ozar, "The Plausibility of Client Trust in Professionals," Business and Professional Ethics Journal, vol.33 (2014), pp.83-98; and Anne C. Ozar, "Trust As a Moral Emotion," in John Drummond and Sonja Rinofner Kreidel, eds., Emotional Experience: Ethical and Social Significance (Lanham MD: Rowan and Littlefield, 2018), pp.137-153.

² For a more detailed account of this topic see David T Ozar, "Professions and Professional Ethics," in Stephen Post, ed., Encyclopedia of Bioethics, 4th edition, (New York: Thomson/Gale, 2014), Vol 5, pp.2526-2537; and for an example of detailed analysis of one profession in terms of this approach, see David T. Ozar, Donald H. Patthoff, and the late David J. Sokol, Dental Ethics at Chairside: Professional Obligations and Practical Applications, 3rd edition (Washington, DC: Georgetown University Press, 2018).

³ See for example, "A Code of Ethics for Scientists," in The Lancet, March 31, 2007; accessed 7/26/2021 at: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(07\)60507-8/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(07)60507-8/fulltext) or "A code of ethics to get scientists talking" in Nature, February 27, 2018, accessed 7/26/2021 at: <https://www.nature.com/articles/d41586-018-02516-x> or "Human Rights in Codes of Ethics of Scientific and Professional Societies," American Association for the Advancement of Science, accessed 7/26/2021 at: <https://www.aaas.org/resources/human-rights-codes-ethics-scientific-and-professional-societies>

⁴ See for example, John A. Rohr, Public Service, Ethics, and Constitutional Practice (University of Kansas Press, 1998); and James S. Bowman and Jonathon P. West, Public Service Ethics: Individual and Institutional Responsibilities, 2nd edition (Routledge, 2018).

July 28, 2021

Scientific Integrity Fast-Track Action Committee (SI-FTAC)
Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, DC 20504

BY EMAIL TO: ScientificIntegrityRFI@ostp.eop.gov

RE: Association of American Publishers Response to Request for Information “To Improve Federal Scientific Integrity Policies” (86 FR 34064)

THE NEW ENGLAND
JOURNAL OF MEDICINE

NEJM CATALYST

NEJM JOURNAL WATCH

NEJM KNOWLEDGE+

NEJM RESIDENT 360

NEJM 医学前沿

NEJM CAREER CENTER

Dear Members of the SI-FTAC:

The New England Journal of Medicine (NEJM) appreciates the opportunity to respond to the Request for Information “To Improve Federal Scientific Integrity Policies” (86 FR 34064). We commend the Office of Science and Technology Policy (OSTP) for your commitment to furthering public confidence in scientific research and preserving scientific integrity. Our comments below focus on responding to the second section of the RFI, “*Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information.*”

NEJM is the most widely read, cited, and influential general medical journal and website in the world and the oldest continuously published medical periodical.

Widely recognized as the gold standard for current research and best practices in medicine, NEJM publishes peer-reviewed research and interactive clinical content for physicians, educators, and the global medical community. The mission of NEJM is to bring health care professionals the most reliable biomedical research and clinical information to inform their practice and improve outcomes for patients.

NEJM is cited more often in scientific literature than any other medical journal, has the highest Journal Impact Factor (91.245) of all general medical journals, and more than a million people from nearly every country read NEJM in print and online each week.¹

NEJM is a publication of NEJM Group, a division of the Massachusetts Medical Society. Thank you for the opportunity to respond.

Communication of peer reviewed clinical and medical research is crucial to U.S. Healthcare and journal publishers play a vital role.

The United States government has led the world in supporting medical research that has improved all of our lives.

Patient-care professionals and the patients they serve rely on medical journal content that is vetted by medical experts, peer reviewed, revised, edited, and enhanced through the editorial process to provide them with results that are placed in the proper context for making evidence-based clinical decisions. Quality-driven, rigorous peer review and conflict of interest rules work to prevent publication of poorly designed or intentionally biased studies that can misinform and mislead physicians and patients. Further, editors work to ensure that conclusions are not overstated or misleading. Considering the misinformation that spread over the last 18 months, this need for quality has become even more apparent.

Each year, our editors filter through over 5,000 research manuscripts submitted and select only the best. Each manuscript accepted for publication benefits from hundreds of hours of work by medical editors, statistical experts, manuscript editors, illustrators, proofreaders, and production staff, who work to ensure that every paper meets exacting standards before it becomes a published NEJM article. These valuable intellectual property enhancements from NEJM and the systems we have invested in to deliver them come at a substantial cost. A subscription-based model is the only model that can finance our comprehensive process.

Our Covid response

During a pandemic, more than ever, health care professionals need credible information to guide their decisions. Our rigorous peer review and editing process improves research reports and prevents the overstatement of results. Our goal remains to bring readers the most reliable information available in a highly expedited manner.

Our strong editorial infrastructure and the subscription model that supports it has allowed us to handle a surge in Covid-19 submissions – which reached more than 200 manuscripts a day – without sacrificing quality. We published more than 500 Covid pieces – articles, letters, and podcasts – from January 2020 through June 2021. Most of these were in addition to our normal volume, which is about 500 articles a year. In addition, we have created a dedicated page on our website with collected Covid-19 articles, all of which are freely available. We also allow this content to be aggregated for broad use within PubMed Central and other public repositories, such as the WHO Covid-19 database.

These efforts are crucial to health care and improving lives in the United States and across the globe.

Recommendations for federal agencies to improve the communication of scientific and technological information

- 1. The U.S. Government should support sustainable business models that deliver the best content, promote competition, and provide author choice.**

We acknowledge that there are various business models for publishing research. However, we remain committed to our current subscription-based publishing model. Our reader-pays subscription model allows us to continuously invest in subject-matter experts, statistical reviews, innovations in science communication, professional publishing talent, and editorial and production systems to ensure that NEJM meets the need of physicians and health care professionals for trusted, rigorously peer-reviewed research and review articles. It also ensures that authors can publish in our pages regardless of their financial means. For these reasons, we believe that a reader-pays subscription model with an appropriate embargo — such as the 6-month embargo we use — can exist alongside a deep commitment to public access.

Further, we believe that mandating a single approach to publishing — particularly one that favors high-volume, rapid publication of medical research with less rigorous or no peer-review — will not result in better care for patients and increases the risk for patient harm and mistrust in science.

2. Advance Principles for Scientific Data Management and Data Sharing Data Management:

In 2016, stakeholders from academia, industry, funding agencies, and scholarly publishers designed and endorsed the FAIR Data Principles to serve as a guideline for those who wanted to enhance the reusability of their data.² Also in that year, NEJM co-authored a proposal from the International Committee of Medical Journal Editors (ICMJE) on sharing clinical trial data.³

We propose the National Institutes of Health work with stakeholders, including publishers, to create an indexing database, similar to MEDLINE, for data sets and objects. Such a database would improve discoverability, drive metadata standards, and facilitate data access.

Data Sharing. There is an obligation to patients who volunteer to participate in clinical trials to ensure that their data are widely and responsibly used. As a condition to publication, NEJM and other medical journals require investigators to submit a data-sharing statement and register a data-sharing plan when registering a trial. Quality data stewardship, guided by policy standards and best practices, would facilitate data sharing, both for federally funded research and during disease outbreaks such as Covid-19.

3. Improve Access to Published Trials on ClinicalTrials.gov

It has been reported that more than 12 years after the passage of the Food and Drug Administration Amendments Act (FDAAA) in 2007, one third of applicable clinical trial results are missing from ClinicalTrials.gov. The Food and Drug Administration (FDA) and NIH are authorized to impose financial penalties for noncompliance but have not.⁴

Publishers can work with authors and funders to improve trial results reporting. NEJM has already taken the lead to improve clinical trial data sharing for the articles we publish and is working with other journals through the International Committee of Medical Journal Editors (ICMJE). This work, both past and future, requires time and resources. NEJM has been a leader in advancing clinical trial data sharing in a way that accounts for the current data management challenges that researchers face. We offer to use this expertise to work with others on a government-sponsored project that allows greater access to data to benefit the greater research ecosystem.

4. Support the Development of Medical Research Article Extenders

As we have seen during the pandemic, there is a great deal of misinformation being shared, especially among the lay public. One way the federal government can assist with clarifying the record is by supplying federal funding for the development and ongoing publication of article extenders (plain-language summaries, videos, podcasts, visual abstracts) of research results — clinical trials, in particular — to ensure accurate understanding by generalist readers. These summaries would serve the information needs of the public, ensure accurate interpretation of research, and would also facilitate reporting by the media. The government could work with publishers to develop standards for these summaries and ensure that they are made freely available on resources such as PubMed Central and ClinicalTrials.gov.

As always, NEJM appreciates the opportunity to provide comments, and we look forward to working with OSTP on our shared goal of ensuring the integrity of scientific publications and peer-reviewed research. Should you have any questions, please contact Alexandria Icenhower, Federal Relations Manager.

Sincerely,



David Sampson,
Vice President, NEJM Group

¹ 2020 Journal Impact Factor, Journal Citation Reports (Clarivate Analytics, 2021).

² Wilkinson, M. D. et al. (2016). The FAIR Guiding Principles for scientific data management and stewardship. *Scientific Data*, 3, 160018, available at <https://www.nature.com/articles/sdata201618>.

³ Taichman DB, Backus J, Baethge C, et al. Sharing clinical trial data — a proposal from the International Committee of Medical Journal Editors. *N Engl J Med* 2016;374:384-38, available at <https://www.nejm.org/doi/full/10.1056/NEJMe1515172>.

⁴ Morten, C., Lurie, P.G., & Seife, C., (2020, April 13) Lost Opportunities from FDA, NIH inaction when sponsors fail to report clinical trial results. *STAT*, available at <https://www.statnews.com/2020/04/13/lost-opportunities-clinical-trial-results-unreported-lost-opportunities/>

July 28, 2021

White House Office of Science and Technology Policy
% Ryan Donohue and Stacy Murphy, Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504
Via ScientificIntegrityRFI@ostp.eop.gov

RE: Request for Information to Improve Federal Scientific Integrity Policies

Ocean Conservancy submits the following comments regarding the Office of Science and Technology Policy's (OSTP) information request to help improve the effectiveness of federal scientific integrity policies to enhance public trust in science.¹ Ocean Conservancy is a 501(c)(3) conservation organization working to protect the ocean from today's greatest global challenges. Together with our partners, we create science-based solutions for a healthy ocean and the wildlife and communities that depend on it. We thank the Biden administration for its dedication to scientific integrity across federal agencies and in the development of federal policy, and we applaud the Presidential Memorandum and public comment request as a critical step to restore accurate science and evidence-based policymaking in our government. In this letter, we briefly outline general recommendations for scientific integrity policies relevant across federal agencies. We then focus on the National Oceanic and Atmospheric Administration (NOAA) and NOAA Fisheries and the need to reaffirm scientific integrity at the agency following examples of the loss of integrity; we also offer some specific recommendations for the agency's policy and who it covers. Finally, we discuss specific actions that OSTP can advance related to federal ocean, coasts and Great Lakes policy.

1. Recommendations for Scientific Integrity Policies Across Agencies

The Congressional Research Service (CRS) published a timely report on federal scientific integrity policies in April 2021, complementing an assessment of nine such agency policies by the Government Accountability Office (GAO) in 2019.² The CRS report identifies common

¹ 86 Fed. Reg. 34064 (June 28, 2021).

² U.S. Congressional Research Service Report R46614, *Federal Scientific Integrity Policies: A Primer*, Updated April 16, 2021; U.S. Government Accountability Office Report GAO-19-265, *Scientific Integrity Policies: Additional Actions Could Strengthen Integrity of Federal Research*; April 9, 2019.

themes and areas for improvement across agencies, such as failures to evaluate and monitor implementation of agency scientific integrity policies, a lack of or uncertainty over procedures for reporting and addressing potential violations of policies, and a lack of a structure for addressing scientific integrity concerns involving multiple federal agencies.³

Ocean Conservancy agrees with the issues raised in the CRS report and encourages the Biden administration to address these concerns as part of its policy improvement process. While the CRS report targets actions that Congress may take, many of the recommendations of the report can and should be achieved by the administration.⁴ We also encourage the administration to assess how scientific integrity policies can support and encourage rigorous and inclusive citizen science and community-engaged research—important sources of data and understanding that are often ignored in federal integrity policies. Additionally, the administration should address the lack of penalties for violating scientific integrity policies and should ensure that investigations cannot be suspended without cause.

2. Reaffirming Scientific Integrity at NOAA and NOAA Fisheries

Science, research, and science-based decision-making are at the core of NOAA’s mission. A strong scientific integrity policy is critical for fostering public trust in the agency and its actions, retaining a strong scientific workforce and maintaining its morale, and ensuring effective ocean conservation and management using science in the implementation of laws and policies. NOAA has a strong scientific integrity policy that was adopted during the Obama administration in response to a March 9, 2009 presidential memorandum.⁵ An assessment by the GAO found that the agency’s policy was consistent with federal guidelines and had clear procedures in place for identifying violations of the policy and addressing allegations of loss of scientific integrity.⁶ Despite the relative strength of NOAA’s scientific integrity policy among federal agency policies, there have still been concerning lapses in scientific integrity at the agency that have revealed areas for improvement. Ocean Conservancy works closely with NOAA and NOAA Fisheries, and we offer specific comments in regards to these lapses in scientific integrity and how they may be addressed in the future.

Political interference and applicability of the policy to Department of Commerce officials

During the “Sharpiegate” investigation⁷ and in a recently suspended investigation into possible political interference in a biological opinion developed around North Atlantic right whales with

³ *Id.* at 11-13.

⁴ *Id.* at 14-15.

⁵ National Oceanic and Atmospheric Administration, NOAA Administrative Order 202-735D-2 *Scientific Integrity*; effective January, 19, 2021.

⁶ U.S. Government Accountability Office Report GAO-19-265, *Scientific Integrity Policies: Additional Actions Could Strengthen Integrity of Federal Research*; April 9, 2019.

⁷ The Hurricane Dorian–Alabama controversy, also referred to as Sharpiegate, arose from a comment made by President Donald Trump on September 1, 2019, as Hurricane Dorian approached. President Trump incorrectly

respect to seismic testing,⁸ gaps in the current policy have become clear. First, while the acting Administrator of NOAA was found to have violated the agency's own scientific integrity policy, there were no penalties for that violation and therefore, nothing to preclude it from happening in the future. Second, the Inspector General (IG) investigation found that employees at the Department of Commerce also violated the NOAA scientific integrity policy, but that the policy did not actually apply to them. Finally, the suspension of the right whale investigation would appear to indicate that political interference can actually stop an investigation into political interference, which is of significant concern. It is incumbent upon the Biden administration to make sure nothing like this can happen again in the future.

Similarly, Commerce went against NOAA's scientific findings in 2017 when it illegally extended the private recreational fishing season for red snapper in the Gulf of Mexico.⁹ The original federal fishing season, set for 3 days, was extended to a total of 41 days, even as agency scientists had found the decision was likely to result in overfishing of the stock and a delay in stock rebuilding. The decision to explore a longer season for red snapper in the Gulf was made by leadership at the Department of Commerce and stemmed from requests from the White House and a dozen members of Congress. The decision to extend the season violated the Magnuson-Stevens Fishery Conservation and Management Act in addition to interfering with the conclusions of agency scientists.

These issues with scientific integrity are in part a result of the fact that policy does not include full accountability up the chain of authority to the Department of Commerce. **We urge the administration to ensure that the Department of Commerce is covered by a similar policy, either independently or by applying the NOAA policy to Commerce employees.** When there are alleged violations committed by leadership at the agency or at Commerce, another complementary approach would be to enable agency scientific integrity officials to work with the IG on the investigation. Any investigation of such future complaints should be conducted in full without interference. Such provisions would make it harder for those seeking to censor NOAA scientists or prevent them from speaking with the public and would protect agency science from undue political influence.

Applicability of the policy to federal contractors and financial award recipients

We further call your attention to another issue of the reach or jurisdiction of the NOAA scientific integrity policy. Many functions of the federal government are carried out by contractors and

included Alabama as a state that would be impacted. Rather than admit this mistake, he showed reporters a weather map which had been altered with a Sharpie marker to show the hurricane's track threatening Alabama. In short, scientific integrity was compromised and NOAA's policy was violated.

⁸ Holzman, Jacob. "Playing politics with science spawns new threat to endangered whales." CQ Roll Call. 5 March 2020. <https://www.rollcall.com/2020/03/05/noaa-fisheries-hed/>.

⁹ See e.g. Rob Hotakainen, "Extending red snapper season might have broken U.S. law" (Dec. 19, 2017), <https://www.sciencemag.org/news/2017/12/extending-red-snapper-season-might-have-broken-us-law>.

other third party individuals and entities who are not federal employees. At NOAA, the existing scientific integrity policy includes these individuals, but leaves to the contracting organizations the duty to investigate alleged misconduct. As a result, contractors producing and using science in close collaboration with federal employees are subject to the internal policies and procedures of their contracting companies, which may not have any requirement to investigate misconduct. Further, contracting firms may have incentives to resolve allegations that are different from those of a federal agency working in the public interest. While the policy at NOAA does offer opportunity for the agency to conduct its own investigation after reviewing the findings from an external investigation, **we recommend that NOAA have a cooperative role in the investigation of all cases of alleged scientific integrity violations by contractors.**

We urge the administration to contemplate who is covered by these policies and whether that coverage reaches relevant federal products and decisions. For example, NOAA Fisheries manages federal marine fisheries with input from eight regional fishery management councils. The councils are financial awardees of NOAA, and as such they are not covered by the policy but are responsible for abiding by the principles in it. Each council is advised by a Scientific and Statistical Committee (SSC) that assists in development, collection, evaluation and peer review of scientific information relevant to fishery management.¹⁰ Members of SSCs include federal employees, state employees, academicians, and independent experts. This varied make-up is essential; however, it poses a challenge for scientific integrity if all members of the body are not covered by the federal scientific integrity policy. Given the often-politicized nature of management decisions and the role of science in the process, **the regional fishery management councils and their SSCs should have a clear framework for how scientific integrity and the scientific integrity policy applies to their work.**

Similarly, there is apparent pressure on scientific data that is produced by universities and other awardees of federal funding for studies that are congressionally mandated, and this pressure remains unaddressed by existing federal scientific integrity policies. One recent example was the Great Red Snapper Count, which was a congressionally mandated multi-year research effort that was funded at \$10 million and involved many entities, including universities and NOAA Fisheries. The results of the study, which was intended to be an independent assessment of the total abundance of red snapper in the Gulf of Mexico, were the subject of intensive political interest. Members of Congress were briefed by the agency on preliminary results, and there were a number of statements made by members of Congress, industry groups, scientists, managers, and the Assistant Administrator of NOAA Fisheries ahead of study finalization about how the results should be used to provide catch advice in the impending fishing season. These statements also preceded decisions made by the Gulf of Mexico Fishery Management Council's SSC on how the results would be considered in setting sustainable fishing levels. This created intense pressure on the SSC to immediately apply the results to management advice, despite the fact that

¹⁰ 16 U.S.C. 1852(g).

the study had not been thoroughly peer reviewed nor had the serious concerns of initial reviewers been addressed. In part because of the flaws in this process, the chair of the SSC immediately resigned; the co-chair who replaced him was shortly thereafter not reappointed. This extremely atypical process upended the regular, inclusive, and peer-reviewed process that usually takes place in the Gulf of Mexico, the Southeast Data, Assessment and Review (SEDAR). The outcomes of this politicized process have undermined science-based fishery management in the Gulf and have had a chilling effect on scientists and stakeholders in the region. We urge the administration to develop policies that shield the scientific integrity of such projects from political influences and ensure interference does not result in circumventing peer review in order to facilitate politically popular outcomes.

Further, we are concerned that a potentially similar situation is now unfolding with the Greater Amberjack Research Program.¹¹ It is not clear whether or how federal scientific integrity policies apply to this type of study, which will influence federal management by NOAA Fisheries.

Individuals and entities receiving federal funding from NOAA should be covered by the scientific integrity policy while conducting funded work, including grant awardees. If financial awardees are not directly covered under the policy, it is still important to establish best practices and principles and set forth clear processes for the federal government's enforcement role when there is research misconduct or a scientific integrity violation. **As with contractors, we recommend that the agency have an active and cooperative role investigating all alleged violations of the policy by recipients of NOAA financial awards. These investigations should be conducted in partnership with the home institution of the award recipient.**

Other recommendations for NOAA and its policy

From Sharpiegate to illegal decisions by the agency around red snapper,¹² the Trump administration created an atmosphere where staff and their science-based decisions were regularly undermined at the agency. NOAA's scientific integrity policy, which has been considered a gold standard, was ignored and undermined by the Trump administration.

With the scientific integrity policy at NOAA now a decade old and currently under review by the administration, we recommend that the agency consider several factors in weighing potential changes. In a review, we recommend including an assessment of strengths, gaps and lapses in implementation; evaluation of whether review and enforcement and response to violations is adequate; consideration of more regular monitoring and evaluation of policy implementation;

¹¹ Gulf of Mexico and South Atlantic Greater Amberjack Research Program, <https://www.flseagrant.org/fisheries/gaj-researchprogram/>.

¹² In 2017, the Secretary of Commerce illegally extended the private recreational red snapper season, resulting in an estimated 2.8 million pounds of extra catch above their limit of 3.8 million pounds. See Ocean Conservancy Blog, "New State Management for Red Snapper Is Driving Overfishing," <https://oceanconservancy.org/blog/2020/06/16/new-state-management-red-snapper-driving-overfishing/>.

opportunities to improve the transparency and detail of reporting on scientific integrity; evaluation of how to improve the scientific integrity commons website and resources; and a consideration to make training comprehensive, mandatory, and inclusive of scientists and non-scientists who manage, supervise, and communicate scientific work.

Finally, we recommend the agency return to the practice of offering an opportunity for public comment when updates are made to the policy and related documents. In 2016, draft updates to the procedural handbook that accompanies the policy were made available to the public for review and comment through a notice in the Federal Register.¹³ Updates to the handbook in 2021, as far as we are aware, were not announced nor made available to the public before being finalized.

3. Recommendations to Office of Science and Technology Policy on the Ocean Policy Committee and Advancing Ocean Data and Knowledge

OSTP has several mechanisms to advance scientific integrity related to ocean, coasts and Great Lakes. Congress statutorily formalized the Ocean Policy Committee (OPC)—an interagency, executive-level committee dedicated to ocean science, technology and management—as part of the National Defense Authorization Act¹⁴. The OPC, co-chaired by OSTP and Council on Environmental Quality, is outlined in legislation to be advised by the Ocean Research Advisory Panel (ORAP) with members who have a diverse range of expertise and knowledge. No seats on the ORAP are currently filled, offering an opportunity for the administration to quickly boost scientific integrity to inform ocean science and management.

The OPC should work to provide additional transparency surrounding federal actions on ocean research, science and management as it relates to data. A federal list or file system with public access should be explored as a means to outline ongoing research efforts occurring in the U.S. EEZ, identifying ways to leverage coordination with ocean science and technology communities and other organizations. Federal agencies and associated lead policy staff should be publicly displayed on an OPC website. In an effort to increase transparency and boost partnership engagement, committees and workgroups should make work plans and meeting summaries available.

The National Strategy for Mapping, Exploring, and Characterizing the U.S. EEZ¹⁵ that falls under the OPC also offers opportunities to define data standards, advance collaborative partnerships, and further advance science and information. Scientific integrity will play a key

¹³ 81 Fed. Reg. 49634 (July 28, 2016).

¹⁴ 10 U.S.C. § 8932, as amended by Section 1055 of the National Defense Authorization Act for Fiscal Year 2021. See Ocean Conservancy Blog, “New Year, New Big Ocean Win,” <https://oceanconservancy.org/blog/2021/01/29/new-year-new-big-ocean-win/>

¹⁵ National strategy for mapping, exploring, and characterizing the United States exclusive economic zone: <https://oeab.noaa.gov/wp-content/uploads/2021/01/2020-national-strategy.pdf>

role especially in defining industry, technology, and nongovernmental partners. The National Strategy, under which large amounts of bathymetry and ecosystem characterization data will be collected, is an unprecedented opportunity to inform resource management or policymaking that permits offshore commercial activities (e.g., offshore renewable energy) while maximizing conservation values. Scientific integrity, including publicly accessible data in appropriate formats, is critical for this long-term effort to be successful.

The administration's commitment to advance 30 gigawatts by 2030 and recent data sharing agreement with offshore wind developer, Ørsted,¹⁶ should be evaluated, expanded and standardized for the entire offshore wind industry rather than one-off commitments from individual developers. There is an opportunity to institutionalize a culture of data sharing and advance scientific integrity policies with emerging industries like offshore renewable energy that are in the early development phases. OSTP should work directly with NOAA and the Bureau of Ocean Energy Management to require all non-proprietary biological and oceanographic data collected by energy companies operating in the U.S. EEZ to be made available to the public. Data should be collected and shared with standard metadata conventions used by the Marine Cadastre, the U.S. Integrated Ocean Observing System, regional ocean data portals or other long-term collaborative data-management efforts.

We thank the Biden administration for taking this first step toward restoring scientific integrity in federal policy making and look forward to working with you.

Sincerely,

Meredith McCarthy Moore
Director, Fish Conservation Program

Elizabeth Cerny-Chipman, Ph.D.
Senior Policy Analyst, Fish Conservation Program

Amy Trice
Director, Ocean Planning

¹⁶ Interior, Energy, Commerce, and Transportation Departments Announce New Leasing, Funding, and Development Goals to Accelerate and Deploy Offshore Wind Energy and Jobs:
<https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/29/fact-sheet-biden-administration-jumpstarts-offshore-wind-energy-projects-to-create-jobs/>



 **Columbia Law School**

SABIN CENTER FOR CLIMATE CHANGE LAW

Comments of the Climate Science Legal Defense Fund and Sabin Center for Climate Change Law at Columbia Law School on the White House Office of Science and Technology Policy's Request for Information to Improve Scientific Integrity Policies

July 28, 2021

The Climate Science Legal Defense Fund (CSLDF) and the Sabin Center for Climate Change Law at Columbia Law School (Sabin Center) respectfully submit these comments in response to the White House Office of Science and Technology Policy's Request for Information to Improve Scientific Integrity Policies.¹

I. Organizational expertise

Since 2011, CSLDF has provided legal support and representation to numerous federal scientists who have directly experienced interference with their work and threats to scientific norms. These have included attempts by federal agency personnel to alter scientific work product for political reasons, and prevent the release of valid scientific work that dealt with what were perceived to be sensitive political topics. Our experience helping scientists address a range of scientific integrity issues gives us unique insight highly relevant to OSTP's current work.

In addition to direct work with affected scientists, CSLDF has published [detailed analyses](#) of scientific integrity policies at a dozen of the most important federal scientific agencies [Attached as Attachment A].² As a result, we have an in-depth understanding of the relative strengths and weaknesses of policies at key agencies. We used that knowledge to develop a [model scientific integrity policy](#) [Attached as Attachment B], with specific proposed language to help agencies address common weaknesses and gaps in coverage in their existing policies.³

The Sabin Center develops legal techniques to fight climate change and trains law students and lawyers in their use. The Sabin Center and CSLDF jointly manage the [Silencing Science](#)

¹ Request for Information to Improve Scientific Integrity Policies, White House Office of Science and Technology Policy, June 28, 2021, 86 Fed. Reg. 34064, <https://www.federalregister.gov/documents/2021/06/28/2021-13640/request-for-information-to-improve-federal-scientific-integrity-policies>.

² Guides to Scientific Integrity at Federal Agencies, Climate Science Legal Defense Fund, <https://www.csldf.org/resource/guides-to-scientific-integrity-at-federal-agencies/>.

³ Model Scientific Integrity Policy for Agencies, Universities, and Other Research Institutions, <https://www.csldf.org/resource/model-scientific-integrity-policy/>.

[Tracker](#),⁴ which has documented 496 actions by federal, state, and local governments to restrict, prohibit, or misrepresent scientific research, education, and discussion since the November 2016 election.

Sabin Center attorneys, working with the Columbia Environmental Law Clinic, have also represented scientists affected by anti-science actions taken by government actors. For example, from 2017 to 2019, Sabin Center attorneys represented scientists who successfully challenged a U.S. Environmental Protection Agency (EPA) policy banning scientists with EPA grants from serving on the agency's science advisory committees.

II. Policies have thus far failed to prevent widespread scientific integrity violations

In his January 27, 2021 Presidential Memorandum, President Biden rightly recognized that “[s]cientific findings should never be distorted or influenced by political considerations.”⁵ Nonetheless, in recent years, science has been politicized to justify policies that benefit influential industry and other groups, often at the expense of the most vulnerable.⁶

Existing scientific integrity policies have done little to stop political interference in, and distortion of, scientific research. The Silencing Science Tracker documents 343 reported anti-science actions by federal government officials since the November 2016 election, well after most relevant agencies had scientific integrity policies in place.

Close to half of the entries in the Silencing Science Tracker (153 entries) involve censorship of scientific information. There are multiple examples of government actors editing scientific reports prior to publication to remove key data or facts,⁷ blocking the publication of entire reports,⁸ or preventing federal scientists from speaking about their work publicly.⁹ In some cases, scientists themselves chose to suppress information, fearing politically-motivated blowback.¹⁰ Improved scientific integrity policies are essential to mitigate this culture of fear and prevent similar censorship and self-censorship in the future.¹¹

The Silencing Science Tracker also records 57 instances of “bias and misrepresentation,” where government actors engaged in “cherry picking” (i.e., only citing scientific studies that support a particular conclusion and ignoring conflicting data), mischaracterized the findings of scientific

⁴ Silencing Science Tracker, <https://climate.law.columbia.edu/Silencing-Science-Tracker>.

⁵ Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking, January 27, 2021, <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/>.

⁶ Romany Webb et al., *When Politics Trump Science: The Erosion of Science-Based Regulation*, 50 ENVTL. L. REP. 10708 (2020).

⁷ See e.g., Silencing Science Tracker, NOAA Fisheries Report Edited by Political Appointees, <https://climate.law.columbia.edu/content/noaa-fisheries-report-edited-political-appointees>.

⁸ See e.g., Silencing Science Tracker, Release of Congressionally Mandated Study Blocked by DOE, <https://climate.law.columbia.edu/content/release-congressionally-mandated-study-blocked-doe>.

⁹ See e.g., Silencing Science Tracker, EPA Scientists' Speaking Engagements Cancelled, <https://climate.law.columbia.edu/content/epa-scientists-speaking-engagements-cancelled>.

¹⁰ See e.g., Silencing Science Tracker, CDC Climate Change Summit Cancelled, <https://climate.law.columbia.edu/content/cdc-climate-change-summit-cancelled>.

¹¹ Romany M. Webb, *How Agency Science is Under Threat*, THE ENVIRONMENTAL FORUM 45 (Sept./Oct. 2020).

studies, or presented sound studies as unreliable or untrustworthy.¹² There are also 38 instances of “research hindrance,” where government actors have attempted to block particular types of scientific research or make it more difficult, including by restricting access to needed data.¹³

Such political interference in scientific research has been reported in at least 22 different federal bodies since the November 2016 election. However, over half of the recorded actions occurred at EPA (83 actions or 24% of the total), the Department of the Interior (DOI) (62 actions or 18% of the total), and the Department of Health and Human Services (HHS) (43 actions or 13% of the total). All three of those agencies have scientific integrity policies that are intended to prevent precisely the type of anti-science actions witnessed in recent years, but were clearly ineffective.

III. Specific suggestions for improving scientific integrity policies

The concerning high frequency of scientific integrity violations at federal agencies that already have scientific integrity policies in place indicates that those policies need to be strengthened, and much more rigorously enforced, if they are to achieve their intended goals. We offer the following specific suggestions for improving the effectiveness of scientific integrity policies.

1) Stronger protection against political interference

Scientific integrity policies at key federal agencies do not always clearly prohibit political interference with science, a critical failing.¹⁴ For example, the scientific integrity policy at the National Institutes of Health (NIH)—an agency playing a crucial role on a national and even global scale in leading research on tests, treatments and vaccines for COVID-19—does not address political interference with scientific research at all.

In other instances, policies mention political interference with science, but use language that is too weak to be effective. For example, the scientific integrity policy adopted by the Centers for Disease Control and Prevention (CDC) describes the CDC’s commitment to avoiding the influence of political issues in the conduct and dissemination of its science,¹⁵ but does not explicitly prohibit the conduct or dissemination of scientific research for political reasons. This approach is clearly insufficient, since there have been several recent examples of such political interference with research at the CDC. For example, in May 2020, CDC officials reportedly blocked the release of a report authored by infectious disease experts that provided community leaders with advice on how to safely reopen following COVID-19 lockdowns.¹⁶

¹² See e.g., Silencing Science Tracker, Accuracy of National Climate Assessment Questioned by Trump Administration, <https://climate.law.columbia.edu/content/accuracy-national-climate-assessment-questioned-trump-administration-0>.

¹³ See e.g., Silencing Science Tracker, Scientific Data and Records to be Destroyed by DOI, <https://climate.law.columbia.edu/content/scientific-data-and-records-be-destroyed-doi-0>, USGS Scientists Ordered not to Model Long-Term Climate Impacts, <https://climate.law.columbia.edu/content/usgs-scientists-ordered-not-model-long-term-climate-impacts>.

¹⁴ See Augusta Wilson, *How Do We Protect Science From the Next Trump?*, UNDARK MAGAZINE, Feb. 25, 2021, <https://undark.org/2021/02/25/protect-science-integrity/>; see also Lauren Kurtz & Gretchen Goldman, *10 Steps that can Restore Scientific Integrity in Government*, SCIENTIFIC AMERICAN, Nov. 16, 2020, <https://www.scientificamerican.com/article/10-steps-that-can-restore-scientific-integrity-in-government/>.

¹⁵ CDC Guidance on Scientific Integrity at 3, https://www.cdc.gov/os/integrity/docs/CDCSIGuide_042516.pdf.

¹⁶ Silencing Science Tracker, Release of CDC Report Blocked, <https://climate.law.columbia.edu/content/release-cdc-report-blocked>.

At other agencies, scientific integrity policies only prohibit political interference in the conduct or dissemination of scientific research by certain categories of employees. For example, DOI's policy, while falling short of explicitly prohibiting political interference, does prohibit "coercive manipulation, censorship, or other misconduct."¹⁷ However, this prohibition applies only to "decision makers,"¹⁸ and only public affairs officers are explicitly prohibited from asking scientists to alter their findings.¹⁹ The scientific integrity policy at the National Aeronautics and Space Administration (NASA) similarly only prohibits public affairs officers from asking or directing federal scientists to alter scientific findings.²⁰ These gaps leave sizeable groups of employees free to engage in such misconduct without violating the policy. This is particularly concerning since mid-level managers have been responsible for some of the most pervasive efforts to undermine politically inconvenient science, particularly climate research.²¹

We recommend that scientific integrity policies include language explicitly making interference with scientific research or activities, or communication of scientific information, a violation of scientific integrity. We also recommend that policies make clear that attempts at political interference with science, even if ultimately unsuccessful, violate scientific integrity. The prohibitions on actual and attempted interference with science should apply to all agency employees, as well as contractors, grantees, and others who participate in or supervise scientific work on the agency's behalf.

2) Stronger protection of scientists' rights to communicate about their work

Some federal agencies' scientific integrity policies do not adequately protect the rights of agency scientists to publicly discuss their work or share personal opinions as private citizens. For example, DOI's policy references the need to ensure that agency procedures allow scientists to speak to the media and the public about their work and areas of expertise, but does not explicitly make interference with scientists' right to communicate a violation of scientific integrity. Perhaps unsurprisingly, then, many DOI scientists have reported being unable to freely speak to journalists and the public.²² This clearly demonstrates the inadequacy of DOI's existing policy in preventing restrictions on scientists' rights to communicate about their work.

¹⁷ Department of the Interior, Integrity of Scientific and Scholarly Activities, 305 DM 3, § 3.7(C)(1), https://www.doi.gov/sites/doi.gov/files/uploads/305_dm_3_final_revised_si_policy_12-16-14.pdf.

¹⁸ "Decision makers" are defined as "Individuals who develop policies that involve, or rely on, scientific activities; implement or manage activities that involve, or rely on, scientific activities; or supervise employees who engage in scientific activities." *Id.* at § 3.5(G).

¹⁹ *Id.*, § 3.4(A)(7).

²⁰ National Aeronautics and Space Administration, NASA Guidelines for Promoting Scientific and Research Integrity 12 (June 2018), https://www.nasa.gov/sites/default/files/atoms/files/nasa_guidelines_for_promoting_scientific_and_research_integrity-july_2018.pdf.

²¹ Lisa Friedman, *A War Against Climate Science, Waged by Washington's Rank and File*, N.Y. TIMES, June 15, 2020, <https://www.nytimes.com/2020/06/15/climate/climate-science-trump.html>.

²² See e.g., Silencing Science Tracker, Public Communication by NPS Scientists Restricted, <https://climate.law.columbia.edu/content/public-communication-nps-scientists-restricted-0>, FWS Scientists Prevented from Discussing or Researching "Politically Contentious" Topics, <https://climate.law.columbia.edu/content/fws-scientists-prevented-discussing-or-researching-politically-contentious-topics-0>.

We recommend that scientific integrity policies include clear language making interference with scientists' rights to communicate with the media and the public about their work and areas of expertise a violation of scientific integrity unless there are compelling reasons for restricting communication (e.g., because it would result in the publication of protected health or other confidential information). Policies should clearly define the circumstances in which restrictions on communication may be appropriate and those imposing the restrictions should be required to demonstrate that the defined circumstances exist. Policies should also explicitly protect scientists' rights to make public statements of opinion (e.g., on social media) as private citizens.

3) Stronger requirements related to conflicts of interest

Avoidance of conflicts of interest in the conduct of scientific research, and the clear disclosure of such conflicts where they do exist, is a critically important aspect of scientific integrity. Yet scientific integrity policies at a number of key agencies make only passing reference to conflicts of interest. For example, at the Department of Energy (DOE), the scientific integrity policy mentions conflicts of interest only in the context of pointing out that employees should accept honors and awards subject to compliance with conflict of interest statutes.²³ The policy does not define conflicts of interest or discuss how such conflicts violate scientific integrity.

Failure to clearly articulate what constitutes a conflict of interest allowed former EPA Administrator Scott Pruitt to issue a directive prohibiting scientists who had received EPA grants from serving on the agency's key science advisory groups (scientists who had received funding from industry were subject to no such restriction).²⁴ Pruitt sought to present this as an attempt to avoid conflicts of interest, but in fact this represented a significant purge of highly qualified and independent scientists from important advisory roles and a distortion of the idea of a "conflict of interest."

We recommend that scientific integrity policies include definitions of both personal and financial conflicts of interest, and explicit language indicating that failure to avoid, or properly disclose, conflicts of interest can constitute a violation of scientific integrity.

4) Establishing clear processes and procedures for filing and investigating complaints

In a number of instances, policies fail to establish clear and straightforward processes for the filing, evaluation, investigation, and resolution of scientific integrity complaints. For example, DOE's current scientific integrity policy does not contain any information at all about how complaints should be filed, or what procedures the agency will follow for evaluating, investigating, and resolving complaints. The EPA is another key scientific agency whose scientific integrity policy is concerningly silent on many of these topics.

We recommend that all agencies designate a scientific integrity official (or similar) who is responsible for receiving and overseeing the investigation of scientific integrity complaints. We

²³ DOE Scientific Integrity Policy, U.S. Department of Energy, DOE P 411.2A, §7(c).

²⁴ Brady Dennis & Juliet Eilperin, *Scott Pruitt blocks scientists with EPA funding from serving as agency science advisers*, WASH. POST, Oct. 31, 2017, https://www.washingtonpost.com/national/health-science/scott-pruitt-blocks-scientists-with-epa-funding-from-serving-as-agency-advisers/2017/10/31/959d91ac-be5a-11e7-959c-fe2b598d8c00_story.html.

also recommend that agency scientific integrity policies include specific practices and procedures that, at a minimum, specify: (1) how and where to file a complaint under the policy; (2) what information the filing must contain; (3) how and by whom a complaint will be evaluated; (4) what the investigation process will entail; (5) mandatory deadlines for responding to complaints, as well as for completing the investigation and publishing findings; (6) the person accused of a violation's right to a hearing; and (7) the parties' rights of appeal and procedures for appeals. More specific recommendations on each of these points are provided in CSLDF's model scientific integrity policy.

5) Whistleblower protections/protection against retaliation

In some cases, agency scientific integrity policies do not clearly protect those who file complaints in good faith, or who participate in the investigation or adjudication of a complaint, from retaliation. Even where agency policies do include such protections, they are often limited. For example, EPA's policy protects employees who report "research misconduct" but not those who report other types of wrongdoing (e.g., censorship). The policy provides no protection to contractors, grantees, and other non-employees, regardless of the type of misconduct they report.

Lack of whistleblower protections can discourage those who are aware of scientific integrity violations from reporting them. In a recent survey conducted by EPA's Office of Inspector General (OIG), 394 employees and contractors indicated that they had "experienced, but did not report, potential violations of the [agency's scientific integrity] policy."²⁵ According to the OIG's report, "fear of retaliation" was a commonly cited reason for not reporting.²⁶

We recommend that scientific integrity policies clearly prohibit any retaliatory action against those who, in good faith, report a suspected violation of scientific integrity, or who participate in the investigation or adjudication of a complaint. On this topic, we also refer OSTP to the comments filed by the Government Accountability Project, which contain further recommendations with respect to whistleblower protections. CSLDF is currently partnering with the Government Accountability Project on a Scientific Integrity Reporting Project, intended to document past and ongoing threats to scientific integrity in order to better understand how to make science more resilient to such threats in the future.

6) Clear and meaningful penalties for violations

Strengthening agency scientific integrity policies is a crucial step, but even the most robust policy means little if it is not well enforced. Unfortunately, lack of confidence that scientific integrity violations will be taken seriously appears to be a significant problem: the survey by the EPA OIG referenced above found that another common reason employees said they chose not to report scientific integrity issues was that they believed it wouldn't matter.²⁷

²⁵ U.S. Environmental Protection Agency Office of Inspector General, *Further Efforts Needed to Uphold Scientific Integrity Policy at EPA*, Report No. 20-P-0173, 10 (May 20, 2020), https://www.epa.gov/sites/default/files/2020-05/documents/_epaoig_20200520-20-p-0173.pdf.

²⁶ *Id.*

²⁷ *Id.*

Agencies have too often failed to confront violations of their scientific integrity policies, particularly violations committed by those in the highest rungs of power within an agency. For example, when the acting chief of the National Oceanic and Atmospheric Administration bowed to political pressure to support then-President Trump's assertion that Hurricane Dorian would hit Alabama (when government scientists were not forecasting any impacts in Alabama from that storm), an independent panel found that he had violated the agency's scientific integrity policy. Yet there were no repercussions.²⁸

In order to create environments in which federal scientists can thrive, scientific agencies need to take steps to ensure that threats to science will be seriously and objectively investigated, and that meaningful remedial action will be taken if those investigations reveal violations of scientific integrity. We suggest that policies detail specific possible penalties, which could range in severity from, for example, issuance of a retraction to suspension or termination, as appropriate based on the seriousness of the violation.

7) Strengthening cultures of scientific integrity

Agencies must also fundamentally strengthen their cultures of scientific integrity via thorough and consistent training on applicable scientific integrity policies. Not all federal employees who participate in scientific activities on behalf of their agencies currently receive this kind of training. A recent report by the U.S. Government Accountability Office²⁹ looked at nine federal bodies and found that four—the Federal Aviation Administration, NASA, the National Institute of Standards and Technology (within the Department of Commerce), and the Office of Fossil Energy (within DOE)—offer no such training, and the latter two offices have not taken any steps at all to promote awareness of their scientific integrity policies among their staff. Agencies need to make scientific integrity training a regular habit.

We believe that if agencies strengthen their scientific integrity policies, and take steps to foster a culture of scientific integrity among their ranks, they can reinvigorate federal science and make it more resilient against political interference and similar threats. Specific proposals on what should be involved in a scientific integrity policy can also be found in the referenced [model scientific integrity policy](#).

* * *

If you have any questions, please contact CSLDF Executive Director Lauren Kurtz (), CSLDF Staff Attorney Augusta Wilson, or Associate Research Scholar at Columbia Law School and Senior Fellow at the Sabin Center Romany Webb Thank you for your consideration of these important issues.

²⁸ Seth Borenstein, *Panel: NOAA Bowed to Political Pressure in Dorian Dispute*, ABC News, June 16, 2020, <https://abcnews.go.com/Technology/wireStory/panel-noaa-bowed-political-pressure-dorian-dispute-71282013>.

²⁹ U.S. Government Accountability Office, Report to the Ranking Member, Committee on Commerce Science, and Transportation, U.S. Senate, *Scientific Integrity Policies: Additional Actions Could Strengthen Integrity of Federal Research*, 12 (April 2019), <https://www.gao.gov/assets/700/698231.pdf>.

Response to Request for Information to Improve Federal Scientific Integrity Policies

Submitted by:

Emily Trunnell, Ph.D.

Katherine Roe, Ph.D.

People for the Ethical Treatment of Animals

Advocacy

In order to restore public trust in science and improve federal scientific integrity policies, federal scientific leaders and research funding agencies, including the National Institutes of Health (NIH), need to re-evaluate the continued overreliance on animal-based research that has proven costly and ineffective. A great deal of scholarly research shows that animal studies are flawed and divert both monetary and intellectual resources from methodologies better suited to curing human disease. Yet the NIH is still funnelling nearly half of its annual budget into ineffective animal-based research, resulting in a paucity of new treatments or cures for human ailments, and a public that doubts the government is prioritizing reliable research that can benefit human health.

Consider the following:

- The US National Institutes of Health (NIH), the world's largest funder of biomedical research, reports that "failure rates [for novel drugs] occur in about 95 percent of human studies",¹ even though these drugs showed success in preclinical experiments using animals.
- Systematic reviews published in peer-reviewed journals document limitations in translating results from studies using animals to treatments for humans for numerous disease areas. Fewer than 10 percent of highly promising basic science discoveries enter routine clinical use within 20 years.²
- A 2015 study determined that between 50 and 89 percent of preclinical research is not reproducible, with animal experimentation implicated as a serious problem area.³
- A 2014 analysis published in *The BMJ* found that – contrary to public perception – studies using animals have not furthered knowledge in the field of human health or led to the development of treatments for conditions affecting humans.⁴ The authors note, "[I]f research conducted on animals continues to be unable to reasonably predict what can be expected in humans, the public's continuing endorsement and funding of preclinical animal research seems misplaced."
- Following a meta-analysis of systematic reviews of preclinical animal experiments across a wide variety of disease areas, University of Oxford scientists found that a lack of measures to reduce bias in animal experiments likely results in overestimation of the benefits of the treatment studied.⁵

- In the existing animal research paradigm, novel drugs take 10 to 15 years to reach the market at a cost of over \$2 billion.⁶
- According to researchers at the Institute for Stroke and Dementia Research in Munich, “More than 1000 neuroprotective compounds have been tested in rodent models with the aim to improve stroke outcome. ... Indeed, many agents reduced brain damage (in most cases measured as decreased infarct volume) in rodent models of experimental stroke. Out of these candidates approximately 50 neuroprotective agents were tested in more than 100 clinical stroke trials, but none has improved outcome in clinical stroke patients.”⁷
- Oncology drugs, which also undergo animal testing, have a success rate of only 3.4 percent.⁸
- There is an abundance of literature documenting the failing of various animal models of neurodegenerative diseases. No animal model has been developed that recapitulates all aspects of a particular neurodegenerative disease.⁹ For Alzheimer’s disease research, the clinical failure rate for new drugs is 99.6 percent.¹⁰ This includes the recent failure of AstraZeneca and Eli Lilly’s lanabecestat, which was hailed as extremely promising, due to futility.¹¹ In Parkinson’s disease (PD), even non-human primate studies do not “constitute a valid scientific modality for the complete understanding of PD and for the development of future neuromodulation therapeutic strategies”.¹²
- HIV/AIDS vaccine research involving non-human primates has been called “one of the most notable failures in animal experimentation translation”.¹³ Rao and Alving of the US Military HIV Research Program state that “human clinical trials still appear to be the only reliable way to determine whether an HIV vaccine candidate will have activity or efficacy in humans”.¹⁴ In a comprehensive review of preclinical and clinical data, Jarrod Bailey reported that of 85 candidate vaccines that were tested in 197 clinical trials, zero were successful; some drugs even increased the risk of HIV infections compared to the placebo.¹⁵ A current search of ClinicalTrials.gov will return more than 700 AIDS vaccine trials, and still, none has been successful.
- In 2013, *Proceedings of the National Academy of Sciences of the United States of America* (PNAS) published a landmark study that had been 10 years in the making and involved the collaboration of 39 researchers from institutions across North America, including Stanford University and Harvard Medical School. Dr Junhee Seok and his colleagues compared data obtained from hundreds of human clinical patients with results from experiments on animals to demonstrate that when it comes to serious inflammatory conditions such as sepsis, burns, and trauma, humans and mice are not similar in their genetic responses.¹⁶ NIH Director Dr Francis Collins authored an article about these results, lamenting the time and resources spent developing 150 drugs that had successfully treated sepsis in mice but failed in human clinical trials. He called this disaster “a heartbreaking loss of decades of research and billions of dollars”.¹⁷
- Despite the prevalence of addiction research conducted on animals, “drugs that effectively curb opioid or psychostimulant addiction by promoting abstinence and preventing relapse

have yet to be developed” and “very little clinical development is currently ongoing”.¹⁸ The data from animal studies was promising in certain drug classes, but these have either failed to be effective in human trials or not been tolerated well by humans, a negative outcome that was not predicted by animal trials.¹⁹

- For heart failure research, “insights gleaned from animal-based research efforts have shown poor translation in terms of deciphering human heart failure and developing effective therapies”, and “lack of concordance between animal models and human disease state has been acknowledged as a major contributing factor [to this translational failure]”.²⁰
- In a survey of 121 animal studies claiming to investigate attention deficit hyperactivity disorder (ADHD), only five were found to be in any way relevant to the hypotheses of the human medical papers in which they were cited. The authors of the survey concluded that “animal research has contributed very little to contemporary understanding of ADHD”.²¹ A similar failure of animal studies to translate into a clinical setting has been noted with bipolar depression research,²² and animal studies have been cited as the primary source of attrition (failure of drugs) in neurobehavioral clinical trials.²³
- Many neuroprotective agents have been developed that are successful in treating spinal cord injury (SCI) in animal models, but clinical trials have been disappointing. Neurologist Aysha Akhtar has described three major reasons for this failure: “differences in injury type between laboratory-induced SCI and clinical SCI, difficulties in interpreting functional outcome in animals, and inter-species and interstrain differences in pathophysiology of SCI”.²⁴ In their systematic review of the use of animal models to study nerve regeneration in tissue-engineered scaffolds, Angius and colleagues noted, “The large majority of biomaterials used in animal models have not progressed for approval to be tested in clinical trials in spite of the almost uniform benefit described in the experimental papers.”²⁵
- A 2014 study found fundamental differences between the species in the innate immune response, stating, “[W]hile in human blood mechanisms of immune resistance are highly prevailed, tolerance mechanisms dominate for the defense against pathogenic microorganisms in mouse blood.”²⁶ Logically, these differences make sense: we humans “do not live with our heads a half-inch off the ground”,²⁷ and we have considerably longer lifespans and a larger body size than do mice.^{28,29} As concisely stated by Leist and Hartung, “[H]umans are definitely no 70-kg mice.”³⁰ Despite the glaring contrast, mice continue to be used for immunological research.
- Despite years of use, animal-based skin irritation studies have never been properly validated. Evidence exists that they are highly variable, of limited reliability, and generally poor predictors of human skin reactions. For example, a comparison of data from rabbit tests and four-hour human skin patch tests for 65 substances found that 45 per cent of classifications of chemical irritation potential based on animal tests were incorrect.³¹
- There is growing scientific consensus that far more is to be gained from human-relevant research methods and technology that are better suited to solving human biomedical and

regulatory assessment paradigms than from reliance on animal studies. As a recent UK industry report emphasised, the time has come to humanise drug discovery and toxicology.³²

- Columbia University scientists Kacey Ronaldson-Bouchard and Gordana Vunjak-Novakovic, in advocating for the use of human tissues *in vitro* during drug development, also make the following observation: “Equally damaging is the cautious elimination of potentially curative new drugs because their adverse effects in animals do not necessarily translate into humans. These false-positive and false-negative readouts create an enormous financial burden, resulting in decision-making in which the potential profitability of a drug is leveraged against the potential risks, rather than on the drug’s potential to improve disease outcomes.”³³
- *The Turkish Journal of Gastroenterology* – the journal of the Turkish Society of Gastroenterology – officially banned the publication of studies involving experiments on animal from its pages. Journal editor Dr Hakan Şentürk wrote that the new policy represents “growing concern about the lack of applicability of animal research to humans”.³⁴ He further commented, “When we recognize that the reliance on inherently flawed animal models of human disease are largely responsible for clinical failure ... it does not make sense to continue to promote this practice. ... Human-relevant approaches should be more aggressively developed and utilized instead.”
- Major scientific breakthroughs in disease areas such as diabetes and breast cancer have relied on studies of human disease in patients; they would not have been possible using animal research.
- Inherent species differences mean that non-human animals cannot serve as analogues for understanding the specific biological details necessary to develop safe and effective drugs for humans. As Wall and Shani write, even the “extrapolated results from studies using tens of millions of animals fail to accurately predict human responses”.³⁵
- Cellular and genetic information about the potential toxicity of a chemical, such as the potential for receptor binding or gene or pathway activation, is obtained more readily with non-animal tests (using human cells *in vitro*) than with animal tests (*in vivo*).³⁶
- In his 2010 article “TGN1412: From Discovery to Disaster”, Husain Attarwala of Northeastern University in the US recounts the tragic outcome of the 2006 clinical trial for Theralizumab, an immunomodulatory drug. Five of the six participants had to remain hospitalised for three months after the initial dose, while the other was comatose. Even six months later, participants suffered from headaches and memory loss. One had to have toes and fingers amputated as a result of gangrene. Studying this and other trials, Attarwala concluded, “Drugs showing safety and efficacy in preclinical animal models may show very different pharmacological properties when administered to humans.”³⁷
- A move away from animal-based research will allow for substantial growth in the science and technology sectors and for faster return on investment in drug research and development.³⁸ An evolution of research funding priorities towards human-relevant methods will get treatments to the patients who need them more safely and likely in less time.³⁹

The above represents only a sample of the existing data that indicate that the animal-research paradigm is failing to produce data that benefit human health. Despite this wealth of evidence that a paradigm-shift is needed, the NIH has not made significant adjustments to its research funding priorities. This failure for animal-based research to translate into human health benefits, and for the NIH to take meaningful action to rectify these failures, has resulted in tax-payers who are dissatisfied with how their money is spent, patients and patient advocacy groups looking outside the NIH for usable research findings, and a public who no longer trusts that the scientific discoveries they hear about in the media will ever positively impact their health.

If the public is to trust the scientific community, and feel confident that federal health agencies are using our finite public funds responsibly and to their benefit, the NIH must make a real effort to fund research, whether basic or applied, that actually leads to effective treatment for humans. The current evidence suggests that basic and applied research involving *animals* is often misleading the public into thinking that new treatments are imminent, while in fact are actually impeding the development of treatment and cures for human ailments.

PETA scientists from a wide-range of disciplines have developed a strategy to phase out the funding of inadequate animal-based experiments. This strategy, named The Research Modernization Deal, lays out 5 steps the NIH can implement to improve the quality of biomedical research funded in the United States. This plan has been endorsed by the National Medical Association, the National Hispanic Medical Association, and numerous other physicians and scientists.

In summary the Research Modernization Deal suggests the National Institutes of Health:

1. Immediately eliminate animal use in fields of research for which animals have been shown to be bad “models” for humans and have impeded progress.
2. Rebalance the public funding of medical research so that the majority goes to sophisticated human-relevant, animal-free research methods.
3. Conduct scientific reviews of the efficacy of animal use to identify additional areas in which such use has failed to advance human health, or in which non-animal methods are now available, and can therefore be ended quickly.
4. Implement a cost-benefit analysis system for research involving animals that includes an ethical perspective and consideration of lifelong harm inflicted on animals, such as is used in the U.K.
5. Work with other world leaders to harmonize and promote international acceptance of high-tech non-animal testing strategies in regulatory toxicity testing.

To read the Research Modernization in full, which includes a more in-depth review of the failures of animal models, and descriptions of numerous non-animal alternatives, please visit [PETA-2021-Research-Modernization-Deal.pdf](#).

¹National Center for Advancing Translational Sciences (NCATS). About NCATS.

<https://ncats.nih.gov/about>. Updated 3 July 2018. Accessed 3 July 2018.

²Contopoulos-Ioannidis DG, Ntzani E, Ioannidis JP. Translation of highly promising basic science research into clinical applications. *Am J Med*. 2003;114(6):477-484.

³Freedman LP, Cockburn IM, Simcoe TS. The economics of reproducibility in preclinical research. *PLoS Biol*. 2015;13(6):e1002165.

⁴Pound P, Bracken MB. Is animal research sufficiently evidence based to be a cornerstone of biomedical research? *BMJ*. 2014;348:g3387.

⁵Hirst JA, Howick J, Aronson JK, *et al*. The need for randomization in animal trials: An overview of systematic reviews. *PLoS One*. 2014;9(6):e98856.

⁶NCATS.

⁷Roth S, Liesz A. Stroke research at the crossroads – where are we heading? *Swiss Med Wkly*. 2016;146:w14329.

⁸Wong CH, Siah KW, Lo AW. Estimation of clinical trial success rates and related parameters. *Biostatistics*. 2018;kxx069.

⁹Potashkin JA, Blume SR, Runkle NK. Limitations of animal models of Parkinson's disease. *Parkinsons Dis*. 2010;2011:1-7.

¹⁰Pistollato F, Ohayon EL, Lam A, *et al*. Alzheimer disease research in the 21st century: Past and current failures, new perspectives and funding opportunities. *Oncotarget*. 2016;7(26):38999-39016.

¹¹AstraZeneca. Update on Phase III clinical trials of lanabecestat for Alzheimer's disease.

<https://www.astrazeneca.com/media-centre/press-releases/2018/update-on-phase-iii-clinical-trials-of-lanabecestat-for-alzheimers-disease-12062018.html>. Published 12 June 2018. Accessed 17 July 2018.

¹²Menache A, Beuter A. Commentary: Lessons from the analysis of non-human primates for understanding human aging and neurodegenerative diseases. *Front Hum Neurosci*. 2016;10:33.

¹³Akhtar A. The flaws and human harms of animal experimentation. *Camb Q Healthc Ethics*. 2015;24(4):407-419.

¹⁴Rao M, Alving CR. Adjuvants for HIV vaccines. *Curr Opin HIV AIDS*. 2016;11(6):585-592.

¹⁵Bailey J. An assessment of the role of chimpanzees in AIDS vaccine research. *Altern Lab Anim*. 2008;36(4):381-428.

¹⁶Seok J, Warren HS, Cuenca AG, *et al*. Genomic responses in mouse models poorly mimic human inflammatory diseases. *Proc Natl Acad Sci U S A*. 2013;110(9):3507-3512.

¹⁷Collins F. Of mice, men, and medicine. NIH. <https://directorsblog.nih.gov/2013/02/19/of-mice-men-and-medicine/>. Published 19 February 2013. Accessed 2 November 2017.

¹⁸Tzschentke.

¹⁹*Ibid*.

²⁰Chandrasekera PC, Pippin JJ. The human subject: An integrative animal model for 21st century heart failure research. *Am J Transl Res*. 2015;7(9):1636-1647.

- ²¹Carvalho C, Vieira Crespo M, Ferreira Bastos L, Knight A, Vicente L. Contribution of animal models to contemporary understanding of attention deficit hyperactivity disorder. *ALTEX*. 2016;33(3):243-249.
- ²²Kato T, Kasahara T, Kubota-Sakashita M, Kato TM, Nakajima K. Animal models of recurrent or bipolar depression. *Neuroscience*. 2016;321:189-196.
- ²³Garner JP. The significance of meaning: Why do over 90% of behavioral neuroscience results fail to translate to humans, and what can we do to fix it? *ILAR J*. 2014;55(3):438-456.
- ²⁴Akhtar AZ, Pippin JJ, Sandusky CB. Animal models in spinal cord injury: A review. *Rev Neurosci*. 2008;19(1):47-60.
- ²⁵Angius D, Wang H, Spinner RJ, Gutierrez-Cotto Y, Yaszemski MJ, Windebank AJ. A systematic review of animal models used to study nerve regeneration in tissue-engineered scaffolds. *Biomaterials*. 2012;33(32):8034-8039.
- ²⁶Zschaler J, Schlorke D, Arhhold J. Difference in innate immune response between man and mouse. *Crit Rev Immunol*. 2014;34(5):433-454.
- ²⁷Mestas, Hughes.
- ²⁸*Ibid*.
- ²⁹Zschaler *et al*.
- ³⁰Leist M, Hartung T. Inflammatory findings on species extrapolations: Humans are definitely no 70-kg mice. *Arch Toxicol*. 2013;87(4):563-567.
- ³¹Robinson MK, Cohen C, de Fraissinette AB, Ponc M, Whittle E, Fentem JH. Non-animal testing strategies for assessment of the skin corrosion and skin irritation potential of ingredients and finished products. *Food Chem Toxicol*. 2002;40(5):573-592.
- ³²BioIndustry Association, Medicines Discovery Catapult. State of the discovery nation 2018 and the role of the Medicines Discovery Catapult. <https://md.catapult.org.uk/FlipBuilder/mobile/index.html>. Published January 2018. Accessed 12 November 2018.
- ³³Ronaldson-Bouchard K, Vunjak-Novakovic G. Organs-on-a-chip: A fast track for engineered human tissues in drug development. *Cell Stem Cell*. 2018;22(3):310-324.
- ³⁴Şentürk H. Moving beyond animal models. *Turk J Gastroenterol*. 2015;26:A-IX.
- ³⁵Wall RJ, Shani M. Are animal models as good as we think? *Theriogenology*. 2008;69(1):2-9.
- ³⁶Hartung T, FitzGerald RE, Jennings P, *et al*. Systems toxicology: Real world applications and opportunities. *Chem Res Toxicol*. 2017;30(4):870-882.
- ³⁷Attarwala.
- ³⁸Meigs L, Smirnova L, Rovida C, Leist M, Hartung T. Animal testing and its alternatives – the most important omics is economics. *ALTEX*. 2018;35(3):275-305.
- ³⁹Kramer LA, Greek R. Human stakeholders and the use of animals in drug development. *Business and Society Review*. 2018;123(1):3-58; Piesing M. How tech could spell the end of animals in drugs testing. *The Guardian*. <https://www.theguardian.com/science/2014/aug/23/tech-end-animals-drugs-testing>. Published 23 August 2014. Accessed 2 August 2018.

To: ScientificIntegrityRFI@ostp.eop.gov

From: Brian D. Marshall, Emeritus Scientist, U.S. Geological Survey

Subject: Request for Information To Improve Federal Scientific Integrity Policies

Email Subject: SI-FTAC RFI

Date: July 28, 2021

In response to the request for information published in the Federal Register on June 28, 2021, I am writing this letter as an individual and emphasize that the opinions expressed herein are my own and not those of the USGS¹ or any other organization.

I retired from federal employment on December 31, 2019 after 35 years of service with the USGS where I served as Research Geologist, Research Hydrologist, Team Chief Scientist, and Supervisory Physical Scientist. I was serving as the laboratory manager for the Energy Geochemistry Laboratory in 2014 when a serious case of scientific misconduct was uncovered. This case, referred to as DOI² case number ESO-S0000422, resulted in investigations by both the USGS OSQI³ and the DOI OIG⁴. The report by the DOI OIG (“Scientific Integrity Incident at USGS Energy Geochemistry Laboratory” 2016-EAU-010) led to a Congressional Subcommittee investigation and a hearing entitled “Examining Decades of Data Manipulation at the United States Geological Survey”⁵ was held on December 6, 2016. This incident was covered extensively in the press and has been called the biggest scandal to affect the USGS. It is likely that the extensive press coverage may have adversely affected the public trust in science.

Before discussing how the 2014 incident of scientific misconduct could have been prevented and the violations of the DOI Scientific Integrity Policy⁶ that led to fraud and abuse, I will provide some background information.

The USGS is an internationally known and respected organization whose data and reports are influential for Earth and ecosystem sciences; these reports are extensively reviewed (in most cases) and are intended to provide unbiased research results to a variety of audiences including decision-makers. However, there have been cases of scientific misconduct; the DOI web site lists 21 closed scientific integrity cases beginning in 2011. Of these 21 cases, only 3 cases resulted in a finding of a loss of scientific integrity. Does this indicate that the DOI Scientific Integrity Policy is working? It is not known how many other potential cases were never reported, but the fact that over 85% of the documented cases were found to be without merit indicates that

¹ U.S. Geological Survey

² Department of the Interior

³ Office of Science Quality and Integrity

⁴ Office of Inspector General

⁵ <https://www.govinfo.gov/content/pkg/CHRG-114hhrg22862/html/CHRG-114hhrg22862.htm>

⁶ DOI Departmental Manual 305 DM 3 (12/16/2014)

employees are either not trained concerning the definitions of scientific integrity and misconduct or the investigations were not conducted in a competent, unbiased manner. Two of the three cases resulting in a finding of loss of scientific integrity (including ESO-S0000422) involve employees intentionally falsifying data from chemical instrumentation. Both of these cases document falsification that was continuing for over a year. In the case of the Energy Geochemistry Laboratory, the falsification spanned over five years, including changes to laboratory management and quality assurance policies. Quality assurance audits conducted by internal and external personnel failed to find the problem in the Energy Geochemistry Laboratory.

It is common for laboratories to analyze standards or certified reference materials similar in composition to the unknown samples that are being studied, both for traceability as well as reproducibility and accuracy of laboratory results. Results of the analysis of these standards should be compiled frequently in order to identify problems in instrumentation or procedures. In both of the cases discussed above, blind standards were routinely submitted to the laboratory. In the case of the Energy Geochemistry Laboratory, the results of blind standards were documented as acceptable by an internal report as well as an external contractor. However, there is evidence that the analysts knew the identities of the blind standards and, in one case, the external contractor corrected data submitted by the analyst as it was obviously in error. Therefore, the results on blind standards for the method in question at the Energy Geochemistry Laboratory, as well as a blind round robin test of the analyses compared to commercial laboratories performing similar tests, failed to find a problem. Because there were suspicions of a laboratory problem and distrust of the laboratory based on an alleged prior incident of poor quality analyses, employees submitting samples to the laboratory were advised to include blind standards or known samples in batches of samples. It was never revealed to me, as laboratory manager, whether or not this was actually done, but there were no reports of the results of these samples. However, during the investigations that ensued after the problem was discovered, employees claimed that they had suspected problems but did not report them⁷. This was in spite of an extensive effort to solicit reports of laboratory issues and the establishment of a new problem reporting and corrective action system in 2011.

In the case of the incident at the Energy Geochemistry Laboratory in 2014, the problem was discovered by a change to a data submittal template that archived raw instrument data separately from the “corrected” data that was uploaded to the laboratory database for review and approval. This template had been used for over a year prior to the problem being found; therefore the extent of the discrepancies between raw data and final data was easily documented and a report of the incident was prepared in a timely manner. The incident was documented in the laboratory corrective action system and immediately reported to local management; employees submitting samples to the laboratory were notified within 60 days, after the report was finalized. A disciplinary action proposed for the analyst generated an inquiry by a personnel specialist into issues of scientific misconduct, resulting in a preliminary scientific integrity investigation by an OSQI employee and the appointment of a Science Integrity Review Panel (SIRP) to conduct a more thorough, supposedly independent investigation. The scientific misconduct complaint,

⁷ One incident of poor quality analysis was reported in an email but without much documentation, and management at the time failed to investigate adequately.

written by the OSQI employee, designated the Science Center Director as the complainant although I initiated the original problem report and investigation.

The SIRP interviewed the same set of employees as the OSQI employee and issued their report of inquiry (SIRP report) in Fall, 2015. The report, which was poorly organized, contained extraneous information regarding employee conduct without regard to a timeframe. The OSQI Director rejected the report, asking the OSQI employee to divide the report into two reports, one considering only the scientific misconduct question and another dealing with all of the other issues that the SIRP report contained. The OSQI Director attempted to release only these two derivative reports, but this proposal was rejected by USGS management. Although rejected as not suitable for purpose and not prepared according to the Scientific Integrity Policy, the SIRP report was the basis for closing the section of the Energy Geochemistry Laboratory that housed the offending employee, re-assigning me, as Laboratory Manager, to a research position, and curtailing further use and development of the laboratory quality assurance system. Portions of the SIRP report contradicted the members own notes and their discussions with employees, indicating that the report did not represent the consensus opinion of the SIRP and was probably not written by the SIRP (violation of Scientific Integrity Policy). Furthermore, although clearly targeted by the SIRP report (parts of which appear to be a “hatchet job”), I was not allowed to see the report until almost a year later (violation of Science Integrity Policy) when I was issued a disciplinary action based entirely on the SIRP report. I have since filed whistleblower complaints with the Office of Special Counsel, followed by an individual right of action appeal to the MSPB⁸. I have also filed complaints with DOI OIG and Congressman Perlmutter (referred to DOI OIG); these investigations cannot go forward until my MSPB appeal is adjudicated (MSPB does not have a quorum to hear cases).

The RFI states “Of interest is information about mechanisms Federal agencies could use to detect or deter potential violations of scientific integrity policies before they occur.” First, employees need to be informed of such policies in detail with clear examples given of what constitutes violation and the potential penalties for violations. As an employee with more than 30 years of service at the time, I was not aware of the details of the Scientific Integrity Policy. Bureaus should ensure that problem reporting and corrective action systems are in place, that employees know how to report problems, and that employees are protected from retaliation for reporting a problem. The USGS appears to have a serious problem adhering to both the letter and spirit of the whistleblower protection laws. In 2020, DOI OIG issued a report titled “Alleged Reprisal by USGS Director”⁹ in which it is concluded that the USGS Director retaliated against a USGS whistleblower. I think it is probable that retaliation for filing complaints and reporting problems is the reason that few employees are willing to report issues. It may be necessary to remove the problem reporting system from the Bureau to an independent entity.

The RFI states “Consider practices ...Ensuring the independence, autonomy, and effectiveness of scientific integrity officials....” In the case of the incident at the Energy Geochemistry Laboratory, it is not clear whether the OSQI employee investigating the case was acting on their own or with some guidance from management. In discussing the SIRP report with another OSQI employee at a later time, I was told that there had been problems with SIRPs in the past and that

⁸ Merit System Protection Board (Marshall v. DOI, case DE-1221-17-0386-W-1)

⁹ Report number 19-0360

OSQI had considered establishing semi-permanent panels. This could alleviate the problem of SIRP members desire to get back to their day jobs as soon as possible as well as potentially providing independence. However, given the serious flaws in the SIRP report on the Energy Geochemistry Laboratory, I would advocate removing this level of investigation to an outside organization specifically trained for these duties.

The RFI states “Consider... reporting practices that promote transparency in the implementation of agency scientific integrity policies and in the handling of any allegations of misconduct.” The level of secrecy surrounding allegations or findings of misconduct leads many USGS employees to distrust management. It also allows management to paint any picture that is desired to enable policies. For example, after the incident in the Energy Geochemistry Laboratory more than one upper level manager stated that the laboratory had no quality assurance system. This was blatantly false but it allowed management to justify the establishment of new quality assurance requirements in all laboratories. Employees were told this was a punitive measure due to the incident in the Energy Geochemistry Laboratory. Without a clear reporting system that provides details of allegations and investigations, employees operate on the basis of rumors. Frustration with new quality assurance requirements as well as a lack of transparency has resulted in employee resignations, retirements, and laboratory shutdowns (at least temporarily).

An excellent laboratory practice implemented in the National Water Quality Laboratory (NWQL) is the establishment of the Inorganic Blind Sample Project. This Project manufactures water standards in large quantity, establishes elemental concentration values and uncertainties, and distributes the standards to participating laboratories. The standards are also used as blind samples to test the methods and statistical results of analyses by the NWQL. One of the most critical needs for chemical analytical laboratories are certified reference materials that are similar in overall composition to the samples being analyzed in the laboratory. Because of problems with so-called blind sample submissions in the Energy Geochemistry Laboratory, including a contractor willing to correct submitted results and employees not reporting results of blind samples that were submitted, I suggest that additional oversight of blind standard production, submittal, and results be moved to a higher authority, either within OSQI or outside of USGS. For production laboratories (those that accept samples on a fee-for-service or contractual basis), this would help enhance both quality assurance and transparency (assuming that results of the submittals are openly published).

I hope that it is clear from the above summary that the DOI Scientific Integrity Policy, although appearing to be adequate on paper, can easily be ignored by managers, enabling pre-determined outcomes of investigations. In the case of the Energy Geochemistry Laboratory, new investigations¹⁰ will find that 1) a second laboratory employee facilitated the hiding of poor quality results; 2) there was no prior similar problem with data from this laboratory¹¹; 3) the SIRP report was prepared outside the scope of the Scientific Integrity Policy and contains numerous errors and false statements; 4) quality assurance policies, including a problem

¹⁰ In addition to the complaints filed with the DOI OIG, I have asked USGS management to perform the root cause analysis required by the quality assurance policy; these requests have been ignored in part because the quality assurance system was curtailed after discovery of the problem.

¹¹ I can find no evidence that supports published statements that some laboratory data collected from 1996 to 2008 should be treated as semi-quantitative.

reporting and corrective action system were operating effectively in the laboratory and were instrumental in finding the data problem; and 5) allegations of ongoing harassment by a laboratory employee referred to incidents that occurred many years prior to the finding of the data problem¹².

Thank you for the opportunity to respond to this important request. I am willing to provide further information if that is desired.

¹² A report that confirms this was presented to the Congressional subcommittee subsequent to the hearing.

Re: Scientific Integrity Fast-Track Action Committee (SI-FTAC) Request for information

To whom it may concern,

COMPASS and The Alan Alda Center for Communicating Science welcome the opportunity to offer our comments to the Scientific Integrity Fast-Track Action Committee on the following topics:

- 2) Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information.
- 3) Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce.

Specifically: supporting the professional development of Federal scientists; supporting scientists and researchers of all genders, races, ethnicities, and backgrounds and advance the equitable delivery of the Federal Government's programs

We offer these comments based on more than 20 years combined of practice in science communication. COMPASS prepares diverse science leaders to become agents of change. We create inclusive, safe, and empowering spaces for learning and transformation, and provide connections and ongoing support as scientists engage outside of the lab and field. With strategic skills and connections to journalists, policymakers, and community leaders, scientists can advance just, equitable solutions that improve the well-being of people and nature. COMPASS has worked with many federal agencies, including EPA, NOAA, USDA, and NASA, to train scientists in science communication, risk communication, leadership development, and community engagement. The Alan Alda Center for Communicating Science works to advance science through education, research, and training in effective and engaging communication. All Alda Center programs and initiatives are designed to empower human connection and build trust. The Alda Center has also worked with numerous federal agencies with an audience centric approach to science communication training. We're excited to share our insights and recommendations from our decades of work with federal scientists.

Recommendations:

Our recommendations are fundamentally about improving the communication of science through the training of scientists, building communities of support, and leadership development. We offer these four recommendations:

1. Invest in science communication training. Like all scientists, federal scientists often need training to communicate effectively with various publics, which they often don't get in the course of their standard education. Well-executed communication training offers the opportunity to practice in a safe space before being in front of their audience. We've seen the demand from the scientists themselves continue to grow for science communication training and leadership development.

Additionally, investing in the development of effective leaders and communicators has a transformative power for individuals and institutions. There is a demonstrated link between communication skills and leadership.

- i. Alumni of COMPASS and the Alda Center programs report increased confidence and competence. Training also helps expand their horizons of what is possible, and we've seen many scientists

shift their approaches to research, public engagement, and career goals in order to have more impact.

- ii. Robust training programs can help build a nucleus of change agents within agencies, and help build the internal networks and relationships to foster a culture that prioritizes building trust, openness and transparency.
- iii. Training puts everyone on equal footing. Scientists of all backgrounds, identities, and levels of positional authority can see themselves as leaders and step into their purpose.

2. Science communication training should be high quality and evidence based. Science communications is a rapidly growing field. Groups like COMPASS and the Alan Alda Center for Communicating Science are established leaders in the field, but there is also a growing community of practitioners (e.g., The Science Communication Trainers Network) who can help agencies design and implement high quality training programs. Our key suggestions for high quality training include:

- i. Create inclusive spaces for learning. All scientists should feel safe and supported in bringing their whole self to the training and their work.
- ii. High quality training is grounded in principles of equity and inclusion, focuses on building trust and relationships across many cultures and identities, and fosters culturally relevant science communication.
- iii. Training programs should be evidence based, drawing from the fields of the science of science communication, boundary spanning between decision making and science, and other applicable research on best practices for adult learning.
- iv. Training should include the opportunity for practice and feedback. For example, COMPASS training programs for federal scientists have included working with former legislative staff members to help to understand the culture and processes of the legislative branch, and the kinds of information they need from scientists to make decisions. Participants practice messaging and receive feedback in real-time.
- v. Prioritize building relationships and communicating trustworthiness. Trust is the foundation of science integrity. Scientists cannot expect their fellow citizens to trust them if they communicate in ways that diminish trustworthiness such as aggressive, dismissive communication, or communication that fails to address audiences' most salient concerns. Training programs can help scientists to avoid these pitfalls and communicate in ways that build trust with communities they serve, particularly in frontline communities and communities of color.

3. Create support systems and incentives for scientists to communicate and engage. Agency scientists face unique circumstances. They have important knowledge and insights to communicate, but may not have the background and training to do so on the front lines. In addition, they often face bureaucratic hurdles in the type and manner in which information can be shared. Communication training should be specialized to these circumstances.

- i. It is not enough just to remove barriers; good communication should be encouraged and rewarded. Leadership can incentivize stronger communication efforts through job performance and promotion or award programs.
- ii. Investments in communication trainings work best when leadership are enthusiastic sponsors, and foster a culture of learning where the communication of science is valued.
- iii. Create the systems and structure for those who have new skills to be put into practice. We know from our experience that scientists need spaces for ongoing practice and reflection in order to continue building their skills. Agency staff focused on communication and policy engagement

(Public Affairs staff, Public Information Officers, etc) should reinforce and support scientists' communication efforts, and foster opportunities for engagement.

- iv. Ensure that there are systems in place to protect scientists whose work puts them at risk of backlash or harassment. Robust support systems and clear policies are especially important where the science is controversial and/or the scientist is from a marginalized identity, as they are more likely to face attacks or harassment.

4. Create opportunities for communities, stakeholders and other key audiences to directly engage in training programs and inform agency scientists about their information needs, their core values and how best to engage with them.

- i. Experts should bring a diverse range of backgrounds, perspectives, and identities into training programs.
- ii. COMPASS has worked with the Environmental Protection Agency on developing a flagship program on risk communication training over the past year. We trained over 125 EPA staff and completed 11 total training sessions. In each training, community leaders, journalists, and policy makers are brought into the training to provide insights and feedback to agency staff participants. This creates the opportunity and space for agency staff to learn directly from these experts and build relationships with key audiences. Experts and participants have both shared the importance of creating space to connect through training, which results in increased positive feelings and mutual respect.
- iii. It is important to ensure the respect, autonomy, and safety of community members and stakeholders who participate in trainings, and to pay people fairly for their time.

Closing

Thank you again for this opportunity to share our thoughts. We welcome the opportunity to be of further service to this important work.

Sincerely,
Dr. Amanda Stanley
Executive Director
COMPASS

Dr. Laura Lindenfeld
Executive Director
The Alda Center Center for Communicating Science



State of Utah

SPENCER J. COX
Governor

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Office of the Governor
Public Lands Policy Coordinating Office

REDGE B. JOHNSON
Executive Director

July 28, 2021

Submitted via electronic mail: ScientificIntegrityRFI@ostp.eop.gov

Dr. Eric Lander
Director
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

Subject: Effectiveness of Federal Scientific Integrity Policies to Enhance Public Trust in Science

Dear Dr. Lander:

The state of Utah (State) appreciates the opportunity to submit comments in response to your Request for Information (RFI) regarding Federal Scientific Integrity Policies. The State thanks the White House Office of Science and Technology (OSTP) for their efforts to enhance the public's trust in science. Utah's State Resource Management Plan emphasizes the importance of utilizing the best available science in making land use decisions.¹ The State strongly supports the multiple use and sustained yield mandate given to federal public land management agencies and hopes this RFI was intended to promote the use of the best available science to meet that obligation.

Local Science Should be Used to Make Local Decisions

The State can identify instances wherein federal land management agencies have disregarded science-backed research regarding endangered species in the name of political

¹ State of Utah Resource Management Plan, at 36, 149, 218, 236.

expediency. One salient example involves the Greater Sage Grouse and Utah's efforts to preserve the species.

Because of the geographical nature of our State, Utah's sage-grouse populations are found in isolated "islands" of habitat, rather than in a contiguous "sea of sagebrush," as sage-grouse habitat has been described in Nevada and Wyoming. Utah has actively and successfully managed this unique population for decades through multiple, state-specific comprehensive sage-grouse management plans, the most recent of which was published in January 2019.

Consistent with these objectives and at the request of then Secretary of the Interior Kenneth Salazar, the State of Utah assembled stakeholder-driven teams in December 2011 to review the local ecology, the factors affecting the viability of the species in each ecoregion, as well as the ongoing and potential human uses of the land. This effort was merged with Utah's successful and ongoing implementation of its sage-grouse management plans. In good faith reliance on the Federal invitation to collaborate on sage-grouse conservation, the State of Utah expended significant time and effort and millions of dollars to revise its existing sage-grouse strategy and develop and adopt a Conservation Plan for Greater Sage-grouse in Utah in 2013 ("Utah Conservation Plan"). The Utah Conservation Plan was based on extensive knowledge attained through years of scientific research and observation of sage-grouse in Utah, with input from Federal agencies and other stakeholders.

Despite these efforts, the Bureau of Land Management ("BLM") and United States Forest Service ("USFS") released proposed plan amendments on May 29, 2015, which rejected the Utah Conservation Plan and adopted a newly developed federal alternative. These nationally mandated provisions, however, failed to support, and actually contradicted the fundamental findings of the best available science regarding conservation of sage-grouse in Utah – the maintenance and creation of useable space for the species. The State of Utah objected to those proposed plan amendments, pointing out multiple instances wherein the amendments failed to account for the best available science in the state. Moreover, then Governor Gary Herbert filed an exhaustive 61-page Consistency Review with the relevant departments, in which he demonstrated that the proposed plan amendments were inconsistent with the Utah Conservation Plan, adopted scientific research that was biased toward outcomes preferred by the Federal government, and rejected the State of Utah's eleven specific Sage-grouse Management Areas that were designed to best address greater sage-grouse conservation within the state. Nevertheless, the BLM and USFS issued Final Federal Plan

Amendments in September 2015, which rejected the Utah Conservation Plan and its associated science.²

A further example of Federal decision making failing to incorporate local scientific knowledge is the history of wildfire suppression on U.S. Forest Service lands in the western United States. The catastrophic wildfires currently ravaging the drought-stricken western U.S. are largely due to a century's worth of fire prevention and suppression, which was recommended by the government-backed National Academy of Science, and intended to protect watersheds and conserve commercial timber.³ The Forest Service's early policy of total fire prevention relied on a limited understanding of the ecological role of fire, and it rejected empirical evidence demonstrating that "light burning", as practiced by ranchers, farmers, timbermen, and Native American Indians, actually improved land conditions.⁴ Rather, a science-as-institution policy based on cafeteria-style data collection resulted in more firefighter deaths and, consequently, more money given to the states by the Federal government to combat fires. The policy incentivized a program that quickly became detrimental to U.S. forests, or to quote Stephen J. Pyne, "[f]ire protection thus became an institution of American affluence".⁵ Even though scientific studies during the past 50 years demonstrate the importance of fire on forest health, changes to fire policy are hampered by the unintended environmental and social consequences of decades of fire prevention and suppression.⁶ Unfortunately, some special interests are bound to seek economic benefit through fund raising, mediation, or litigation if efforts intended to remedy these unintended consequences are implemented.

Examples of Greater Sage-grouse management and wildfire suppression are just two examples of situations where a disregard for local scientific understanding and research has resulted in unhealthy landscape conditions and has had an undeniable effect on the public's trust. The State asks the office of OSTP to emphasize the importance of tailoring local science to local land management decisions. Internal policies at federal land management agencies need to be reformulated to ensure that national or political ambitions do not override genuine scientifically based research and proposals aimed at addressing local needs.

² In 2019, the Trump Administration amended the 2015 Plan to address state-specific sage-grouse management plans. Those 2019 amendments are the subject of ongoing litigation in the District of Idaho, wherein the court enjoined the amendments and reverted back to the 2015 Plan. See *Western Watershed Projects, et al. v. U.S. Dep't of the Interior*, Case No. 1:16-cv-00083-BLW.

³ Stephen J. Pyne, *Flame & Fortune, Forest History Today* (1999). Available at <https://foresthstory.org/wp-content/uploads/2017/01/Pyne.pdf>.

⁴ Forest History Society, *U.S. Forest Service Fire Suppression*. Available at <https://foresthstory.org/research-explore/us-forest-service-history/policy-and-law/fire-u-s-forest-service/u-s-forest-service-fire-suppression/>.

⁵ Id. at 6.

⁶ Id at 6.

Comprehensive Agency Review of Federal Law and Policies

One perceived shortfall in scientific integrity that diminishes public trust in Federal science is the failure of an executive agency to ensure that its bureaus and offices adopt policies that (1) are consistent with the executive agency's scientific integrity policy, and (2) fully comply with codified statutes and regulations. The public should distrust any science-backed Federal policy or program that falls short of either requirement, especially the latter. Reviewing bureau and office-specific policies for consistency with an executive agency's broader scientific integrity policy is a daunting task. However, this task is critical to detecting or deterring potential and existing violations. To illustrate the need for internal consistency and careful review, consider the following example of our Nation's reliance on archaeological science with respect to cultural resource management.

Title 54 USC § 306108, commonly known as Section 106 of the National Historic Preservation Act, requires Federal agencies to consider how their proposed undertakings will affect historic properties, then give the Advisory Council on Historic Preservation an opportunity to comment.⁷ The procedures for complying with the requirement are detailed in 36 CFR § 800.3–800.13, also known as The Section 106 Process.⁸ In short, this process establishes the undertaking, identifies and evaluates historic properties, assesses effects to historic properties, and resolves any adverse effects. Each agency or bureau within an executive agency typically adopts policies and procedures that allow it to comply with these laws while fulfilling its unique directives and goals. Because scientific activities are integral to complying with the Section 106 Process, bureau and office-specific policies must align with the executive agency's policy for scientific integrity.

The lion's share of our Nation's cultural resources consists of prehistoric and historical archaeological artifacts, features, sites, and districts. Archaeological science with its attendant theories and methods is integral to each step of the Section 106 Process, and it must be directed by individuals who possess the requisite knowledge, skills, experience, and integrity. Title 54 USC § 306131(a)(1)(a) "requires each Federal agency responsible for the protection of historic resources, including archaeological resources, to ensure that all actions taken by employees or contractors of the agency shall meet professional standards under regulations developed by the Secretary [of Interior]." Accordingly, the Secretary of Interior has established Professional Qualification Standards (PQS) for archaeology, history, architecture, and historic architecture:

⁷ Effect of undertaking on historic properties. Available at <https://www.govinfo.gov/content/pkg/USCODE-2014-title54/pdf/USCODE-2014-title54-subtitleIII-divsnA-app-dup4-chap3061-subchapI-sec306108.pdf>.

⁸ See Subpart B—The Section 106 Process. Available at <https://www.achp.gov/sites/default/files/regulations/2017-02/regs-rev04.pdf>.

(b) *Archeology*. The minimum professional qualifications in archeology are a graduate degree in archeology, anthropology, or closely related field plus: (1) At least one year of full-time professional experience or equivalent specialized training in archeological research, administration or management; (2) At least four months of supervised field and analytic experience in general North American archeology; and (3) Demonstrated ability to carry research to completion. In addition, to these minimum qualifications, a professional in prehistoric archeology shall have at least one year of full-time professional experience at a supervisory level in the study of archeological resources of the prehistoric period. A professional in historic archeology shall have at least one year of full-time professional experience at a supervisory level in the study of archeological resources of the historic period.⁹

These PQS are indeed the professional qualifications stipulated in 54 USC § 306131(a)(1)(a).¹⁰ It seems reasonable to expect that the executive agency tasked with establishing these PQS, the Department of Interior (DOI), would ensure that its bureaus and offices complied with them to ensure the integrity of science-backed policies related to cultural resources. However, this is not the case with the BLM, which manages more surface land acres and subsurface mineral estate than any other government agency in the U.S.¹¹ Unlike other DOI bureaus and offices, the BLM currently will permit an individual without a graduate degree to function as a principal investigator—the person responsible for designing and executing a science-based research project to meet the compliance requirements of the Section 106 Process.¹² Again, the PQS state that a graduate degree is one of the *minimum* qualifications. BLM’s policy of permitting applicants who do not meet this requirement is clearly inconsistent with law and DOI’s own policy regarding scientific integrity.¹³

⁹ The Secretary of Interior’s Professional Qualification Standards are published at 36 CFR § 61, Appendix A. Available at <https://www.govinfo.gov/content/pkg/CFR-1998-title36-vol1/pdf/CFR-1998-title36-vol1-part61-appA.pdf>.

¹⁰ Through email correspondence with the National Park Service (NPS) in February 2019, then-NPS Chief Archaeologist, Dr. Stanley Bond, confirmed that the PQS are “... the applicable standards and guidelines that must be met for any project that is federally funded, permitted, or takes place on federal or tribal lands. Individuals working on federal projects must meet the Secretary’s Professional Standards.”

¹¹ See *What We Manage*. Available at <https://www.blm.gov/about/what-we-manage/national>.

¹² See § 12B2b(2)(a)(ii) of *BLM Manual 8150—Permitting Uses of Cultural Resources (Public)*. Available at https://www.blm.gov/sites/blm.gov/files/uploads/mediacenter_blmmanual8150.pdf.

¹³ Appendix L of the *Scientific Integrity Procedures Handbook* 305 DM 3 (December 16, 2014) states “[the] credibility and reputation of Department of Interior (DOI) as a science-based agency is directly related to the credibility and reputation of the scientists who work here”, and further that “[a] credible and reputable scientist fulfills particular requirements and expectations” (e.g., laws, regulations). Available at

Members of the public, especially archaeologists whose careers focus on these priceless, non-renewable resources, are right to distrust Federal decisions about cultural resources when the “science” informing these decisions lacks integrity. Scientific activities—research design, sampling, data collection, analysis, and hypothesis testing—are suspect when they are directed by unqualified individuals. With respect to the example cited above, the DOI could conduct a comprehensive review of bureau and office policies to ensure they are consistent with Federal law and the DOI’s own scientific integrity policy. The Task Force on Scientific Integrity may also investigate whether BLM’s decision to deviate from the SQS resulted from improper political interference.¹⁴

Thank you for your consideration of the State’s comments. Please contact us if you have questions or if we can assist in anyway at the number or address below.

Sincerely,

A handwritten signature in black ink, appearing to read 'Redge B. Johnson', with a long horizontal line extending to the right.

Redge B. Johnson
Executive Director

https://www.doi.gov/sites/doi.gov/files/elips/documents/305%20DM%203_%20Handbook%20-%20Scientific%20Integrity%20Procedures.pdf.

¹⁴ See § 2(b)(2) of President Joseph R. Biden’s *Memorandum on Restoring Trust in Government through Scientific Integrity and Evidence-Based Policymaking* (January 27, 2021). Available at <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/>.

From: [Elizabeth Geltman](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Cc:
Subject: [EXTERNAL] SI-FTAC RFI Wednesday,
Date: July 28, 2021 4:53:07 PM

Good day,

This note is written in response to your request for comments pursuant to 86 Fed. Reg. 34064 (June 28, 2021).

U.S. General Services Administration (GSA) began revamping Regulations.gov during the Trump administration and published the new version in February 2021. While improvements, such as a standard comment form make the commenting process easier for the general public, there are a number of changes that severely set back public confidence in both science and the regulatory process.

A major problem is the decision to no longer allow the public to download data from the Regulations.gov site. In the classic site, users could download all documents from a docket in the form of a bulk download and as an organized spreadsheet describing the data. This ability was important for both researchers and for public commenters to gain an understanding of what comments are made and by whom. The ability to download and investigate the data given to various agencies is critical to establishing trust in government. Greater ability to see submitted commenting data allows the public to understand and verify changes in regulation by seeing who urged those changes and why.

GSA should bring back the ability to download in real time (1) bulk download comments and agency documents and (2) spreadsheets describing all comments and documents.

A second problem is changes to the ways users are now allowed to search comments. In the past, users could search within dockets and among all dockets using key terms of the user's choice. Now users can only search by posted date or best match. Users can no longer search for comments with attachments or search for comments by name. Nor can users gain this information by downloading a spreadsheet. The combination of not allowing bulk search, not allowing downloading of a summary spreadsheet of all commentors and changing the search mechanism creates a website that is now extremely opaque.

GSA should also change the search mechanism back so that users have greater flexibility in searching.

Modernizing Regulations.gov is a great idea. Requiring all comments (including comments sought by the White House such as this) to be submitted on Regulations.gov as a centralized, standardized site is an even better idea. It is important, however, that the new site create greater transparency rather than increasing opacity. Please remove the new restrictions so that researchers and commenters can resume use of the site in manners that best serve democracy.

Thank you for allowing me to comment. I look forward to presenting my ideas further during the listening sessions on July 29 and July 30, 2021. Please contact me with questions.

Best,
Elizabeth Geltman

Elizabeth Geltman
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Director, Atlantic Emerging Technologies & Industrial Hygiene Training Center (NIH R25ES027082)
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American Economic Association

Office of the Data Editor, Email: dataeditor@aea-pubs.org

SI-FTAC Response to “*Request for Information To Improve Federal Scientific Integrity Policies*”

Dear Members of the Scientific Integrity Task Force,

My name is Lars Vilhuber, Executive Director of the Labor Dynamics Institute at Cornell University. I am an academic researcher, and I hold positions in various professional societies that relate to the topic you are tasked with. I am a member of the public and a taxpayer.

I am the inaugural and current Data Editor at the American Economic Association, and it is this role that I am responding to your [Request for Information To Improve Federal Scientific Integrity Policies](#), issued on 2021-06-28.

In my role as Data Editor, I am tasked with the job of assessing and ensuring the integrity of the empirical and numerical results published in the AEA's eight journals. Most of the time, this entails ensuring that data is as broadly accessible as possible, because that is the simplest way in ensuring that many researchers can trust the results published in scientific articles. However, we also conduct active checks on the computational reproducibility of the code provided by authors, which requires that we, or a trusted third party, has active, short-term access to data, including data that is subject to legal or procedural access restrictions. In the past two years, my team and I have assessed over 1,000 articles that were conditionally accepted in the AEA's journals. I thus have an acute understanding of the many challenges that accessing data and computing resources for the purpose of integrity checks pose.

I am also the current Chair of the American Statistical Association's Committee on Privacy and Confidentiality, which is tasked with informing the ASA's membership of developments in the field of protecting the privacy and confidentiality of respondents in surveys and administrative data. One could argue that our job there is to make sure that our membership is aware of the tradeoff between privacy and access. In my response, I speak for neither the ASA nor for the committee, but draw on my experiences in that role.

As one of the editors and member of the governing board of the Journal of Privacy and Confidentiality, I have encouraged an informed but scientific discussion of the issues surrounding privacy protection, and of the latest technological and legal developments in that field. As such, I am quite aware of many of the tricky issues surrounding privacy and access. In my response, I do not speak for the journal's editorial or governing board, but draw on my experiences in that role.

I am also chair of the scientific advisory committee of the French research data access system, and on the board of the Canadian research data center network, both organizations tasked with the difficult job of providing secure but broad access to confidential data. My opinions here do not engage or constitute a position undertaken by these foreign institutions, but I draw on my experiences observing how other countries handle issues of data access, privacy, and integrity.

Finally, in the early 2000s, I was a leading member of the team that implemented the statistical data production and publication system underlying even today the Census Bureau's Quarterly Workforce Indicators. As such, I was acutely aware of the many challenges, but also opportunities, when attempting to make detailed and confidential data on the US workers available to the broadest possible audience, while ensuring transparency, traceability, and integrity of the statistical production process. I am not currently a member of that team, and I most definitely do not speak for the U.S. Census Bureau in any capacity.

(1) The effectiveness of Federal scientific integrity policies and needed areas of improvement; (2) good practices Federal agencies could adopt to improve scientific integrity (3) other topics or concerns that Federal scientific integrity policies should address.

In the following, and in response to your request for information, I will highlight a few issues that should merit your attention.

1. Several federal statistical agencies have policies on scientific integrity, which are well laid out. They are not, however, universally adopted. I would encourage your taskforce to ensure that every **federal statistical agency adopt and publish explicit policies on scientific integrity**.
2. Policies define possible actions and activities, which need to be performed by federal staff. **These activities need to be funded**. Adherence to policies by federal staff is improved by making compliance with policies a part of job evaluations, and by providing staff with the resources (time, funds) and training to understand and support such policies.

3. **Predictability of access times** when data are not freely downloadable. When there are unavoidable application procedures, the process should be as transparent and predictable as possible. Public statements of processing times, public statistics on compliance with those processing times should be available. Importantly, such application procedures also must be suitably funded, so that compliance with stated deadlines is actionable, not wishful thinking.
4. **Simplification and standardization of access procedures, nomenclature, and legal basis across the federal government**, for instance by implementing streamlined and simplified application procedures when those are necessary (trusted researchers, enhanced legal foundations and mandates of access). The federal statistical system has a bewildering array of access procedures, ranging from click-through licenses, to legal agreements that need to be signed by requestor's organizations, to security clearances necessary to access highly secure facilities. At the AEA, we regularly investigate and test the procedures, to ensure that others, not just the original authors of a manuscript, can reasonably access the data. The terminology and legal framework differs across even similar agencies - "special sworn status" at the Census Bureau is broadly similar to "designated agent" at the Bureau of Labor Statistics, but not identical. This creates a steep learning curve for anybody wishing to navigate the system. Even simple contractual transactions for data access involve many individuals, many rounds of correspondence. Scaled up to 100s of researchers, these varied and incompatible processes cost researchers and the U.S. government a lot of money, and create friction in the efficient use of data, even when guaranteeing the security of the data. While work on a single access portal for the National Secure Data Service is underway, simplification of terminology for other data files that are available outside of that framework should also be considered.
5. **Streamlined researcher certification**: In certain other countries, individuals can be pre-vetted for access. "Accredited researchers" are uniformly vetted in the UK, and listed on [public pages](#), regardless of access environment or project. In Canada, expedited access for experienced researchers - those with certain affiliations and prior experience on secure data access - is being considered. Pilot projects in the United States on university-managed "[researcher passports](#)" have not found the traction they deserve, maybe because this needs to be a task centralized with the federal government.
6. **Streamlined approval for reproducibility-related access**. At the AEA, when assessing the computational reproducibility of research conditionally accepted for publication, we often run into the problem of timely access to confidential data. In general, we have two options: we can request access to the data ourselves, or we can ask others to conduct such reproducibility assessments. In order to request access to the data ourselves, we almost always have to initiate access

requests that are completely disconnected from the authors' original request. Yet we attempt to do no more - by design - than the original authors aimed to do, and we do not intend to publish any new results, only verify existing results. It would be extremely helpful if a **streamlined access for a reproducibility team** were feasible - and it would save the federal government time and money. Every reproducibility attempt accesses data under the exact same justification that was previously authorized, and generates no new publications. A simple reference to the previously approved access request should suffice, in combination with any personal assurances that are legally required. At the AEA, we are trialling such streamlined access procedures for German secure data access and with certain commercial providers of proprietary data. We have had no success with the federal statistical system.

7. The second path to obtain assurances that researcher results are computationally reproducible is to request support from the federal agencies that control access to the data, i.e., ask them to run code, or to otherwise verify that the code provided by authors has successfully been used to generate the result. The former option - a staff member runs the code - requires that staff dedicate some time to such a task - akin to providing a referee report when a journal editor asks for input. However, in almost all cases where we have asked federal agency's leadership for such support, we have heard that there is funding to support use of staff time, since it "is not in the mandate of the agency." **Providing both funding, and a mandate, for reproducibility checks by agency staff should be encouraged.** I note that such activities don't just generate costs for agencies - they also provide benefits to agencies. Agencies can become aware of the latest type of analyses being conducted with their data, may learn about new econometric or programming techniques, and can serve as a skill enhancing activity.
8. **Publication of permanent digital identifiers**, using industry standards, that move with the data throughout the archival lifecycle. For instance, data should not change identifiers when moving from an agency to the National Archives. Examples include DOI and Handles, but the federal government is large enough that the application of a US government identifier system would be sufficient if universally applied. Such identifiers should be assigned at the earliest possible opportunity, not just upon publication of the data. Identifiers should be assigned to all relevant objects, including especially those accessible only through application procedures of varying degrees. This is already being done by German and French systems of secure data access, see for instance the confidential "Linked Personnel Panel" in Germany (assigned the DOI [10.5164/IAB.LPP1617.de.en.v1](https://doi.org/10.5164/IAB.LPP1617.de.en.v1)), or the "Panel tous salariés", the French equivalent of the Census Bureau's Longitudinal Employer Household Panel

(assigned the DOI [10.34724/CASD.85.1177.V1](#) for the 2017 cross-section, and similar DOIs for all prior years).

9. Scientific integrity is supported by verifiability, and traceability. For the publications of the AEA, we assess the provenance of data back to their source, and then request that authors provide computer code and instructions documenting all subsequent modifications. This should be standard practice for all government publications, whenever they use or convey data - backed up by publicly available code and traceable source data. While any such publications go through an extensive review process, that review process does not leave public artifacts. **Replication packages for government publications** are a good way to start, and are not hard to implement when following best-practices in coding and development. The AEA, for authors publishing in our journals as well as in [collaboration with other journal editors](#), has [compiled guidance](#) that would also be applicable to many other publication types.
10. **Public-use code and specification documents** should be envisioned for all new and revised data products. By following industry-standard secure coding standards, code and specification documents can be written from the outset in a way that does not reveal any unavoidable secret parameters. While this is hard to implement for existing code - millions of lines of code would need to be reviewed - it is quite a bit easier to never let secret parameters enter code as it is created and continuously reviewed. (These are practices we followed when implementing the original QWI codebase, and when defining policies for maintaining the codebase)

I appreciate this opportunity to provide you with these recommendations. I am available and would be happy to brief OSTP, the White House Scientific Integrity Task Force, and OMB on the recommendations, their origins, effectiveness, and their importance to the economics community.

Sincerely,



Lars Vilhuber
Data Editor
American Economic Association

Comments of Richard W. Briggs Ph.D. for SI-FTAC RFI

To Whom It May Concern:

I have been retired from MR physics (imaging and spectroscopy) for 6.5 years. During my career, spanning over 30 years (nearly 40 years including graduate school and postdoctoral work), I experienced only good and informative enforcement of whistleblower education and enforcement at public universities. This included education and enforcement about sexual orientation, science and its conduct specifically and generally, and conflicts of interest.

I have one complaint about non-objective behavior at the VA. The VA Inspector General acted very unprofessionally about 2007 when a contract dealing with Gulf War Illness to UT Southwestern in Dallas was pre-emptively terminated halfway through the funding period. The VA Inspector General did so after interviewing only those from the VA side. The report of the VA Inspector General was filled with lies and half-truths, appearing to be mainly from interviews with a VA person who was almost never prepared and almost never read the contract materials carefully. That to me destroyed what little was left of the VA's scientific credibility.

But it wasn't until the presidency of Donald J. Trump that there were concerted and unrelenting attacks on science and scientific credibility, on all fronts. Never has government in the U.S. been so corrupt, and never has the machinery of science been so adversely affected. Bastions like the NIH and CDC were adversely affected, as were nearly all governmental agencies.

All the recommendations of the UCS white paper "Help The White House Strengthen Federal Scientific Integrity" should be enacted, for starters. This will help science, not politics, govern in areas as diverse and important as clean air and water, climate change, global warming, medicine, the COVID pandemic, and safe communities and democracy, for years to come.

Richard W. Briggs, Ph.D.

Retired MR Physicist (at Penn State's Hershey Medical Center, the University of Florida in Gainesville, UT Southwestern Medical Center in Dallas, and Georgia State University in Atlanta) (did postdocs at Yale University and Oxford University)



July 28, 2021

Dr. Eric S. Lander
Director
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504
Submitted via email to ScientificIntegrityRFI@ostp.eop.gov

Re: 86 FR 34064 – Request for Information to Improve Federal Scientific Integrity Policies

Dear Director Lander,

On behalf of the American Educational Research Association (AERA), thank you for the opportunity to provide feedback to the Request for Information (RFI) to Improve Federal Scientific Integrity Policies.

AERA is the major national scientific association of approximately 25,000 faculty, researchers, graduate students, and other distinguished professionals dedicated to advancing knowledge about education, encouraging scholarly inquiry related to education, and promoting the use of research to improve education and serve the public good. Founded in 1916, AERA as a scientific society has long been committed to building cumulative knowledge, disseminating sound and trustworthy research, and enhancing research transparency. The AERA Code of Ethics addresses broad principles that include integrity, as well as ethical standards on the conduct of research which education researchers are expected to adhere to in their work. These ethical standards include data sharing, conflicts of interest, and accurately reporting on and communicating research results.¹

We appreciate the ongoing efforts of the Biden administration and the White House Office of Science and Technology Policy (OSTP) to ensure that federal agencies adhere to highest standards of scientific integrity. Over the past decade, we have been pleased to see the further development of scientific integrity policies at National Science Foundation and the Institute of Education Sciences (IES) at the U.S. the Department of Education, and the progress made to implement the Foundations for Evidence-based

¹ AERA Code of Ethics: American Educational Research Association Approved by the AERA Council February 2011. (2011). Educational Researcher, 40(3), 145–156.
<https://doi.org/10.3102/0013189X11410403>

Policymaking Act (Evidence Act). The Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking is an important next step in protecting federal research and statistical collections from political interference, as well as advance practices to ensure that data and publications resulting from federal funding are made available.

Integrity in research is essential to ensuring public trust in the data and scientific findings that are produced by federal agencies and from federally-funded researchers. The previous administration, in suppressing releases of data, banning the use of specific language in scientific findings produced by federal agencies, making appointments to scientific advisory boards of persons with political viewpoints rather than essential scientific expertise, and limiting participation in the research enterprise, sowed public distrust in science. Federal agencies also have a responsibility to be attentive to integrity in terms of openness to diverse methodologies and interdisciplinary collaborations that could otherwise be dismissed or ignored. We appreciate OSTP's actions to ensure that scientific integrity policies are in place and adhered to in the conduct of research and statistical collections done by or funded through federal agencies. Our comments that follow speak to specific issues raised in the RFI.

Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information:

We have appreciated that NSF and the Institute of Education Sciences (IES) have developed policies for making publications and data available resulting from grants. In addition, both agencies have also required the submission of a data management plan in grant applications that highlight how researchers will make data available, particularly through trusted repositories. We encourage additional interagency efforts to provide resources and professional development for federally-funded researchers to share relevant data at the time of publication, to preserve and share the full study data at a specified time after the completion of a project, to invest in replication studies, and to submit registered reports to journals considering them or to pre-register research findings for enhanced research transparency, reproducibility, and replication. We also encourage consideration of providing resources to scientific publishers or to awardees to help accelerate the process of making accessible more quickly scientific content.

We acknowledge limitations in communicating research outputs, including determining appropriate ways to measure and value these scientific contributions, particularly in the cases of building multiuser data bases or sharing data and details on instrumentation and code. A second limitation is how to communicate the science residing in publications and data in ways meaningful and accessible to the public that our sciences serve. With NSF support, AERA has underway an initiative in collaboration with the Council of Graduate Schools on *Examining Impact and Fostering Academic Support for Open Science and Scholarly Products* that should be useful on these issues.

We also acknowledge and express concerns about previous attempts to limit the participation of federal scientists in scientific conferences or in the activities of scientific

societies. On this last point, we urge OSTP to provide guidance that maximizes the flexibility for federal scientists to present their own research, engage in collaborative activities, and receive professional development to continue building their methodological skills. Such participation helps to advance the scientific enterprise and the role of the federal workforce and can be done cognizant of conflict of interest guidance and high standards of research integrity.

Federal agencies should also encourage making accessible null or negative research findings, as they are important for science. In all fields of science, including in education research, null and negative findings can inform future studies of programs and can speak to potential issues in fidelity when implementing a promising program in different or expanded settings.

Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce:

Regarding equity in the scientific workforce, we applaud the administration for overturning the Executive Order on Combating Race and Sex Stereotyping. In producing this Executive Order, the previous administration failed to take into account evidence showing the benefits of exposure to diverse perspectives. We also applaud the administration to taking an evidence-based approach to developing the federal scientific workforce.

We have seen several promising initiatives supported by federal agencies; we point to a couple of examples that can inform the development of the federal scientific workforce. The NSF INCLUDES initiative has grown to include alliances and a national coordination hub to create shared measures, develop resources that highlight evidence-based practices to increase STEM engagement for underrepresented populations, and to scale programs that have shown success to increase STEM engagement, access, and persistence. In addition, the [Pathways to the Education Science Research Training](#) program at IES provides grants for Minority Serving Institutions to provide students in undergraduate and master's degree programs education research experiences and mentorship

In addition to ensuring the independence and autonomy of the scientific integrity officials and chief science officers, we would also encourage OSTP to incorporate the Office of Management and Budget (OMB) statistical policies to ensure the independence of statistical activities that take place within federal agencies. As agencies continue to implement the Evidence Act, the independence of statistical officials and evaluation officials will be especially important in evaluating programs with sound data in the course of evidence-building activities.

Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices:

Federal agencies, institutions, and other stakeholders need to continue, if not expand, collaboration for data sharing through promoting best practices for scientific integrity in training and workshops and developing infrastructure. Several federal agencies have contributed, for example, to the development of the Inter-university Consortium for Political and Social Research (ICPSR) and the work it has accomplished progressively as a repository since 1962 to provide quality data, access (in public use and restricted data form), and training. Most recently, IES has provided grant support for the Registry of Efficacy and Effectiveness Studies in a partnership between the Society for Research on Educational Effectiveness and ICPSR. NSF has also supported workshops to explore and implement best practices on research transparency and research ethics.

We also encourage federal agencies to expand their efforts for developing resources for research grantees to engage in open science practices. We have been pleased to see the development of policies around data management plans for grant applications to the Institute of Education Sciences (IES) and NSF in the Standards for Excellence in Education Research (SEER) by IES. In incorporating the SEER principles in grant applications, IES has supported the development of resources and tools to guide IES grantees meet requirements to inform cost analysis, pre-registration, and open data.

Other important aspects of scientific integrity and effective approaches to improving trust in Federal science:

We wish to highlight two topics that we urge OSTP to prioritize:

1. Continuing work on to expand upon the 2013 memorandum on Increasing Access to the Results of Federally Funded Scientific Research

AERA provided input on several RFIs that OSTP advanced in 2020 to build upon the 2013 memorandum related to the public access of federally-funded research. We wish to echo previous comments here to ensure the availability of scientific publications resulting from federal grants and potential collaboration with publishers and scientific associations that publish research. There are options that publishers and scientific societies offer to have published articles available prior to the 12-month timeframe that also provide financial resources to scientific societies. As one example, AERA has long offered the option for authors to pay an article processing charge in order to provide ungated access to authors. AERA provides toll-free links for journalists and science writers covering education research.

We also encourage OSTP to continue building on ongoing efforts to ensure that data that inform findings from federally-funded research are made available for the purposes of further analyses, reproducibility studies, and replication research. Some individual agency efforts include supplemental guidance from the National Institutes of Health (NIH) to including allowable costs for data management and sharing and the allocation of resources to cover article-publishing costs related to data and code. IES also has noted specific guidelines in its Requests for Applications that highlight necessary elements of a data element plan. We urge OSTP to encourage agencies to support

reasonable costs for access to data sets and code from federally funded research and to encourage data sharing as part of scientific integrity policies.

2. Appointments to the National Board for Education Sciences (NBES) in response to the consideration of scientific advisory boards

As the advisory board for IES, members of the NBES provide essential stakeholder input on IES activities, including approval of the agency priorities and an annual report to Congress. NBES has not held a meeting since November 2016 due to a lack of a quorum of members. IES Director Mark Schneider released proposed priorities available for public comment in 2019, and they have not been formally approved by NBES as required under the Education Sciences Reform Act. A full NBES roster that includes experts with significant contributions in education research and users of education research and evidence-based products would provide key stakeholder feedback to IES and help preserve the integrity of the agency's work. AERA can serve as a resource to OSTP and the White House in providing potential appointees.

We appreciate the opportunity to provide input to OSTP in restoring trust in science and data produced by federal agencies. Please do not hesitate to call on AERA if you have any questions or if we can be helpful.

Sincerely,

A handwritten signature in black ink, appearing to read 'Felice J. Levine'.

Felice J. Levine, PhD
Executive Director

From: [Julian Herszage](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Julian Herszage's public comment for SI-FTAC RFI).
Date: Wednesday, July 28, 2021 4:58:34 PM

I am writing to you today to contribute with a public comment to the report on scientific integrity.

As a scientist, I know the value of science in making public policy decisions.

Sound decisions require strong safeguards for scientific to integrate to avoid biased decisions. The most important topic where sound science is key to make the right decisions, for current and future times, are public health and global warming, which of course are strongly linked to each other.

As a donor to the Union of Concerned Scientists (UCS), I urge you to take in consideration their recommendations to ensure and safeguard scientific integrity.

You can find their recommendations summarized below.

Thank you for your consideration and for seeking public comments on these fundamental issue.

Julian Herszage, PhD

The main scientific integrity concepts that UCS outlined are here:

As the Office of Science and Technology Policy works to improve federal scientific integrity and promote public trust in science-based decisions, we urge the federal government to:

- * Strengthen communication and publication policies, so that all scientists can openly share their discoveries and we, the public, can be active participants;
- * Prevent political interference in science and preserve scientific independence, so that scientists can do their work without being unethically influenced by political interests or conflicts of interest;
- * Train, protect, and empower federal employees, so that all civil servants can do their jobs, report wrongdoings if needed, and remain safe from retaliation;
- * Prioritize underserved communities, so that environmental laws are enforced thoroughly and equitably and communities can play active roles in research and decisionmaking; and
- * Invest in a robust, diverse federal scientific workforce, so that our nation's scientists represent and are invested in our diverse nation.

July 28, 2021

Office of Science and Technology Policy
Eric Lander, Director and Alondra Nelson, Deputy Director
Eisenhower Executive Office Building
725 17th Street NW
Washington, DC 20503

Dear Director Lander and Deputy Director Nelson:

I am writing in response to the request for information to improve federal scientific integrity policies both generally and specifically regarding "addressing emerging technologies and evolving scientific practices."

I am not a scientific expert, but I have worked for ten years in noise activism attempting to bring change to policies - I should say non-policies - that allow automakers to introduce sounds into the environment, the soundscape, public spaces, that are inappropriate, loud, and discordant, and that disrupt sleep and confuse nearby drivers and cyclists. Originally this was somewhat limited to use of horn honking sounds to indicate to car owners that their cars were locked. Currently that feature has grown to include other scenarios. Additionally, some automakers such as Tesla are using the outside speaker intended for AVAS sounds to broadcast sounds that are inappropriate and are used by drivers as a joke, seemingly to get a laugh out of confusing pedestrians with the sounds of bodily functions.

Individuals and even non-profit noise activist groups have no recourse, as no one within Congress or NHTSA or SAE will engage with us on this issue. When I wrote to EPA about it, Gina McCarthy wrote back saying that it should be addressed locally. But local law enforcement and elected leaders have no power to influence decisions related to automotive design.

I serve on several committees with people who are involved with addressing similar forms of noise pollution. Noise is not a nuisance or merely an annoyance. Noise disrupts sleep and affects hearing and non-hearing health. Some forms of noise are especially harmful to vulnerable groups who are even less likely to complain. Because noise is not taken seriously enough as a health hazard, "noise complaints" are often the only way to address the problem.

I would be happy to meet however briefly with a member of your legislative staff, and my committee colleagues would be happy to do so as well, whether by Zoom or another remote platform, or in person in Washington, DC.

Thank you for your consideration.

Respectfully,



Jeanine Botta, MPH
Co-founder, Committee on Noise and Health, Environment Section, American Public Health Association
Member, Acoustical Society of America

Frederick Duhring, Professional Engineer, Seattle, WA 98119

Recommendations To Improve Federal Scientific Integrity Policies

7/28/2021

Dear OSTP:

Thank you for the opportunity to write. I am a professional engineer and the owner of a mechanical engineering business in the State of Washington. I have responded to prompts 1, 2, 3 and 4 of the RFI.

1. On the effectiveness of federal scientific integrity policies in promoting trust in federal science.

Policy should be established, where lacking, to give scientific integrity officials the power to investigate political interference coming from an agency's leadership or outside an agency.

Policy should require scientific integrity officials to report to an agency's highest-ranking civil servant and work with OSTP on cross-government issues such as open-data initiatives, the implementation of scientific integrity policies, and strategies to investigate and resolve alleged scientific integrity violations.

When a violation of scientific integrity allegedly is committed by agency leadership or outside of the agency, scientific integrity officials should be able to inform and work with the inspector general in the investigation of such interference.

2. On effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information:

Policies should be easily accessible to members of the public on the agency website.

Policies should contain significant, explicit language calling for open communications between agency employees and the public, including through social media.

Policies should clarify that only scientists and subject-matter experts may edit the scientific content of agency communications.

Policies should declare the right of scientists to publicly express their personal views without seeking prior permission, provided it is clear that they are not speaking on behalf of the agency and that they are not using agency time to express these views.

Policies should declare the right of scientists to maintain accuracy as the final reviewers of content—e.g., press releases, blogs, and social media postings—that will be released publicly in their names or that significantly relies on their work.

Policies should ensure that scientists may speak with media without prior approval and may receive and respond to media requests directly, without being routed through a public affairs office.

Agencies should create well-defined, consistent, and transparent clearance procedures for scientific publications, presentations, and conference participations.

For official work, agencies should specify reasonable time limits for reviewing and clearing scientific publications, presentations, and participation in scientific conferences, after which time scientists are free to move forward regardless of whether a review has occurred.

For non-official work (peer-reviewed publications or conference presentations that do not rely on non-public agency data, for example), scientists should be able to assume written clearance from supervisors and other

reviewing officials (i.e., a scientist may move forward with their non-official work) on the condition that scientists make specified changes no later than 30 days after submission.

Agencies should declare that no internal review is required for scientific work done on employees' personal time and that does not use nonpublic government data or resources.

Agencies should declare the right of scientists to review official agency content that will be released publicly in their names or that significantly relies on their work.

Agencies should establish policies that aim to increase the transparency of rulemaking processes.

Agencies should require that, during the notice-and-comment phase of rulemaking, public commenters who include scientific or technical research disclose their funding sources and sponsoring organizations.

Agencies should preemptively publish records of all research, sources, and correspondences—including meetings and phone calls—used to inform rule-drafting.

Agencies should ensure that redlined versions of rules, which document edits and changes that OIRA makes during the rulemaking process, are accessible to the public when a rule is published on regulations.gov, as required by Executive Order 12866, Section 6(a)(3)(E)(iii).

Agencies should enhance digital accessibility in the federal rulemaking process.

Agencies should ensure that the following are available in clear, plain language: proposed rules in all stages of the rulemaking process; instructions and explanations of the public's various venues of participation; and suggestions for commenters to effectively share experiences, offer value statements, and learn more about an issue.

The homepage of each agency website should provide a one-stop point of access for all proposed rules open for comment, including links to other important websites such as the Federal Register and regulations.gov.

Processes and requirements for utilizing regulations.gov must be standardized across all agencies, while accommodating agencies' varying needs.

3. On effective policies and practices federal agencies could adopt to address scientific issues and the scientific workforce.

Invest in a robust federal workforce that is diverse in expertise, experience, race, ethnicity, gender identity, and sexual orientation.

Agencies should bolster scientific career opportunities, including on scientific advisory committees, so that these positions are accessible to experts from diverse backgrounds—particularly those that have historically been underrepresented in federal science.

Agencies should revamp recruiting strategies to attract strong candidates by establishing relationships with universities, community-based organizations, and the private sector.

Agencies should expand relationships with Historically Black Colleges and Universities; Latino-serving institutions; Tribal colleges and universities; Asian American, Native Hawaiian, and other Pacific Islander institutions; and other schools and groups that graduate or support underrepresented candidates.

Enhance accountability regarding interactions between scientists and political officials.

Agencies should publish a policy outlining measures to ensure that political officials do not inappropriately influence the work of scientists and other experts at agencies, and that agencies will hold officials accountable to these policies.

Agencies should identify individuals who are permitted to communicate with scientists and experts during the technical and scientific stages of regulatory development.

Agencies should formalize a process to log all phone calls and meetings (both in-person or virtual contacts) between political officials (both at the agency and White House) and agency scientists and experts.

Ensure that science-based rulemaking is transparent and protected from interference.

Agencies should make redlined versions of agency rules, documenting edits during the rulemaking process, accessible to the public at the time rules are published on regulations.gov

Agencies should preemptively publish records of all research, sources, and correspondences by the agency to inform the rule-drafting phase for any science-based regulatory proposals.

Agencies should avoid applying deliberative process protections in the rule-drafting stages.

Prevent conflicts of interests in science-informed decisionmaking.

Agencies should explicitly define conflicts of interest and establish guidelines about which conflicts would disqualify individuals from participating in committees, panels, and other activities.

Agencies should require that scientific leadership positions be filled by individuals with specialized training or experience relevant to the positions for which they are nominated.

Agencies should publicly disclose conflicts of interests and recusal statements of all political officials in a timely manner, with clear, specific timelines and deadlines for these disclosures.

Create policies that ensure political officials cannot impede the collection or access to federally funded data.

Agency policies should ensure that agency scientists who request data for official work receive these data in a timely manner, as long as the requests do not violate existing regulations.

Agency policies should require that the agency gives notice before removing datasets from public websites, and that the agency makes the best effort to keep the data publicly available.

Agency policies should ensure that the public has access to unclassified, federally funded data in a timely manner and with appropriate context to enhance public understanding.

Agency policies should create enforcement mechanisms, including meaningful penalties for noncompliance, to ensure that agency personnel comply with the aforementioned policies.

Prevent the politicization of research funding, to ensure that grant processes are independent and based on scientific merit.

Agencies should commit to rigorous, independent reviews by in-field experts of scientific proposals for federal grants and funding.

Agencies should require peer-reviewers to recuse themselves from review if they have a direct conflict of interest, per the conflicts-of-interest guidelines laid out in these recommendations.

Agencies should declare that political appointees may express opinions on grant solicitations, but only qualified career staff may review and decide on the scientific merit of grant proposals.

Agencies should establish mechanisms to ensure that, once grant funding has been awarded and distributed, political officials cannot rescind, reallocate, or limit use of that funding, nor can political officials at any agency move to delay use of funding for political reasons.

Create rigorous peer-review policies that protect federal science from political interference. These policies should detail the agency's commitment to, and processes to ensure, transparent and independent peer review beyond the Office of Management and Budget's (OMB) 2004 "Final Information Quality Bulletin for Peer Review." They should clarify that, when feasible and appropriate, an agency's official scientific research should undergo independent peer review, with at least one reviewer external to the agency and all peer reviewers technically qualified and selected based on expertise. They should ensure that scientific research that has already been appropriately peer-reviewed is not subject to politically motivated delays in the publication process. They should require that all personnel involved in a peer review—including reviewers, agency contractors, and administrative staff—disclose financial ties to institutions potentially affected by the review. Finally, they should require that peer reviewers' comments on documents that rely on science and agencies' responses to those comments be publicly available, while protecting the anonymity of reviewers.

4. On effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices:

I would recommend that the scientists within the leadership and supervisory levels of any federal scientific body be bound by a code of ethics. The fundamental canons of such code would be something like this:

All scientists in the leadership and supervisory ranks of federal scientific bodies shall:

- (1) Hold paramount the safety, health, and welfare of the public,
- (2) Issue public statements only in an objective and truthful manner,
- (3) Disclose all known or potential conflicts of interest that could influence or appear to influence their judgment or the quality of their services.
- (4) Avoid deceptive acts, and
- (5) Conduct themselves honorably, responsibly, ethically, and lawfully.

The actual code of ethics could expand on the above, and each federal scientist in the leadership and supervisory ranks should receive training and testing on it, and be bound by its provisions. Several professional organizations have developed codes of ethics, and one or more of these might be helpful in developing a code of ethics suitable for federal scientists. I would be willing to assist in drafting such a code if asked.

Once a code of ethics in place, its existence should be publicly advertised, and a copy made readily accessible to any citizen.

Sincerely,

Frederick Duhring

We are submitting the below suggestions as members of the Build-a-Cell, synthetic cell engineering community currently funded as NSF Research Coordination Network.

The below responses are informed by our experience of coordinating an international research network of 78 labs across 14 countries. The views expressed in this response are not representing every Build-a-Cell member. This document was prepared by Kate Adamala and Carlise Sorenson.

Contact info to authors: soren776@umn.edu and kadamala@umn.edu.

2. Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information.

How can Federal agencies (e.g., NIH, NSF, DoD, DOE) better communicate the value and impact of science and technology (and, more specifically, engineering biology and biotechnology) to the general public?

Scientific discoveries and technologies have a wide range of global impacts. The global Build-a-Cell community exemplifies the range of support and interest. There are several prominent reasons to ensure that communities far and wide are included in scientific discussion. The first of which is to not be left in the dark. When communities are engaged in scientific progress, they have a voice to communicate specific values, concerns, and priorities. Open discussion of this sort increases trust in new technologies.

Understanding new science and anticipating technology shifts also allows communities to build science into infrastructure and the economy. Not only does this provide a springboard for new technologies to yield greater social impact, but communities can better compete with developing economic sectors and adapt to changes.

Despite the importance of improved communication, it's often a difficult task. Large federal agencies can improve communication strategies by supporting more local science communication. A smaller more targeted audience allows communicators to address much more specific cultural values and concerns that are overlooked or lumped together when done at the federal level. For example, on a national level bioengineering is valued for competitive technologies, biosecurity, etc. On a small local level topics such as improved healthcare or environmental protection may hold greater weight and understanding as they connect more specifically with community values. Furthermore, connecting with a trusted community leader before initiating communication efforts helps give trusted support to any such initiatives.

Science is currently suffering from a lack of public trust that is largely based on understanding. It is therefore crucial to minimize any barriers to understanding such as jargon, over-complicated data, and scientific elitism. Jargon, scientific terminology that is difficult for non-scientists to understand, alienates audiences and breeds distrust. Translating jargon improves

accessibility, increases understanding, and thus helps build trust in the scientific community. Overly-complicated data or poor data visualization equally alienates audiences. Minimizing barriers to understanding such as these will help reduce the sense of scientific elitism that holds general audiences from engaging with new science.

How do we use our programs and products, such as Build-a-Cell roadmap and white papers, to communicate technical advancements and impacts of engineering biology? How are Build-a-Cell commitments and initiatives intended to improve communication of science and technology in ways that could be adopted to improve communication efforts by Federal agencies?

The Build-a-Cell model highlights open communication between research groups as well as with the public. We have developed tools such as a roadmap, mission statement, and white papers to increase transparency and understanding. These papers function in two parts: first, as a device to facilitate impactful internal communication and second, as a method of transparent communication with the public.

The roadmap and mission statement were written with input from many group partners to provide a common understanding of long-term goals, priorities, and obstacles. Through the process of discussing these items internally we accrued a broader understanding of our global and local concerns and priorities. Communicating these items internally helps to focus projects and increase collaboration step-by-step towards long term goals.

Detailed mission statements and roadmaps are also a tool to encourage public understanding and trust. They detail long-term goals, the reason/impact of these goals, specific action steps, timelines, and anticipated roadblocks. This level of transparency from a scientific organization or initiative allows the public to better understand the importance of achieving long-term goals and allow the public to meaningfully engage in discussions and trajectory.

Frequent publication of white papers serves as a method of accountability. Publications demonstrate the progress made towards long-term goals and provides further discussion on the impact of stepping-stone goals along the way. This also serves to maintain public interest and allow for more insightful discussion of scientific trajectory. As new information is discovered there may be a need to re-address long-term goals.

3. Effective policies and practices Federal agencies could adopt to address scientific issues (e.g., scientific misconduct, equitable delivery of the Federal programs, gaps in current scientific integrity policies related to emerging technologies) and the scientific workforce.

We propose to use examples of Build-a-Cell efforts like the safety and security working group, and biosafety workshops we run, as well as white and peer reviewed papers we are preparing, to support developing a general model of accountability and improve participation across all of the scientific community, funders, regulatory experts and the general public.

The global nature of the Build-a-Cell community brings a range of cultures, economy, and policy settings to the discussion table. Several useful tools for facilitating cross cultural discussion and collaboration. For example, the open biosafety workshops allow for fruitful conversations covering all global biosecurity concerns. This in turn helps community members strategically coordinate across policy and region to plan for and/or address key biosecurity concerns.

4. Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices.

We believe that one of the most effective ways to foster accountability and integrity is to ensure full transparency of research results. This could be achieved by **Federal support for open access publishing, and/or providing research journal access through public libraries.**

In the interest of effective paywall-free knowledge transfer among researchers, open-access data repositories are needed. This will not only facilitate transfer of experimental protocols but also sharing of data and blueprints for synthetic cell modules, effectively boosting access of interested students to the field. Moreover, standardization efforts that strive to provide universal norms for the design and assembly of synthetic cell modules and interfaces in a plug-and-play manner will be facilitated.

Specific implementation of such a platform could be arranged inspired by the software development and version control platform GitHub that has experienced community wide acceptance within the computer science field. Importantly, the successful installation of such a strategic open-source platform for synthetic biology would require the commitment and financial support from funding bodies, regulatory agencies and political authorities.

5. Other important aspects of scientific integrity and effective approaches to improving trust in Federal science.

Currently the **Federal regulations do not respond quickly enough to the changing research environment.** To ensure public trust in Federal science, the policy needs to keep up with the concerns arising from state of the art research capacities.

We believe that federal funding for science needs to contains strict safety and security checks. Especially in all aspects of engineering new biological systems, like our work on engineering synthetic cells, it's crucial that regulatory agencies develop regulations and protocols as fast as the research is developing. Ideally, regulations would be in place before certain experimental systems and capabilities become reality.

For example, when the first synthetic cell comes to life, it will be the only organism on Earth not shaped by the checks and balances imposed by evolution over the last 4 billion years. It is our responsibility as researchers in the field to inform the regulatory agencies about the possibilities and implications. We believe it should be responsibility of the Federal government

to respond to the research progress and develop safety regulations (like BNSL classification updates, publishing guidelines or safety protocols for Federally funded research).

Developing robust, Federally coordinated malice analysis and rapid safety regulation response would provide strong base for solving possible public safety concerns.

Importantly, this is an opportunity for the US government and US based research community to take leadership role in setting standards for the safety, security and fostering public trust in research worldwide. If the US government pioneers accountability and safety response to rapidly developing research progress, this model could be adopted by other research communities around the world.

The Build-a-Cell collaboration models international accountability, providing example of how research communities can coordinate across geographical boundaries and lobby our respective governments for regulations and adequate response.



Comments of the Government Accountability Project on the White House Office of Science and Technology Policy's Request for Information to Improve Scientific Integrity Policies

July 28, 2021

The Government Accountability Project respectfully submits these comments in response to the White House Office of Science and Technology Policy's Request for Information to Improve Scientific Integrity Policies.¹

About Government Accountability Project

Government Accountability Project is a nonpartisan 501(c)(3) not-for-profit organization founded in 1977 that serves the public interest by leading the nation and the world in whistleblower protection. Our staff attorneys provide legal representation to whistleblowers in both the public and private sectors, present whistleblowers' verified disclosures to public officials, advocacy groups, and journalists to prompt reform, and advocate for whistleblower protection laws in the United States and internationally. Government Accountability Project has drafted, spearheaded the campaigns to pass, or helped defend all of the federal whistleblower protection laws that exist today.

Government Accountability Project, along with its Climate Science & Policy Watch program and Food Integrity Campaign, has for more than 40 years confronted the government and some of the world's most powerful corporations by working with government employees and contractors of the Environmental Protection Agency, the Department of Energy, the Nuclear Regulatory Commission, the Food and Drug Administration, the Forest Service, the Department of Homeland Security, the Department of Interior, the U.S. Global Change Research Program, and other agencies whose missions depend on accurate data and evidence-based policymaking. Science experts working with Government Accountability Project have exposed such serious concerns as inappropriate censorship of climate science documents intended for Congress and the public; unsafe practices that threatened worker safety and the environment at Hanford, Rocky Flats, and other nuclear weapons sites; and dangerous health risks of pharmaceuticals like Vioxx.

These comments reflect our own thinking about threats to, and how to protect, scientific integrity, as well as insights we've gained through collaboration with other NGOs including the Climate Science Legal Defense Fund (CSLDF), Public Employees for Environmental Responsibility (PEER), the Union of Concerned Scientists (UCS), the Jacobs Institute, March for Science, the Environmental Data and Governance Initiative (EDGI), and others. We generally endorse the policy positions on scientific

¹ Request for Information to Improve Scientific Integrity Policies, White House Office of Science and Technology Policy [hereinafter "Request for Information to Improve Scientific Integrity Policies"], June 28, 2021, 86 Fed. Reg. 34064, <https://www.federalregister.gov/documents/2021/06/28/2021-13640/request-for-information-to-improve-federal-scientific-integrity-policies>.

integrity put forth by these organizations,² including comments submitted by these groups in response to this RFI.

We have recently partnered with the Climate Science Legal Defense Fund (CSLDF) in an endeavor to gather direct information, securely and confidentially, from federal employees who have experienced and/or observed scientific integrity violations in the workplace. Together we are encouraging government scientists via a [secure webpage](#) to share their detailed stories as part of our Scientific Integrity Reporting Project and are broadcasting the project through social media and other means, such as our joint July 13 [opinion piece](#) in *Scientific American*. We intend to share insights gleaned from this project with public policymakers in the Executive Branch and in the US Congress.

Our Expertise and Experience Base Comes Largely from Our Clients

Many of our clients, past and present, are government scientists who have suffered retaliatory measures in the federal workplace simply for defending science and scientific integrity against nefarious political interference and ideologically based attacks. Such clients have included, for example, James Hansen (NASA), David Graham (FDA), William Sanjour (EPA), and Rick Piltz (USGCRP); we have also assisted in whistleblower cases for climate scientists Joel Clement (DOI) and George Luber (CDC). Our comments stem largely from our collective experiences with these courageous whistleblowers in the scientific community and the issues and problems they have identified.

We've learned first-hand of some of the devastating consequences to scientists who suffer both insult and injury: insult when the scientific research they work so hard to conduct and report is distorted, diminished, censored, or suppressed; and injury when they face retaliatory measures such as termination or demotion simply for pushing back, for protecting scientific integrity. Retaliation can be as severe as termination or demotion of the whistleblower, can result in significant financial loss and psychological trauma, and can mar career legacies and professional reputations even for some of our nation's most talented and skillful scientists. We have observed that retaliation occurs regardless of whether the attempts to erode scientific integrity are successful or not. This means that there are instances when dedicated public servants who have had the courage to push back against those who would compromise science and have been successful in defeating attempts to distort, censor, suppress, or otherwise meddle in scientific research and reporting – have been successful in protecting scientific integrity all on their own – are not only unrewarded for doing so but instead are made to suffer punishing workplace circumstances. Alerting an agency's Scientific Integrity Officer of such defeated attempts results in no action taken because scientific integrity was preserved and, technically, no violation of SI policy took place, and the perpetrators are not held to account. Even in cases where the attempted meddling is successful and SI policy violations are reported and pursued, the ultimate negative consequences to the perpetrators are generally too mild to serve as a deterrent to future attacks

² Examples include PEER's May 27, 2010 Memo to OSTP, *Examples of Scientific Integrity Policy Failures –Lessons Unlearned* at URL www.peer.org/wp-content/uploads/2021/05/5_27_21-Memo-to-Scientific-Integrity-Task-Force.pdf; CSLDF's *Model Scientific Integrity Policy for Agencies, Universities, and Other Research Institutions* at URL <https://www.csldf.org/resource/model-scientific-integrity-policy/>; and a report by UCS issued August 25, 2020: *A Roadmap for Science in Decisionmaking* at URL <https://ucsusa.org/resources/roadmap-science-decisionmaking>

on science and scientists. Either outcome is both unfair to and demoralizing for those public servants who have acted with integrity and courage and have provided a valuable public service by acting as the first line of defense in the protection of science against nefarious political interference.

Other Observations and Concerns

We are also troubled by the so-called “chilling effect” on scientists that tends to take hold when an anti-science political environment is marked by sustained attacks on science and scientists. Self-censorship exercised broadly as a protective measure by scientists fearful of speaking out and risking their jobs and livelihoods places a proverbial blanket of silence over the free and open communication of crucial scientific findings to policymakers and the public – and thus erodes evidence-based policymaking so crucial for good governance.

We are also deeply concerned about the so-called “brain drain” that occurred all throughout the last administration when hundreds of career scientists – especially those working in the highly politicized area of climate change – quit their government jobs out of disgust and/or protest. Some did so noisily by notifying the press or otherwise making public their departure and the reasons behind it, but many more left quietly and invisibly to the public. We encourage the OSTP to conduct an analysis that quantifies these departures and assesses the damage done to our nation’s scientific prowess.

Recommendations for Strengthening Government-wide Scientific Integrity Policies

One of the best ways to combat these serious problems and to grow and strengthen the federal workforce engaged in science and technology research and development is to bring about the strengthening of government-wide SI policies.

We can make the following recommendations for improving the overall effectiveness of government-wide Scientific Integrity Policies. To the extent is permitted by law, the President through the OSTP should require that each agency or department’s SI policy, at a minimum:

- Ensures the free and unfettered communication of federal scientists with the media and Congress
 - Prohibits political interference in communication with the public, media, or Congress by making it a punishable SI violation
 - Allows federal scientists to publicly express their professional and personal opinions regarding their scientific expertise as private citizens and making interference in such communications a punishable SI violation
- Ensures clear and transparent reporting mechanisms for observed SI violations and attempted violations
 - All federal employees who experience or observe attempts to interfere in the scientific process or in scientific reporting should be encouraged to make an immediate report to the SI Officer – the rule should be “if you see something, say something”

- OSTP should issue guidelines for agencies to adopt regarding when and how to file complaints regarding SI violations with the Inspector General Office
- In no case should any entity for submitting complaints (such as an agency harassment office) be required to notify the complainant's superior officers when one or more of those superiors are the target of the complaint
- Explicitly acknowledges the essential role of whistleblowing in enforcing SI policies and incorporating the full range of existing whistleblower protections in law
 - According to a 2019 Government Accountability Office report, *Scientific Integrity Policies: Additional Actions Could Strengthen Integrity of Federal Research* at URL <https://www.gao.gov/products/gao-19-265>, each of nine federal agencies selected for examination by GAO were following OSTP's guidance to adopt appropriate whistleblower protections. However, we strongly encourage the OSTP to more closely examine each agency's SI policy to determine the extent to which existing whistleblower protection provisions are acknowledged and incorporated
- Establishes meaningful deterrence by raising the stakes for violating SI policy through the mandatory application of negative consequences for both successful SI violations and attempts at SI violations that are ultimately unsuccessful.
 - OSTP should consider attaching specific means of discipline commensurate with varying levels of SI violations; means of discipline could include mandatory program transfer, temporary suspension, demotion, and employment termination
 - OSTP should consider publishing the identities of SI violators and the nature of the violations (whether successful or attempted and unsuccessful).
- Sets mandatory training requirements for all federal employees regarding scientific integrity; according to the GAO³, not all federal scientists in agencies with science programs receive adequate training and this must be remedied so that training is uniform across all relevant agencies and departments.

SI Policy Provisions for Interagency Science Programs

In addition, the OSTP SI Task Force and Fast-Track Action Committee must take action to address and remedy a serious loophole in federal SI policy: the complete lack of applicable SI policies or provisions for federal interagency science programs. Our recommendations are focused on the interagency science program with which we have the most familiarity: the US Global Change Research Program (USGCRP) as codified by the Global Change Research Act of 1990 and governed by the Subcommittee on Global Change Research within the OSTP apparatus.

³ US Government Accountability Office, 2019: *Scientific Integrity Policies: Additional Actions Could Strengthen Integrity of Federal Research* at URL <https://www.gao.gov/assets/700/698231.pdf>.

- Even though the USGCRP has 13 participating agencies and departments, each with its own SI policy in place, none are applicable to the activities and products of the USGCRP itself. This must be remedied during this administration to protect the body of crucial research and reporting that this interagency program has been conducting for over three decades.
 - The USGCRP produces and publishes a variety of reports that are crucial to our collective understanding of basic scientific findings regarding climate change and the full range of climate change impacts on regions and economic sectors as part of the National Climate Assessments required by the GCRA.
 - Under both the George W. Bush and Donald J. Trump administrations, for example, climate change was highly politicized and federal climate science and scientists fell under sustained attack from the White House. Thus, the USGCRP became a vulnerable target. For example, the first National Climate Assessment published in early 2000 was suppressed by the Bush White House to the extent that federal officials were prohibited from referencing the set of reports or discussing them in meetings. The incentive to tamper with the Fourth National Climate Assessment issued in 2018, so as to diminish or call into question its scientific messaging, was widespread and strong among political appointees under the Trump administration – fortunately, the set of peer-reviewed reports were issued intact. The lack of any applicable set of standards and rules around protecting scientific integrity for the USGCRP and other interagency science programs is an oversight that must be corrected.

Our staff contacts for these comments are Dana Gold, Senior Counsel and Director of Education (DanaG@whistleblower.org) and Anne Polansky, Senior Scientist (AnneP@whistleblower.org) who also serves as our Climate Policy Analyst for our watchdog operation Climate Science and Policy Watch, founded in 2005 by federal climate science whistleblower Rick Piltz, found at URL <https://whistleblower.org/climate-science-watch/>. Thank you for the opportunity to express our views and recommendations regarding this most important and crucial public policy matter.

From: [Pierson, Steve](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Wednesday, July 28, 2021 9:34:17 PM

Hello,

I write to provide comments to improve federal scientific integrity policies on behalf of the American Statistical Association (ASA). The ASA Committee on Professional Ethics oversees the writing of the ASA Ethical Guidelines for Statistical Practice

(<https://www.amstat.org/asa/files/pdfs/EthicalGuidelines.pdf>). In response to the Request for Information To Improve Federal Scientific Integrity Policies (86 FR 34064), the committee shares these guidelines because of their fundamental relevance to scientific integrity.

The ASA Ethical Guidelines for Statistical Practice are rooted in the principles of respect, fairness, transparency, and accountability. Within the guidelines, topics include the communication of scientific and technological information (RFI Topic 2, Guideline Principles A, B and C), addressing scientific issues and the scientific workforce (RFI topic 3, Guideline Principles E and F), and improving the training of scientific staff (RFI topic 4, Guideline Principles A, F, and H). Key ideas based on the Guidelines that are relevant for policies that are intended to promote scientific integrity include the following:

- The ethical statistical practitioner uses methodology and data that are relevant and appropriate, without favoritism or prejudice, and in a manner intended to produce valid, interpretable, and reproducible results (Principle A).
- The ethical statistical practitioner is candid about any known or suspected limitations, defects, or biases in the data that may impact the integrity or reliability of the statistical analysis. Objective and valid interpretation of the results requires that the underlying analysis recognizes and acknowledges the degree of reliability and integrity of the data (Principle B).
- Ethical statistical practitioners report the limitations of statistical inference and possible sources of error (Principle B).
- Regardless of personal or institutional interests or external pressures, the ethical statistical practitioner does not use statistical practices to mislead any stakeholder (Principle C).

Thank you for your consideration.

Sincerely,

Steve Pierson, Ph.D.

Director of Science Policy

American Statistical Association

Promoting the Practice and Profession of Statistics®



From: [Hill, Terri Delegate](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Thursday, July 29, 2021 12:02:18 AM

1. The effectiveness of Federal scientific integrity policies in promoting trust in Federal science –

Any employment required oath taken or employment contract sign by employees of the federal scientific agencies should explicitly include language as to their responsibility to uphold the values of truth and scientific integrity even in the face of political and other pressure, whether from within or without, to do otherwise.

Official statement and messaging to the public must identify and acknowledge countervailing pressures to shape recommendation and positions: i.e. the eschewing of use of masks in March 2019 should have included statements like “while there is some evidence that wearing of mask, in addition to adoption of physical distancing practices may give added benefit in mitigation of transmission of the Coronavirus, at this time because of questions around the adequacy of our protective equipment supply chains for medical personnel and other front line workers, as well as to the ability to effectively instruct the public on the proper use of mask wearing, and need to avoid giving a false sense of safety that might lessen adherence to distancing and good sanitization practices, mask wear by the public is not recommended at this time.”

And similarly , in 2021 “ we are in part no longer recommending mask wearing by vaccinated people because we think it is important tha there be tangible benefits in allowed behavior for the vaccinated so as to encourage others to get the vaccine, as the desired communal health benefits can/will not be realized otherwise.

Terri L. Hill, M.D.

Delegate – Maryland District 12

From: [Kit Kubitz](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Thursday, July 29, 2021 12:03:38 AM
Attachments:

The 2009 Presidential memorandum and its six principles to guide recommendation for Presidential Action to guarantee scientific integrity dealt with personnel (selection and retention of candidates), rules and procedures, scientific and technical information, public availability of scientific findings, procedures to address compromise of scientific integrity, and whistleblower protections. These areas are also generally reflected in the GAO-19-265 report on Scientific Integrity Policies.

That report also suggested having agencies ensure a culture of scientific integrity, select candidates with subject matter knowledge and integrity, have peer review of data and research, identify and disclose conflicts of interest, have whistleblower protections, and facilitate the free flow of scientific information.

It also recommended that agencies establish principles for conveying scientific and technical information to the public.

In addition to the 2009 principles, and the GAO-19-625 recommendations, the following ideas and principles might also enhance the scientific integrity and trust of federal agencies, commissions, and actions.

1. Have an outside review body for agencies which examines, and critiques or supports major agency decisions or actions. For example, the Advisory Committee on Immunization Practices examines and reviews vaccine recommendations and their benefit, risk, and evidentiary basis after FDA approval of vaccines, whether on an emergency use basis or a full licensing basis.
2. Have agencies explain the detail of their decision-making and scientific conclusions based upon the initial evidence, review of relationships between evidence and logical steps to conclusions, and any uncertainty or variability in the underlying evidence or conclusions. For example the FDA has a structured benefit risk approach to drug or therapy approval, which looks at the issue to be decided, i.e.

the medical need, and the degree to which it requires a significant decision, the evidence of benefit, risk, and uncertainty in the data on each, and the resulting conclusion weighing the need for decision, data on benefit and risk, and result.

For example the recent decision on an Alzheimer's drug by the FDA appears to be based largely on a highly unmet serious medical need, but the uncertainty of data regarding benefits, as well as some risks, was not well communicated.

3. Utilize a validation, verification, and testing approach for agency decisions, which encompasses looking at the decision to be made, the necessary data to be gathered and how the data will be utilized, and then examining the results of decisions, to see whether the actual decisions reflect reality or in some way deviate from scientific truth and evidentiary support. This is an area where an outside agency to review decisions and support or critique agency processes may as indicated in point 1 above, be useful.

4. Have full and simple explanations of how agencies make and made their decisions, what evidence was considered, and how the agency weighed all the evidence. For example the CDC has published 1 or 2 page description of how it made vaccine approval decisions. See How CDC is Making Covid-19 Vaccine Recommendations, updated Mar 3, 2021, which describes the process, FDA approval, ACIP meeting, descriptions of who is receiving vaccine (age, race, ethnicity, underlying medical conditions) and side effects.

Response to:**Request for Information To Improve Federal Scientific Integrity Policies****Name:** Leslie D. McIntosh**Name of Organization:** Ripeta, *a Digital Science Company***Type of Organization:** Other**Other Type of Organization:** Technology Company**Role:** Researcher and Executive Leader***Prepared by:*** Leah Haynes, Mary Uhlmansiek, and Leslie D. McIntosh**Introduction**

Ripeta thanks the Office of Science and Technology Policy (OSTP) for the opportunity to submit comments on improving Federal scientific integrity policies. Ripeta is a company led by a team of researchers and data scientists dedicated to making better science easier. Our tools and technology automatically scan manuscripts for key scientific quality indicators and provide critical feedback to authors, publishers, funding agencies, and institutions on the quality of reported research.

We applaud the work of OSTP and Federal agencies in the development and implementation of policies to promote trust in federally funded science. OSTP has been central in setting policies and practices for Federal agencies to put in place to advance scientific integrity, including the 2013 memo on *Expanding Public Access to the Results of Federally Funded Research*¹ and the 2009 Presidential memo on *Scientific Integrity*². These memos have strengthened federal funding and research integrity policies, ultimately increasing the availability of open data, software, and code. Additionally, the work of OSTP on *Desirable Characteristics of Repositories for Managing and Sharing Data Resulting from Federally Funded Research*³ is critical for ensuring the locations where data is shared are sustainable and reputable.

Especially in light of the novel COVID-19 pandemic, we believe it to be essential to further improve the efficacy and integrity of scientific research by ensuring the scientific reproducibility, availability, and quality of data. As a result, our recommendations center around the topics of the effectiveness of Federal scientific integrity policies in promoting trust in Federal science, effective policies and practices Federal agencies could adopt to improve the *communication* of scientific and technological information, and effective

¹ [Expanding Public Access to the Results of Federally Funded Research](#)

² [Memorandum for the Heads of Executive Departments and Agencies 3-9-09](#)

³ [Request for Public Comment on Draft Desirable Characteristics of Repositories for Managing and Sharing Data Resulting From Federally Funded Research](#)

practices Federal agencies could adopt to improve *training* of scientific staff about scientific integrity and transparency into their scientific integrity practices.

#1 The effectiveness of Federal scientific integrity policies in promoting trust in Federal science:

Promoting trust in science means developing a system that verifies:

- Individuals conducting science;
- Institutions funding science;
- Independent scientific research.

Federal scientific integrity policies must implement mechanisms to monitor science and stakeholders within the scientific ecosystem. While not altogether new, the internet has facilitated the reach of misinformation, disinformation, and fraud. General trust in scientific information will continue to deteriorate without checks in place to establish authority in scientific research and communication.

This authority should be defined by well-informed and trained individuals and institutions that reflect the demographic makeup of this country. We are in need of a deliberate and intentional support system that both fosters and funds a more diverse workforce in which all individuals are able to contribute to the pursuit of better and more trustworthy science.

#2 Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technological information:

Improving scientific communication and technological information recommendations:

- Verify the expertise of scientific researchers and authors;
- Use persistent identifiers;
- Enforce and check data sharing practices (specifically the use of trustworthy repositories).

We believe that a fundamental aspect of improving scientific communication involves developing a system of checks that verifies the validity and integrity of transmitted information. This would include verification of the expertise of scientific researchers and authors of scientific publications as well as verification of their processes. Enacting a system of routine and automated checks on quality indicators for scientific research would improve not only communication of scientific and technological information but also trust in the information itself. This may be facilitated by increased use of persistent identifiers (e.g. ORCIDs, DOIs, RORs, RRIDs) in order to better document and track information throughout the process of scientific research and publication. The use of

registered reports and protocols may also increase trust in the integrity of the research process and methods.

More fundamental than checks such as these, however, is the actual availability of information (e.g., data, code, software, protocols, and materials) necessary to replicate scientific research. Ripeta's analyses have shown significant variability in scientific researchers' data sharing methods.⁴ Researchers share data many different ways including within their papers, upon request, through a repository, or not at all. The ease of accessibility to data thus varies significantly. Many government funders have clearly stated their preference for data to be shared through trustworthy repositories yet this occurs less than 15% of the time in data availability statements. We believe that Federal agencies should not only encourage but actually enforce and verify the sharing of data.

#4 Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices:

In order to ease the implementation of policies and practices as previously discussed, it is important to train graduate students on quality research practices and the importance of scientific integrity. By standardizing scientific reporting practices and training students accordingly, we may normalize more robust reporting which would facilitate the aforementioned system of automated checks on quality indicators and improve scientific communication and integrity. Important parts of standardized scientific reporting practices would include the inclusion of individual statements addressing data availability, code and software availability, authorship, ethics, and more as well as a generally accepted structure for scientific publications.

⁴ [Anatomy of Data Sharing: Where to Share \(2021\). Ripeta. Online resource.
https://doi.org/10.6084/m9.figshare.14923899.v1](https://doi.org/10.6084/m9.figshare.14923899.v1)

From: [MBX OSTP Scientific Integrity RFI](#)
To: FW: SI-FTAC RFI
Subject: Thursday, July 29, 2021 9:50:50 AM
Date:

From: Gulbransen, Thomas
Sent: Wednesday, July 28, 2021 4:35 PM
To: MBX OSTP Scientific Integrity <ScientificIntegrity@ostp.eop.gov>
Subject: SI-FTAC RFI

Dear Task Force:

Thank you for requesting input on these topics vital to scientific integrity. The input below reflects my personal views and should not be attributed to any organizations that I am associated with professionally.

Please consider including harassment among the actions which can trigger indictment of an individual for scientific misconduct. Scientists and researchers must be given the opportunity to work in an environment where they do not feel threatened physically, intellectually, or emotionally on the basis of any of the protected categories, e.g. gender, age, sexual orientation, ethnicity, etc. Policy updates should protect scientists and researchers from anyone whose actions create a threatening environment, during work hours or among work colleagues after hours. In addition to institutions' best practices and training protocols with respect to proper code of conduct, scientific integrity can be strengthened further by the disincentive of an investigator being found guilty of scientific misconduct. Compromising a colleague's physical, intellectual, and or emotional well-being through interpersonal harassment is among the worst harms to scientific integrity.

Of course, such a policy upgrade must be practicable and protective of the privacy and legal rights of every individual involved in such incidents. Clear definitions of all forms of harassment and levels of severity must be codified. Likewise, objective processes and authorities must be established to communicate, investigate, and determine the level of severity and adjudicate commensurate penalties associated with the harassment claim.

Thank you for considering this improved protection for our workforce.

Tom Gulbransen
Member of public, government, and non-profit
Program Director

From: [MBX OSTP Scientific Integrity](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: FW: [EXTERNAL] SI-FTAC RFI Comment on Scientific Integrity
Date: Thursday, July 29, 2021 9:52:00 AM
Attachments: 1



American Economic Association

Committee on Economic Statistics >www.aeaweb.org/about-aea/committees/economic-statistics<
Committee on Government Relations >www.aeaweb.org/about-aea/committees/government-relations<

July 28, 2021

Dear Members of the U.S. Scientific Integrity Task Force,

The American Economic Association (AEA) Committee on Economic Statistics and Committee on Government Relations are pleased to respond to the Federal Register request for information (86 FR 34064) in support of the Scientific Integrity Task Force, the White House Office of Science and Technology Policy, and the White House Office of Management and Budget (OMB) as they collaboratively work with Federal agencies and stakeholders to review the effectiveness of agency scientific integrity policies and practices. Established in 1885, the AEA is a non-profit, non-partisan, scholarly association dedicated to the discussion and publication of economics research. The Association supports established and prospective economists with a set of career-enhancing programs and services. The Committee on Economic Statistics (AEASat) promotes AEA member access to current, detailed, useful economic statistics provided by the Federal government and other sources. The Committee on Government Relations is charged with representing the interests of the economics profession in Washington DC and other locations around the country without taking a position on questions of economic policy or on any partisan matter.

As background, we attach and refer you to the AEA Committees' January 2021 Report to the Biden/Harris Administration on Necessary Improvement in the U.S. Statistical Infrastructure (Also available at ><https://www.aeaweb.org/content/file?id=13507><). That report's first recommendation directly addresses the integrity of government statistics which are relied upon to operate government programs, guide business decision making, and inform a broad public with reliable measures of the economy, the nation's health, and the performance of America's education, justice, and other systems. To wit:

The Executive Branch, with legislative support from Congress, must act to prevent politicization of federal statistics. This is essential in strengthening the public trust that will be needed to help halt or reverse alarming reductions in survey participation and restore confidence in the accuracy of federal statistics. Two means toward this end are for:

Congress, collaborating with the White House Office of Management and Budget (OMB) must enact legislation that puts into law what is now a collection of OMB Statistical Directives, as well as the recommendations embodied in "Principals and Practices for a Federal Statistical Agency," issued by the U.S. National Academies of Science.

The OMB Statistical Policy Directives had been followed as norms and good practice for decades, always vulnerable to Presidential elimination, which was not recognized as a threat until recently. Statistical Policy Directive #1 (><https://www.federalregister.gov/documents/2014/12/02/2014-28326/statistical-policy-directive-no-1-fundamental-responsibilities-of-federal-statistical-agencies-and><) is particularly relevant to statistical integrity as it states that "Federal statistical agencies...must function in an environment that is clearly separate and autonomous from the other administrative, regulatory, law enforcement, or policy-making activities within their respective Departments," a critical requirement to prevent political interference in the scientific process of statistical measurement. Reinforcing this Directive is the National Academy of Sciences' *Principles and Practices for a Federal Statistical Agency* (><https://www.nap.edu/catalog/25885/principles-and-practices-for-a-federal-statistical-agency-seventh-edition><). This revered and much-used NAS advice compels agencies to assure: Trust among data providers and credibility among data users; Independence from political and other undue external influence, including necessary authority to protect independence; Wide dissemination of data; Commitment to accuracy and other measures of quality; Qualified professional staff; and Active research programs.

The OMB and Congress should consider making the Directors of all official statistical agencies and units career staff, (meaning no political appointees), or fixing terms of Directors' political appointments as non-coterminous with the President.

The AEA Committees' report also recommends that:

The White House/Office of Management and Budget must elevate the role and stature of the Chief Statistician of the United States, to empower him or her to lead and champion a strong federal statistical system. The Chief Statistician of the United States heads the Statistical Policy Branch of the OMB's Office of Information and Regulatory Affairs and is charged with providing coordination, guidance, and oversight for designated official statistical agencies of the U.S. and their activities. In recent years the influence of the Chief Statistician has declined and the office is grossly understaffed to carry out the position's essential responsibilities.

Some important elements of this solution entail: Creating a Deputy/Associate position at the Senior Executive level to equate this office with that of the Chief CIO and other top-level offices in OMB; Increasing staffing levels so that they are consistent with national and international needs for U.S. statistical policy and representation; Assuring that substantively qualified staff oversee each of major official statistics' subject areas, including, for example, health, economic and demographic statistics. All of this should be done while recognizing the necessity of retaining a career (not politically appointed) Chief Statistician, with requisite professional qualifications, who also assures that the clearance of survey instruments and questions is apolitical.

Finally, while not a part of the attached report, we also note that facilitating public trust in the integrity of federal statistics would be furthered by a federally-funded effort to institute secure multi-party computation as the basis for making statistical data available.

We appreciate the opportunity to advance these critical recommendations. Our Committees are available and would be happy to brief OSTP, the White House Scientific Integrity Task Force, and OMB on our recommendations, their origins, effectiveness, and their importance to the economics community.

Sincerely,

John Haltiwanger
Professor of Economics, University of Maryland, and
Chair, American Economic Association Committee on Economic Statistics
Kenneth Troske
Professor of Economics, University of Kentucky, and
Chair, American Economic Association Committee on Government Relations
Contact: Katherine Evans, Washington Area Representative, American Economic Association. E-mail: kitty.s.evans@aeapubs.org. Phone: 301-974-1644

From: [Jennifer Brown](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Cc:
Subject: [EXTERNAL] Written Comments regarding Scientific Integrity Listening Session: Science & Education
Date: Thursday, July 29, 2021 12:15:31 PM

Please find my written comments on scientific integrity and education below.

My name is Jennifer Brown, I am a PhD candidate in neuroscience at the University of Minnesota, Twin Cities. All views presented here are strictly my own.

The definition of scientific integrity should be expanded to include the conduct of individual scientists in their treatment of each other and their trainees (graduate students and postdocs). Abuse or mistreatment of any kind, or the appropriation of work product should not be tolerated. Additionally, the integrity of science should be the collective responsibility of everyone in the field of science. This means that scientists at all stages should be encouraged to speak out about the science used to inform law and policy. This could help to combat dis-information and make scientists more accessible and active participants in their communities. In order to do this, agencies, institutions and individual mentors, people in positions of power, should work towards changing the academic mindset that science alone is enough and will speak for itself. Recent events have shown with increasing clarity that science can't speak for itself. Scientists at all levels should be encouraged to take part in policy discussions, and be encouraged to be active on various issues. Requiring any individual funded by a government agency to include a community impact or public communication of results plan section in grants, or requiring all grantees to attend a training on science policy and broader scientific integrity is one possible path. Thank you.

Submission – Testimony

Scientific Integrity Listening Session: Communications – Wed. July 28, 2021

On the Communications and Response Lessons of HIV-1 and SARS-CoV-2

Communication and evidence-based leadership are keys to addressing any pandemic.

I am an internal medicine and clinical immunology specialist with an MPH from Harvard in health policy and management. I witnessed the incubation of the HIV-1/AIDS virus in New York City from 1970 to 1981 first as a medical school student and then as an internist.¹ I saw my first AIDS patient in the fall of 1978 three years before AIDS was described in the December 10, 1981, issue of *The New England Journal of Medicine*. I am currently researching and writing a book tentatively titled: *Out of Africa, Out of New York: How AIDS Spread Around the World*.^{2 3}

History provides critically important pandemic lessons. We ignore them at our peril.

A current Smithsonian Institution exhibit on pandemics, titled *Outbreak: Epidemics in a Connected World* mentions the incubation of HIV/AIDS by New York City but fails to address it.^{4 5} Remarkably, the Reagan White House took five to six years (from 1981 to 1986-7) before it even acknowledged publicly the presence of HIV/AIDS in the United States.⁶ In 1986, the White House finally requested that Surgeon General C. Everett Koop write a report on AIDS to the American people. Dr. Koop wrote his report in secret even from President Reagan and the White House. He simply mailed it to the White House as he did to the rest of the tens of millions of American households.

The White House did not develop a national HIV/AIDS Strategy until 2010.⁷

¹ Oryshkevich, B A. "New York City's health care crisis: AIDS, the poor, and limited resources." *JAMA* vol. 261,3 (1989): 378.

² <https://1drv.ms/b/s!AgAEn1pbwhx7j5wi6b8HDUmaccRPPQ>

³ Gilbert, M Thomas P et al. "The emergence of HIV/AIDS in the Americas and beyond." *Proceedings of the National Academy of Sciences of the United States of America* vol. 104,47 (2007): 18566-70. doi:10.1073/pnas.0705329104

⁴ <https://naturalhistory.si.edu/exhibits/outbreak-epidemics-connected-world>

⁵ <https://1drv.ms/w/s!AgAEn1pbwhx7j-I07arKIL6KIPgXYQ?e=uPRvtw>

⁶ Tina L. Perez & George N. Dionisopoulos (1995) Presidential silence, C. Everett Koop, and the surgeon general's report on AIDS, *Communication Studies*, 46:1-2, 18-33, DOI: 10.1080/10510979509368436

⁷ <https://obamawhitehouse.archives.gov/sites/default/files/uploads/NHAS.pdf>

I have been a keen and welcoming student of the COVID-19 pandemic.

Pandemics are a fundamental challenge to any society or country.

Ideally, one communication source would be providing authoritative self-correcting information and leadership in any given pandemic. But all outbreak causing pandemics begin locally. Localized information and control measures must address all outbreaks of an ongoing global pandemic. Nationwide funding, coordination and cooperation may be essential in addressing a pandemic, but it cannot supersede local capacity and measures.

The United States is huge, diverse, and complex with blurred federal and state responsibilities making such strategic and communications choreography difficult to achieve.

During this pandemic, in part because of the character of the President Trump administration, pandemic leadership and communication from the US Federal Government was fragmented, contradictory, and at times disinforming.

Dr. Fauci often spoke as a solo overinterpreted voice. He spoke alone although he undoubtedly represented a consensus point of view. He represents at most the National Institute of Allergy and Infectious Disease. The National Institutes of Health represent the brilliant but focused biomedical research wing of the federal government. It has little capacity to address pandemic responses.⁸

Thus, the US did not benefit from a single expert voice providing consistently authoritative scientific information during this pandemic. Consistent success is difficult in any pandemic since pandemics usually begin with an emerging, often unknown incompletely understood disease and spread as remarkably stealthy dynamic outbursts. Built-in skillful and reassuring self-correction is vital to communication and leadership in any pandemic. *The White House Pandemic Playbook* of President Obama pointed to these challenges and provided federal guidelines.⁹

The United States faces a fundamental challenge in any pandemic. It is a Federal Republic with widely dispersed increasingly diverse, and ever more densely populated states and territories. Both public health and pandemic control are historically local not federal responsibilities. The Centers for Disease Control have generally consultative responsibilities to the states. They do lead on interstate outbreaks, national vaccination programs, and on international public health responsibilities. President Trump was thus technically, if not strategically, correct in deferring our pandemic response to state and local governments. At the same it is exceedingly difficult for any single federal agency to choreograph a coherent national response to a new rapidly spreading multilocal, dyssynchronous viral pandemic.

⁸ Panem, Sandra. *The Aids Bureaucracy*. Harvard University Press, 1988.

⁹ <https://stacks.stanford.edu/file/druid:hy459js4845/Pandemic-Playbook.pdf>

In 1983, I bicycled across the United States with thirty-three Harvard College students immediately after completing my health management and policy degree at Harvard. This Ride embedded in me the breadth and diversity of this country. Anyone desirous of designing national policy should undertake a similar experience.¹⁰ My Ride across America quickly debunked many of the global public health notions I aspired to.

In the late 1990s, while working in a FQHC community health center in Williamsburg (Brooklyn, New York), I tried to engage the Centers for Disease Control in tracking the global dissemination of influenza, that I observed, by the globe-trotting, yet insular, ultra local, and ultra-Orthodox Jewish community. I quickly understood that neither the federal government nor the CDC possess the granularity to address such small communities who nevertheless can spread outbreaks and pandemics both globally¹¹ and locally.¹²

In effect, when it comes to health care and public health, we are the United Countries of America.¹³ California not only exceeds in population Canada, but it spends more money on health care than does Germany. Texas has a larger population than Australia's, Florida than that of the Netherlands, Minnesota more than Denmark's. These smaller countries have done much better than us in this pandemic.

A German hospital, not the United States, designed a COVID-19 reference test within three days of the public dissemination by the Chinese of the SARS-CoV-2 genome.¹⁴ Yet, the United States spends annually almost three times as much money on its hospitals than Germany spends on its whole health care system. The brilliant effort of Professor Doudna of the University of California at Berkeley to get our university based medical schools to set up pop-up COVID-19 testing laboratories nationwide fell by the wayside.¹⁵ Only the University of California at Davis followed suit with an orchestrated plan.¹⁶ The absence of evidence based local state leadership in this pandemic led to inaction by some of our best equipped and most generously funded health care resources, our university based academic medical centers, and medical schools.

¹⁰ Gordon PR, Gray L, Hollingsworth A, Shapiro EC, Dalen JE. Opposition to Obamacare: A Closer Look. *Acad Med*. 2017 Sep;92(9):1241-1247. doi: 10.1097/ACM.0000000000001725. PMID: 28445216.

¹¹ Zucker, Jane R et al. "Consequences of Undervaccination - Measles Outbreak, New York City, 2018-2019." *The New England journal of medicine* vol. 382,11 (2020): 1009-1017. doi:10.1056/NEJMoa1912514

¹² <https://www.brownstoner.com/brooklyn-life/coronavirus-hasidic-brooklyn-schools-weddings-cases-growing-social-distancing-williamsburg>

¹³ Slack, Charles W, and Warner V Slack. "The united countries of America: benchmarking the quality of US health care." *Mayo Clinic proceedings* vol. 86,8 (2011): 788-90. doi:10.4065/mcp.2011.0311

¹⁴ Corman, Victor M et al. "Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR." *Euro surveillance : bulletin European sur les maladies transmissibles = European communicable disease bulletin* vol. 25,3 (2020): 2000045. doi:10.2807/1560-7917.ES.2020.25.3.2000045

¹⁵ IGI Testing Consortium. "Blueprint for a pop-up SARS-CoV-2 testing lab." *Nature biotechnology* vol. 38,7 (2020): 791-797. doi:10.1038/s41587-020-0583-3

¹⁶ <https://www.nytimes.com/2021/01/30/us/college-coronavirus-california.html>

Well over 95% of all Centers for Disease Control employees are based in the Atlanta region and the vast majority of National Institutes of Health Employees are based in the metropolitan Washington DC, Bethesda MD region.

Generic not localized public health messaging and strategies from Washington did not play well in the COVID-19 pandemic.

At the start of the AIDS pandemic, the CDC, unfamiliar with the local New York City public health challenges developed the pseudoscientific myth of “Patient 0”.¹⁷ It took thirty years for scientists to debunk fully that transparent falsehood.¹⁸ The CDC also failed to recognize fully the importance of drug addiction to the spread of AIDS and of AIDS to our indigent and minority communities.¹⁹

Canada’s decentralized approach to COVID-19 served it better. Five of its provinces and territories registered no deaths or deaths in single digits as of July 26th, 2021, during this pandemic.²⁰ Canada’s pandemic morbidity and mortality has been far less severe than that of the USA. Despite producing no vaccines and despite a late start, Canada has surpassed USA vaccination rates.²¹ Because of the presence of capacity in place in the form of universal insurance, Canada was at a tremendous advantage in addressing its pandemic. Canadians felt both the right and the responsibility to participate in nonpharmaceutical interventions and vaccination.

We must now prepare for the inevitable next pandemic by belatedly learning the lessons of the HIV-1/AIDS Pandemic and the more recent lessons of the SARS-CoV-2/COVID-19 pandemic.

¹⁷Auerbach, D M et al. “Cluster of cases of the acquired immune deficiency syndrome. Patients linked by sexual contact.” *The American journal of medicine* vol. 76,3 (1984): 487-92. doi:10.1016/0002-9343(84)90668-5

¹⁸ Worobey, Michael et al. “1970s and ‘Patient 0’ HIV-1 genomes illuminate early HIV/AIDS history in North America.” *Nature* vol. 539,7627 (2016): 98-101. doi:10.1038/nature19827

¹⁹ Drucker, Ernest. *A Plague of Prisons: The Epidemiology of Mass Incarceration in America*. United Kingdom, New Press, 2013.

²⁰ <https://www.statista.com/statistics/1107079/covid19-deaths-by-province-territory-canada>

²¹ <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html>

August 3, 2021

Office of Science & Technology Policy
ATTN: Scientific Integrity Fast-Track Action Committee
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, DC 20504

Submitted electronically via email: ScientificIntegrityRFI@ostp.eop.gov

Dear Scientific Integrity Fast-Track Action Committee Members,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide input on [FR Doc. 2021-13640](#), “Request for Information to Improve Federal Scientific Integrity Policies.” As a coalition of 30 scientific societies representing a range of biological and biomedical research fields, FASEB appreciates the importance of scientific integrity policies both for ensuring sound science and fostering public trust in science, both of which are critical for science-based policymaking. Following a period during which scientific information was suppressed, distorted, or ignored, we commend the efforts of your committee to assess existing Federal scientific integrity policies and practices while exploring new ways to build public trust in science-based policymaking.

Before addressing the specific questions posed in the RFI, we would like to make the committee aware of several recent FASEB efforts that could further inform your work. In 2015, FASEB’s Science Policy Committee hosted a symposium that explored emerging concerns about the inability to reproduce published biomedical research findings and determine ways in which a variety of stakeholders, ranging from individual researchers and research institutions to scientific societies and publishers, could enhance the transparency of research methods and results. This symposium and three follow-on roundtables informed the 2016 report, “[Enhancing Research Reproducibility: Recommendations from the Federation of American Societies for Experimental Biology](#).” While initially intended to prepare researchers for forthcoming changes in the National Institutes of Health (NIH) grant application requirements, many of the recommendations are applicable to the broader scientific community.

In 2017, FASEB partnered with NIH’s National Institute of General Medical Sciences to host a workshop on “[Responsible Communication of Basic Biomedical Research: Enhancing Awareness and Avoiding Hype](#).” The goal of this workshop was to explore the role of “hype” – overselling or misrepresenting research findings – on the scientific enterprise and public trust in science. Participants included a diverse group of experts, including scientists, communications scholars, academic and corporate communications officers, policy advisors, and journalists. Discussion topics included the challenges of communicating science in the current media landscape, motivations for certain forms of

science communications, inherent features of science that make communicating about it challenging, and the role of press releases in promoting research progress. Again, while the emphasis was on basic biomedical research, many of the discussions and suggestions are broadly applicable across STEM fields.

As a result of our deliberations leading up to the 2016 report on research reproducibility, FASEB has explored the ways in which shared research resources or “cores” support the efforts of individual investigators with high-quality equipment and reagents as well as designated technical expertise. In 2017, these efforts culminated in series of [recommendations](#) that highlighted the potential of shared research resources to promote rigorous research practices, quality technical training, and collaborative research gleaned from a [community survey](#). Earlier this year, a FASEB Task Force issued a [report](#) that explored opportunities for overcoming systemic challenges related to effective incorporation of shared research resources across the research enterprise.

In addition to our more extensive efforts, FASEB also submitted [comments](#) in response to an RFI issued last year by the Department of Health and Human Services’ Office of Research Integrity seeking input on strategies for fostering research integrity and responsible conduct of research. Key themes from those comments that the committee might want to consider for the current RFI include:

1. Supporting development and implementation of research integrity and responsible conduct of research training for all members of a laboratory, including principal investigators, core facility staff, staff scientists, postdoctoral scholars, graduate and undergraduate students, and technicians;
2. Working with scientific publishers to establish uniform expectations to address research integrity, as many have developed extensive resources that could serve as excellent resources for Federal training modules;
3. Offering research integrity and responsible conduct of research training modules in conjunction with scientific conferences, workshops, and other professional development opportunities.

For the current RFI, FASEB offers the following specific feedback:

Topic 2: Effective policies and practices Federal agencies could adopt to improve the communication of scientific and technical information

The COVID-19 pandemic has provided a unique opportunity for Federal agencies to gather real-time data about communication of scientific information that resonate with non-technical audiences. First and foremost, Federal agencies should strive to offer uniform messaging on a specific issue, be it a virus or an emerging technology. Uniform messaging minimizes confusion – both for those receiving and delivering information – and also maximizes resources, both staff and documentation. By pooling resources, staff efforts can be focused on tailoring communications to the specific audiences to ensure clarity and retention of key information.

Uniform messaging can only be effective if the audience trusts the individual delivering the information. For technical information, trust can be established by highlighting the credentials of those communicating the information to reassure audiences that the message reflects scientific information rather than partisan preference. Pairing a technical expert with an appropriate and respected community leader is also an effective strategy for relaying technical information.

Topic 3: Effective policies and practices Federal agencies could adopt to address scientific issues and the scientific workforce.

A key challenge for Federal scientific integrity policies and practices is the rate at which potential problems are detected and addressed. Investigations of potential violations of scientific integrity policies frequently take several months and sometimes years to reach a public resolution, and in many cases, there is an additional lag associated with correcting the publication record. To ensure timely processing of reports of potential scientific integrity violations, agency integrity offices should be provided sufficient resources to investigate such inquiries.

Additionally, there should be a clearer articulation that violations of scientific integrity policies have consequences. Stating potential penalties for violating these policies, such as canceling current grant funds and limiting the ability to apply for future research grants, should serve to deter most scientific malfeasance. However, when penalties are assessed, we recommend broadly publicizing the infractions and resulting penalties to reiterate commitment to scientific integrity and proper stewardship of Federal resources.

FASEB also encourages Federal agencies to seek ways to reward research teams and organizations demonstrating excellence in scientific integrity. This could include spotlighting effective training modules and practices or even rewarding efforts to correct the scientific record in the case of evolving experimental methods and data analysis capabilities. Rewarding desired behaviors is just as – if not more – important than punitive actions against bad actors.

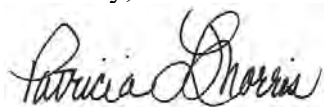
Topic 4: Effective practices Federal agencies could adopt to improve training of scientific staff about scientific integrity and the transparency into their scientific integrity practices.

Reiterating our [2020 feedback](#) to the Department of Health and Human Services Office of Research Integrity, FASEB strongly recommends regular training in research integrity and responsible conduct of research for all members of a research team, not just trainees. Principal Investigators are critical for setting the tone for good lab practices, and thus including them as well as other scientific staff members in such training highlights the fact that responsible research practices are dependent upon the research team and laboratory culture.

As indicated throughout our comments, scientific integrity is dependent upon effective communication with a range of stakeholders. Therefore, FASEB also recommends that Federal scientific integrity and responsible conduct of research training include communications modules as part of the core curriculum.

FASEB appreciates the opportunity to provide input on this important topic. We look forward to working with OSTP and Federal science agencies to reinforce the importance of scientific integrity as a core value of research community and an integral component for fostering public trust in science.

Sincerely,

A handwritten signature in black ink, appearing to read "Patricia L. Morris". The signature is fluid and cursive, with the first name "Patricia" being more prominent.

Patricia L. Morris, MS, PhD
FASEB President

From: [Venkatesan Thimmakondur Samy](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Humble request to re-review my NSF grant proposals
Date: Thursday, July 29, 2021 3:30:48 PM

Dear Policymakers,

My name is Dr. Venkatesan Thimmakondur Samy. I currently work as a voluntary Adjunct Faculty (non-payment basis) in the Department of Chemistry and Biochemistry, San Diego State University, San Diego, CA, USA. The main reason I agreed to work as a voluntary faculty is due to the fact that I can submit research grant applications to the federal funding agencies and have the opportunity to do some good science. I also strongly believed that the United States respects intellectual property and good science and that's the whole reason I moved to the US.

As I mentioned in the listening session today morning, so far ten of my research grant proposals have been rejected. The National Science Foundation (NSF) has rejected seven of my research grant proposals so far. The National Aeronautics and Space Administration (NASA) has rejected three of my research grant proposals so far. These events happened during the years 2017 to 2021. I have written a small opinion piece in LinkedIn and hereby I kindly request you to go through this article when time permits.

<https://www.linkedin.com/pulse/how-get-experimental-preliminary-data-without-any-thimmakondur-samy/>

Also, through this email, I humbly request you to re-review two of research grant proposals submitted to two different divisions of the NSF. In my opinion, I do not think that the review process was conducted in a fair manner. I have listed the proposal numbers and contact details here below for your convenience.

1. Proposal No: 2108496

Title of the Proposal: Collaborative Research: Experimental and Theoretical Investigation of New Astronomically Relevant Molecules

Program Title: GALACTIC ASTRONOMY PROGRAM

Program Code: 1216

Funding Opportunity Number: NSF 18-575

Division/Area of Science: Division Of Astronomical Sciences

Program Contact Name: Harshal Gupta

Program Contact Phone:

Program Contact Email:

2. Proposal No: 2102234

Title of the Proposal: Theoretical Design of New Molecules with A Planar Tetracoordinate Carbon Atom

Program Title: Chem Struct,Dynmcs&Mechansms A

Program Code: 9101

Funding Opportunity Number: NSF 20-577

Division/Area of Science: Division Of Chemistry

Program Contact Name:

Program Contact Phone:

Program Contact Email:

As a voluntary Adjunct faculty, I am not getting paid. However, in the last few years, because I love doing science, I have done ample amount of work and published 14 research articles till date without any research funding. To be honest, I can no longer go like this without having any support. Therefore, I kindly request you to provide some research funding and restore the faith in the grant reviewing system.

Thank you in advance,

Sincerely,
Venky

Dr. Venkatesan Thimmakondur Samy

Adjunct Faculty, Department of Chemistry and Biochemistry

San Diego State University, San Diego, CA 92182-1030 USA

From: [Elizabeth de Laperouse](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Scientific information
Date: Thursday, July 29, 2021 4:21:59 PM

I just saw the sessions on scientific knowledge and information so missed the sessions that took place yesterday and today.

For many years I have worked on science and public policy. My work began with the Stem Cell Research debate. The science was clear and showed promise but the public was concerned about the words used and the scientific community did not realize how important words are. Before the issue of stem cell research the word embryonic was often used to refer to early stages of development. The groups opposed to this research were able to equate embryo to embryonic and make people think embryos were being hurt or destroyed for research purposes. At the time it was commonly understood that an embryo is created at implantation of a fertilized egg. This was and is not allowed. All research is done on fertilized eggs before implantation. But the damage was done and to this day embryonic stem cell research is viewed by many as unethical. Fortunately for medical research, couples who have used fertility treatments to have a child and have left over fertilized eggs can donate those eggs for research. So the research continues and has lead to significant treatments that help people with conditions that were untreatable. But this research cannot be carried out in States with leaders who are against embryonic stem cell research. Not a position based on science but one based on religious belief that life begins at conception/fertilization and before implantation.

My next science and public policy experience was with chemicals. Here I found myself even more dangerous. People who are anti chemical are just as committed to their view and will not entertain the perspective that chemicals are everywhere and it is how they are used that needs to be controlled. Water is a chemical and too much can kill you. As anti Chemical groups raise alarms about pesticides, fertilizers and chemicals in food and drink, they fail to realize we allow chemicals, nicotine that is known to cause cancer. Phthalates sound bad but have been around for decades and are safe as used. Just because it is spelt strangely does not make it bad. Many of the “natural “ products are far more harmful. The FDA needs to do better at making sure “natural” products do what the people selling them say they do. With COVID all sorts of bogus treatments are being promoted.

Liz de Laperouse

From: [DAVID E. ORTMAN](#)
To: [MBX OSTP Scientific Integrity RF1](#)
Subject: [EXTERNAL] Comments Public Listening Sessions on Scientific Integrity and Evidence-Based Policymaking Session #3 - July 30, 2021
Date: Thursday, July 29, 2021 7:58:56 PM

Comments of David E. Ortman, Attorney-at-Law,
on Public Listening Sessions on Scientific Integrity and Evidence-Based Policymaking - Session #3- July 30, 2021

It is extremely troublesome that the Bureau of Reclamation over the past decade has refused to listen to scientific integrity and evidence-based policymaking. For example, in the Yakima River Basin in south central Washington, the Bureau of Reclamation has been busy funding studies of new irrigation storage dams or pumping projects in Washington State's Yakima Basin despite the fact that they have been found to be environmentally damaging and uneconomical:

https://wrc.wsu.edu/documents/2014/12/ybip_bca_swwrc_dec2014.pdf/<

[BENEFIT-COST A YAKIMA BASIN INTEGRATED PLAN PROJECTS](#)

BENEFIT-COST ANALYSIS OF THE YAKIMA BASIN INTEGRATED PLAN PROJECTS REPORT TO THE WASHINGTON STATE LEGISLATURE December 15 2014 Principal Investigators: Jonathan Yoder, Project Lead and contact author Director, State of Washington Water Research Center

wrc.wsu.edu

National water policy cannot afford to continue the mistakes of the last century and taxpayers cannot afford to subsidize uneconomical new water storage projects.

In addition, there are problems with the NOAA "DROUGHT MONITOR":

In a *Seattle Times – Pacific NW*, July 4, 2021, article Lorene Edwards Forkner wrote: "...here in the Puget Sound region, dry summers with little rain are not drought - they're normal."

Indeed. The average annual rainfall of Richland, WA is 8.1 inches, in Yakima, WA it is 8.5 inches, and in Wenatchee and Moses Lake, WA it is 9 inches. This is not "drought," this is "normal."

So what are we to make of NOAA's Drought Monitor scale as presented on their website?

No drought
Abnormally Dry
Moderate Drought
Severe Drought
Extreme Drought
Exceptional Drought

[>https://www.climate.gov/maps-data/data-snapshots/data-source-drought-monitor](https://www.climate.gov/maps-data/data-snapshots/data-source-drought-monitor) <;

If you start the scale by telling the public that your area is "Abnormally Dry," that would seem to already raise alarm bells. But is that better or worse than "Moderate Drought?"

And if your area is already in "Severe Drought" how much worse can "Exceptional Drought" be?

The actual descriptions are also less than helpful:

"Areas shown in yellow are Abnormally Dry. In general, this category indicates land that is **going into or coming out** of drought.

Tan areas are experiencing Moderate Drought: water supplies **may** be low and damage **may** occur to crops and pastures.

Orange areas are in Severe Drought: water shortages are common and crop and pasture losses **are likely**.

Red areas are experiencing Extreme Drought. Areas in this category **may** experience widespread water shortages and major losses of crops and pastures; forests in these areas become dry and susceptible to fire.

Dark red areas are in Exceptional Drought. Shortages of water in streams, reservoirs, and wells in these areas **can** lead to water emergencies. Failed crops, barren pastures, and tinder-dry forests **may** be widespread across these areas."

In other words (pun intended), lots of qualifiers. Seems like there should be “something” between no drought and “Abnormally dry.” Also, wouldn’t it be better to develop a measurable scale where, for example:

+N: above normal precipitation/snowfall for the year

0: normal precipitation/snowfall for the year

-1: 1-3 inches less precipitation/snowfall for the year

-2: 4-6 inches less precipitation/snowfall for the year

-3: 7-9 inches less precipitation/snowfall for the year

-4: 10-12 inches less precipitation/snowfall for the year

-5: 13 or more inches less precipitation/snowfall for the year

Compare this to:

Tornado Scale

Fujita Fastest 1/4-mile (mph)

Number

0 40-72

1 73-112

2 113-157

3 158-207

4 208-260

5 261-318

><https://www.spc.noaa.gov/faq/tornado/ef-scale.html> <;

or the

Hurricane Wind Scale

Category One Hurricane (Sustained winds 74-95 mph, 64-82 kt, or 119-153 km/h)

Category Two Hurricane (Sustained winds 96-110 mph, 83-95 kt, or 154-177 km/h)

Category Three Hurricane (Sustained winds 111-129 mph, 96-112 kt, or 178-208 km/h)

Category Four Hurricane (Sustained winds 130-156 mph, 113-136 kt, or 209-251 km/h)

Category Five Hurricane (Sustained winds 156 mph or higher, 136 kt or higher, or 251 km/h or higher)

><https://www.nhc.noaa.gov/pdf/sshws.pdf> <;

Yes, tornados and hurricanes are discreet events, while droughts can cover entire states and regions. Still, it seems that if the first Drought Monitor alert is “Abnormally Dry,” it’s like pulling the fire alarm when a fire extinguisher may be the proper response.

From: [Zach McKinney](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Comment: Science Education must focus on scientific Process (method) more than content
Date: Thursday, July 29, 2021 8:58:34 PM

Dear OSTP 'Team Integrity' –

THANK YOU, first and foremost, for hosting these listening sessions, and for your broader initiative on Scientific Integrity.

Unfortunately, I missed today's session due to having tactfully assumed that it was scheduled at the same time (2pm EDT) as yesterday's session – will the recording of the session be made publicly available?

In any event, my comment on the topic of science education is that I see in science education a critical need to cultivate an understanding of science not as a body of knowledge, but rather as a dynamic, iterative, and intensely participatory *process* of continually seeking, refining, and applying knowledge. Thus, in addition to teaching what is known about the world (and the limits thereof), science curricula should place equal emphasis on the scientific *process* of formulating compelling hypotheses, designing rigorous experiments to evaluate them, and drawing sound conclusions from the data, and *repeating the process!*

Many thanks for your listening and your service to both science and humanity,

-Zach->

Zach McKinney, PhD

From: [Fred Wood](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Re: revised submission SI-FTAC RFI
Date: Friday, July 30, 2021 10:50:05 PM

TO: SI-FTAC Task Force

RE: Revised Response to RFI Request for Information to Improve Federal Scientific Integrity

From: Dr. Frederick B. Wood, BSEE, MBA, DBA, as Member of the Public, formerly Senior Associate, Office of Technology Assessment, US Congress, formerly Computer Scientist, National Institutes of Health/National Library of Medicine/USDHHS, Retired, formerly Adjunct Professor, Communication, Technology, and Culture Program, Georgetown University, and formerly Research Scientist, Program of Policy Studies in Science and Technology, The George Washington University. The views expressed are the author's and not necessarily those of prior employers or other affiliated organizations or associates.

I have elected to focus my comments on the need for a cross-cutting Framework for Scientific Integrity that would integrate key information about Federal scientific research in a manner that would support all the major topics of the listening sessions and the RFI. Therefore, I would list this Framework concept under item 5 in the RFI.

This revised submission reflects some comments made during the three recently completed listening sessions on Federal Scientific Integrity, co-hosted by OSTP and the Federal Task Force on Scientific Integrity.

Revised Draft Conceptual Framework for Scientific Integrity

General Topic(s) (searchable)

Key Words (searchable)

Type of Science: (select one or more)

Foundational.
Well established.
Developmental.
Breakthrough.
Exploratory.

Fields of Science (select all that apply)

Scientific Discipline(s) (drop down list)

Multidisciplinary (drop down list of relevant disciplines)

Interdisciplinary (fill in description)

Research Methods (select all that apply)

- Theoretical study.
- Conceptual study.
- Pilot project.
- Field study.
- Case study.
- Exploratory controlled trial.
- Randomized controlled trial. (drop down list of types)
- Quantitative survey.
- Qualitative survey or interviews.
- Mixed methods.
- Ethnographic and/or Demographic analysis.
- Community-Based Research.
- Citizen Science Research.
- Statistical Analysis. (may apply to various methods)
- Data Analytics. (may apply to various methods)
- AI and Computer Learning. (may apply to various methods)
- Computer and Systems Modeling (may apply to various methods)
- Systemic reviews and meta-analysis (of multiple researches).
- Other (fill in).

Research Results (aka Data) Parameters

- Sample size.
- Data set size.
- Data collection methods.
- Data collection period of time (/planned/start/ongoing/stop as applicable).
- Data confidence and/or uncertainty levels (to the extent applicable/available).
- Key assumptions and/or uncertainties, where applicable.
- Funding sources, declared conflicts of interest.
- Data review process (e.g., expert, peer, outside, community, stakeholder, mixed, blended--drop down list).
- Data review participation (select all that apply);
 - Diverse researchers;
 - Research participants;

- Potentially impacted communities;
 - Minority and underserved communities.
 - Indigenous communities.
 - Interested general public.
 - Subject matter science & policy advocates.
 - Other subject matter experts (not otherwise covered).
- Data corrections or retractions.
- Other data quality factors.

Research/Data Access

- Easily findable.
- Properly indexed with key words and meta-data.
- Electronically accessible and downloadable.
- User friendly platforms.
- All research and resulting data that is fully or partially funded by Federal taxpayer dollars.
- In all scientific disciplines and fields of study.
- Accessible at no cost to the public.

SOURCES: Based on the author's research and analytics experience, and incorporating key elements from the Federal Scientific Integrity public documentation issued or provided in connection with this Task Force activity and the related public listening session comments.

Thank you for your consideration.

Please advise if you have questions or need clarification.

Best wishes.

Frederick B. Wood

From: [Randy Randol](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] More Feedback on the policy questions posed
Date: Saturday, July 31, 2021 8:37:31 AM

Yesterday's online session was illuminating.

OSTP should focus its attention on existing law(Information Quality Act) and the existing directive for benefit cost analysis(E.O. 12866).

Agencies have routinely ignored the IQA requirements for INDEPENDENT review of Highly Influential Scientific Assessments to avoid scrutiny of the data and models used for policy.

Transparency is crucial for INTEGRITY.

OSTP needs to force OMB to exercise its authority rather than rolling over and ignoring the transgressions by the agencies.

The most recent example is the use of the "2021 Interim Values of the Social Cost of Greenhouse Gases(SC-GHG).

The National Academy of Sciences, Engineering and Medicine was asked by the Obama Intergency Working Group to provide guidance on how to proceed with BCA using the SC-CO₂, SC-CH₄, SC-N₂O metrics.

In its 2017 report NASEM had strong and clear recommendations that tracked the IQA. Without exception, EPA and DoE proceeded to ignore the explicit concerns:

1- The Integrated Assessment Models(DICE, PAGE and FUND) cannot be used for any Benefit Cost Analysis(BCA) unless and until substantial changes are made(see Appendix G).

2- A simplified climate model should be used(the only model that passes muster under the IQA is the MAGICC model)

3- The time frame for the analysis should be limited so that the results can be validated.

4- **Averaging** the results of models is never acceptable.

Science integrity has to start with agencies following the law as a rule NOT THE EXCEPTION.

Agency staff that do not comply need to be removed from their positions. The agency IGs need to be held accountable for policing and enforcing INTEGRITY.

We do not need another layer of bureaucracy to hide behind.

Other issues that must be addressed under the “scientific integrity” rubric:

Use of data and models beyond the reach of the IQA should be forbidden.

Use of journals to publish tax-payer funded research that do not meet IQA standards should be forbidden. Paywalled journals fall into this category.

All RAW data generated by tax-payer funded research needs to archived and protected from manipulation.

All models/computer programs used in tax-payer funded research must be available for use by independent scientists. NO PROPRIETARY MODELS/COMPUTER PROGRAMS SHOULD EVER BE FUNDED BY TAXPAYERS.

Thank you for considering these comments.

A.G. Randol III, PhD

Co-Founder

VA Scientists and Engineers for Energy and Environment

From: [Bevin Wathen](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [WARNING: UNSCANNABLE EXTRACTION FAILED][EXTERNAL] Response
Date: Saturday, July 31, 2021 3:14:33 PM

31 July 2021

Thank you to the teams that are working so hard to address these issues of Science, Technology, Public Trust, and Integrity, and thank you for the opportunity to participate and reach out to you regarding these issues.

I speak to you today from the perspective of a citizen, and as a middle-aged single mom and engineering student, researcher, and consultant, who has been disabled, living in Louisville, Kentucky. I am working to build a way to work and solve some of the accessibility issues that people face with disability. I knew engineering was the best path to address these issues with my background and experience, and I walked straight into a pandemic on my quest into engineering school post my last neurosurgery in 2019.

What I have lived and seen within community, be that while isolated with disability, with my loved ones in their struggles of daily life, or through this pandemic, is not able to be summarized simply, and it spans over 40 years of lived experience. There exists extensive hurt, grief, and suffering and these panels are absolutely essential to create the path forward for future generations to not only survive, but to thrive. I am forever grateful to be an American, no matter how hard the challenge we face in community.

I wish I had all the answers, but I am one person, and I absolutely do not know everything.

What I am hearing from and with people at the base, is lack of access to what they need. The people charged to help (professional or otherwise) are tied up in red tape and hurdles to attempt to help those in need. The legal system and codes are not up to date with how fast science and technology is moving. Our infrastructure is crumbling, and that is essential to critical care, emergency response, commerce, education and work. Consumer protections are not effective. People feel abandoned and afraid as they struggle to stay above water. They are tired of people in authority completely unaware or incapable of supporting their needs. They see you on screens showing up however you do in your daily life and work, while they are fighting everyday merely to survive, carrying extensive debt and responsibility with aim to protect their children, families, and communities. Americans at the base are facing Impossible odds and probabilities. They are carrying extensive personal hurt, guilt, and shame as their own while they fail to grow or make sense of their experience. They also have no idea how or what people in different roles are actually doing, or how these people are showing up to solve the issues, and rarely have time to learn about it. They've even questioned me as I have ventured off to learn all about it.

This isn't new.

Yesterday, I reached out to five different agencies to try to get help to protect myself and my children. I was hung up on by automated systems in most phone calls.

This is not unlike what I experienced as I was trying to navigate and identify pathways for medical help last year during a global emergency. People at the base cannot protect

themselves or their families, or make better decisions to protect themselves while the first responders do their jobs, if they do not have a centralized authority communicating emergencies honestly and effectively. Our amazing technology can be built better to help!

You have families trapped in systems of neglect, Leaders that politicize health and healthcare, while everyday human beings don't have access to the help, healthcare, or basic needs to provide for themselves or their children. You have victims of abuse being blamed as 'asking for it' by merely existing and being held accountable for terrible options, and entire groups within society referring to the emergency services lines as DNR lines. If you have not worked in medical environments, DNR means 'Do Not Resuscitate'. You have women and children who often cannot make it out of domestic violence situations alive, and if they do, they are forced to provide access to those children by laws put in place that protect abusers rights. You have laws that will sentence a person to life for minor drug offenses, people convicted that did not participate in crimes, and murderers and violent offenders that rape and kill people who can get off on technicalities, afford better lawyers and assistance, or have time served within years for things that are clearly inhumane behaviors. You have judges and lawyers and social workers exhausted by the constant daily fight to sort all of this nonsense, while people at home are trapped and afraid, because if they speak the truth of their experience they know they may be stalked, hunted, or killed for telling the truth.

This is the reality of America.

People are afraid of constant surveillance,

while also being concerned that that surveillance will not protect them.

They are afraid of agencies in the Department of Justice that are charged to protect them, and Americans can no longer identify who the helpers actually are, or who to trust.

Trauma and hardship makes this hard for any healthy human with the best resources or connections to navigate- it is exponentially harder for people without these things.

You want to ask a question about the problems with Science, Technology, Integrity and public trust, I invite you into the lives of my loved ones and community, who they are, and what they have lived in the land of 'industry', with social, technological and education systems, that are incapable of addressing them where they are as individuals navigating real life. We are one of many States trying to rise through all of this, and the census bureau data shows that effectively.

There are a million different channels for 'information' that have been created, usually with good intent, to provide access, that have been weaponized by abusive users, and the abused are left with the mess and fallout of the consequences to figure it out. The tools aren't always the problem- the abusers of those tools are, and it is easy for those without training or understanding in technology, science, engineering or medicine to mistrust the messenger, or to mistrust the tools that scientists, researchers, or educators are attempting to build to solve the actual problems for people on the ground.

I don't really care what 'side' you affiliate with, but if people don't get real about this, and start to come together as teams to solve it, we will have stunted growth and sick uneducated people beyond compare- and no one wants that for anyone, whether they are here or anywhere else in the world.

I have seen amazing people working so hard over the last 20 months on my journey further into science and engineering education, work, and stewardship. I know we can meet and do

this. We have to bridge the gap and meet people where they are. Everyday people frequently do not trust your perfection models and 'integrity' cloaks- they feel you are not them, you do not speak their language, you do not care what happens to them, and you also will likely destroy anyone who speaks up for them- either on purpose, or by neglect of responsibility for your choices and actions chosen for them. They believe they will be left to 'figure it out' and 'accept their fate' while you do whatever it is that you do and they try to stay alive at the same time.

I believe that you care to show up for such an impossible job. I am okay if I make a mistake in believing that, or am wrong, so that we all learn better. That is how I have decided to show up and serve my community in hopes to make it better.

Your citizens and base are not stupid, even if they don't say things in ways you prefer to be addressed in their hurt and frustration.

People who are in trauma and need help cannot identify who is who anymore.

This is not safe for our scientists, professionals, first responders, communicators, legislators, or our community members or civilians. It is unacceptable. No one should fear for their life or safety to exist, ever, and especially not here in our country. I tell you these things because people are exhausted, not because you personally have created the problems. If you do not know where people are in their suffering or coping mechanisms, we cannot build forward or identify the areas that need support and reframing. Please keep working, and know that it is in grounding with your humanity and best intention, we will build to solve the issues of our people and the environment that we share together.

I support you every step of the way however I can.

Thank you for your work.

It matters to me and my family
to know you are there,
more than you may ever know.

Bevin Wathen

From: [Wickiser, John Kenneth Dr.](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Cc:
Subject: [EXTERNAL] Improving Scientific Integrity across the federal enterprise: Inserting Purposeful Ethical Analysis into the Entire Scientific Process
Date: Saturday, July 31, 2021 3:43:37 PM

Esteemed colleagues,

Thank you so much for the opportunity to listen to concerned citizens providing input to your panel. I would like to advocate for the purposeful inclusion of Ethical Analysis at all points along the scientific research timeline from the formulation of ideas, to the construction of an experiment, to the execution of the experiment, to the analysis of collected data, and to the sharing of those data.

We all abide by the appropriate and strict Human Subjects Research and animal research regulations and policies to ensure the protection of people and animals involved in the work but we do not have a similar infusion of purposeful ethical analysis into work done outside research involving human subjects and animals. I recently suggested that the Office of the Secretary of Defense fund an Ethical Philosopher to serve in the role of guiding West Point students and faculty in conducting their work and while the proposal was not funded, it did spark a discussion about how we train young academic researchers (being inclusive of Humanities, Social Sciences, and STEM fields). Most scientists of my vintage experienced their ethical training as part of an NIH program to ensure graduate students kept proper laboratory notebooks. NIH has improved it significantly since then (<https://researchethics.od.nih.gov/CourseMap/index.aspx>) but it really addresses the basal expectations for what really should result in trust between federally funded researchers and the public. I argue that if challenging ethical discussions about research – whether it involve data, molecules, cells, animals, or people – were included at all points along the entire process, young scientists and engineers would develop a culture of honesty and ethical consideration that would go a long way to bridge the divide between federally funded researchers and the public they serve.

Secondly, I want to bring to your attention the Ethical Philosopher and Cultural subject matter experts in addition to the accomplished STEM scientists and engineers at West Point. These uniformed officers and government civilians have a unique combination of academic subject expertise and real-world experience with military operations that pose complex ethical and cultural challenges. Our teammates would gladly serve as SMEs on committees such as your Scientific Integrity panel as your team deemed appropriate and helpful. Please don't hesitate to reach out to me and I will be happy to either serve or connect appropriate SMEs with your team.

Thank you for working hard to address this important issue for the nation.

v/r Ken

J. Kenneth Wickiser, PhD
Associate Dean for Research
Professor of Biochemistry
Director, Academic Research Division
West Point, NY

<https://www.westpoint.edu/centers-and-research/academic-research-division/leadership>

From: [Stauffer, Barbara](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] July 29 OSTP Listening Session Comments
Date: Monday, August 2, 2021 2:42:10 PM
Attachments:

Thank you for organizing this listening session.

Attached and below are the comments I made in today's listening session. Also, there is a lot of discussion in the chat about the need for effective science communication, and I and/or my colleagues at the Natural History Museum would be happy to discuss this further with you and your team. There are a lot of strategies that can be used to improve science communication, but it requires time and resources. Even more so, it requires that the science community recognize, respect, and genuinely value the training and expertise of the education and communications professionals who can help them do this.

OSTP Listening Session – Scientific Integrity

Comments by Barbara Stauffer

July 29, 2021

I'm Barbara Stauffer, Chief of Community Programs at the National Museum of Natural History, and I'd like to speak to the importance of diversifying the field of science to:

- Produce a more science-literate society
- Open the field of science to a wider range of perspectives
- And ensure that no population feels excluded from – or even worse, targeted by – the scientific endeavor.

Along with our collections, research, and exhibitions, we offer programs for students, including preK-12 school field trips, youth programs, internships, and graduate fellowships. And we offer professional development for teachers. But just offering the programs isn't enough, we need to attract and retain a more diverse range of participants, especially from underrepresented populations.

To do this we need an active and sustained effort to coordinate and improve our recruitment, onboarding, training, mentoring, and retention processes across our many student programs. By doing this we can address many of the factors that contribute to the lack of diversity in the field, including (but not limited to)

- Training teachers and prioritizing Title 1 schools to counteract the inequitable access to science instruction in schools,
- Partnering with minority-serving organizations to offer paid internships and fellowships

to students from underrepresented populations,

- Providing strong administrative and mentoring support before, during and after any experience with us,
- Creating a network of program alumni, teachers, and students that can continue to support each other.

So, I know this sounds straightforward, but it is a lot of effort, and we are just getting started, including with the fundraising. But we believe strongly that initiatives like this are essential if we are to put in place the internal systems and to conduct the external outreach that is needed to create inclusive cultures and train a new generation of science literate citizens and diverse science professionals.

Thank you.

Barbara

Barbara Stauffer

Chief of Community Programs

Office of Education and Outreach

SMITHSONIAN INSTITUTION

NATIONAL MUSEUM OF NATURAL HISTORY

[Facebook](#) | [Twitter](#) | [Instagram](#)

From: FW: [EXTERNAL] Hope you can
To: help Tuesday, June 29, 2021
Subject: 3:59:16 PM
Date:

-----Original Message-----

From: Dawn Davey
Sent: Tuesday, June 29, 2021 3:38 PM
To: MBX OSTP Scientific Integrity <ScientificIntegrity@ostp.eop.gov>
Subject: [EXTERNAL] Hope you can help

To try to make my story and concerns short:

Learned I am implanted, in my ears, and abi multi channel possibly? I have MRIs and all doctors covered it up..every time I try to get help to somehow remove the ear implants and do something to somehow disconnect from hearing what these people say, and stop the torture..doctors won't hardly address it, because I have no memory of where or who? The implants came from..I'm not trying to sue anyone or cause problems it's just horrible that the torture continues, and it's scary , incredibly scary that if my children ended up in my position, and tried everywhere for help, and no one would acknowledge them..that they would be tortured and on remote neural monitoring forever, until someone tells the truth, and doesn't be so afraid of getting blamed all I want is my life back the way it was before this heinous thing happened to me..I've talked to FBI , they said they don't investigate that stuff..homeland security (ice) said they handed the case to someone else, this was not they're jurisdiction, attorney generals asst. said I just need to get the RF equipment out of my house(2 sets of private detectives confirmed I had in my house..but no one will help remove it..and I'm still trying to learn exactly what it looks like, it was criminals that did this, and people want to blame police, government and it just doesn't add up..I think they just never figured out what was happening in my house yet...but have faith god got us this far for a reason, it's gonna be ok, and we can heal and forget and spend rest of life peacefully, I've gone through this 13 years, and am thankful to have survived, and just desperately want it to stop

Thank you for caring

Dawn Davey

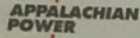
Sent from my iPhone

From: [Maureen](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Fracking
Date: Tuesday, June 29, 2021 3:08:27 PM

Oil fracking has gone in here illegally for 15 years that I've watched tankers unmarked going up and down the highway. My gf in Colorado mentioned to me the flowers in evergreen are all whit now in by the sides of the road. The earth won't be able to stand much more abuse. Put these two things together while you turn a blind eye is called cancer from the water everyone drinks. Please make people aware of this

From: [Danny Wake](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL]
Date: Tuesday, June 29, 2021 2:52:06 PM

First off I'm going to email you personally myself okay and if you're requesting information to approve Federal scientific Integrity policies the first thing I want you to do is come up with a figure of income that you have ready to put in my hand and then we can discuss information to improve Federal scientific Integrity policy other than that your request for information to improve Federal scientific Integrity policy is going to fail.



Non-Payment/Return Mail:
PO BOX 24401
CANTON, OH 44701-4401

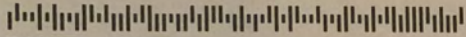
Amount due on or before **\$85.27**
July 12, 2021
Bill mailing date is Jun 18, 2021
Account #028-134-358-7-8

SERVICE ADDRESS: DANIEL ADAMS, 1184 LONG FORK RD TRLR, PECKS MILL, WV 25547-9010

CY 15



001898 8514005 000 01 001



DANIEL ADAMS
1184 LONG FORK RD
PECKS MILL WV 25547-9010

00073737
MSP 37

Notes from APCO:

Make this bill the last one sent in the mail! Go paperless and get email alerts when your bill is ready. Sign up at AEPpaperless.com!

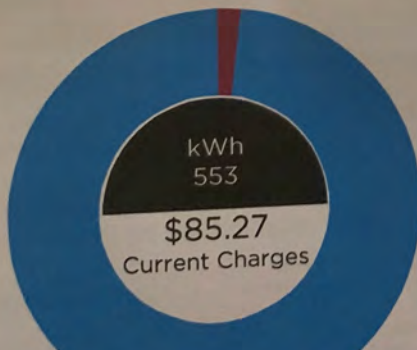
Usage History (kWh):



Current bill summary:

Billing from 05/20/21 - 06/17/21 (29 days)

Consumer Rate Relief \$1.59



Methods of Payment

- appalachianpower.com
- PO Box 371496
Pittsburgh, PA 15250-7496
- 1-800-611-0964 (fee may apply)

Need to get in touch?

Customer Operations Center: 1-800-982-4237
Outages: appalachianpower.com/outages
or 1-800-982-4237



Access Code: 5318
Account Number: 07712-121842-09-6
DANIEL ADAMS
1184 LONG FRK RD
PECKS MILL WV 25547

Account Summary

Promotional Offer:

Billing Period	Due Date	Amount
04/27/21 - 05/26/21	May 27, 2021	\$4.86
Previous Balance & Payments		
Balance Last Statement		-\$58.50
Payment(s) Received By 04/28/2021		\$0.00
New Charges		-\$58.50
Total Amount Due		\$63.36
		\$4.86

PIAD!!!

Account Details

PAYMENTS

04/29 Credit Card Pymt
Previous Balance

- \$8.50

BUNDLED SERVICES

04/27 -05/26 Bundle

-Internet 200

-Phone

Retail 150.94

Savings -100.94

You Pay 50.00

Total Bundled Services \$50.00

ADDITIONAL SERVICES & EQUIPMENT

Internet

27 -05/26 Altice Gateway

10.00

Ways to Pay

Pay your bill, upgrade your service, or manage your account at suddenlink.com

Additional options:

Auto Pay

Manage at suddenlink.com

Support App

Download at suddenlink.com

In Person

Visit suddenlink.com

location near you

Phone

1-800-850-7651

From: [อนรรักษ์ ศรีจันทร์](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL]
Date: Saturday, July 3, 2021 10:58:00 AM

เรียนท่านผู้อำนวยการ

เนื่องจากกระผมไม่สามารถอ่านข้อมูลการแจ้งข่าวและเอกสารต่างๆจากทางท่านได้ครับเพราะถูกปิดกั้นในส่วนของการเรียนรู้และการใช้งานเอกสารต่างๆจากผู้แอบอ้างและขโมยผลงานต่างๆที่กระผมประดิษฐ์และศึกษารวบรวมเรื่องราวต่างๆจึงขอความกรุณาแจ้งเป็นเอกสารถึงทางสถาบันวิทยาศาสตร์แห่งประเทศไทยในเรื่องราวที่กระผมได้รับโอกาสจากทางท่านในการเข้าศึกษาต่อและทำการวิจัยและศึกษาในองค์กรของท่านด้วยครับ

กราบขอบพระคุณเป็นอย่างสูงครับ

นาย อนรรักษ์ ศรีจันทร์

03/07/2021เวลา09:56PMตามเวลาในประเทศไทย

From: [Lilian Castro](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL]
Date: Friday, July 2, 2021 1:54:03 PM

Need help please

From: [kimberlykahl](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] REG: Health care and COVID-19 vaccine
Date: Thursday, July 1, 2021 5:22:57 PM

I recently received a notice that the State of Illinois is aware I have had my Covid19 one shot vaccine. I was only finally able to get my shot [even though I am disabled by the Federal Government] because my mother fell and fractured her clavicle bone. At the location we were allowed to jump to the front of the line, because she was in the sling preventing her from moving her arm. I was using my cane to walk with her. She has yet to receive her notification from either the State of Illinois, the Railroad retirement board (her retired, deceased husband) that she has been vaccinated. We both carry our Covid19 cards with us. I am in receipt of my documents from Centers for Medicare & Medicaid Services recvd and dated 6/28/2021 mailed 6/23/2021. THE IMPORTANT PART HERE IS THE MAIL CARRIER WHOM DELIVERS OUR MAIL IS FRIENDS WITH A PERSON WHO CAUSED AN ACCIDENT IN OUR DRIVEWAY. I am fearful the Mail Carrier and his friend are deliberately delaying critical medical and information. Regarding my health and my mothers, further evidence of this delay is; I get food stamps for my mother and myself the renewal form for this was received open. I hand delivered the renewal form to our closest location. We have not reported him to our Park Forest Postmaster fearing we will stop receiving mail altogether. A substitute carrier reported him after she found our mail tucked under the matt under all the empty sorted containers. Last year we voted early, bye mail, but my

ballot was delayed so we went to our village hall to deposit our mail in ballots. I am functionally MUTE my only form of communication is usually the computer system. My mom is hard-of-hearing. Today she received a call from Humana telling her a script was ready for pick-up a Walgreens and had to explain she DOES NOT WANT HER scripts mailed because we cannot trust our mail carrier. The integrity of the health care files as well as computer files sent from locations are to be private. When I send a TIP to the FBI or even a communication to Washington, DC the need for privacy in personal communication is essential for the safety of all parties involved. {currently my gmail is being flooded with solicitations from both democratic and republican party members} BECAUSE I AM ON SSI I have no funds to donate to anyone! stay safe -kmk-

From: [cnewob](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Federal Integrity
Date: Tuesday, June 29, 2021 4:03:12 PM

My Federal Government has no integrity. My country has allowed us to be abused for four years. I can't get those years back. How I feel about my country I would never believe. No man has stood up and stopped Mr. Trump from his daily abuse to the people. No one demanded honesty. Our entire Congress has only assisted with Trump lies and abuse he delivered. There is not a single Republican that stopped Trump..

Terror is what I live with daily. What is so horrible, I am damaged from Trump . My own government has allowed me to be abused everyday.
Cynthia Bowen

From: [Lucas Hollela](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL]
Date: Tuesday, July 6, 2021 5:25:02 AM

Ok wellcome back tanzania

From: [Moran, Nancy A](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Cc:
Subject: [EXTERNAL] Research on glyphosate and honey bees
Date: Tuesday, July 20, 2021 5:38:11 PM
Attachments:

It is my understanding that you have invited input on the topic of glyphosate formulations and bee health. My research group works on bee biology and has some relevant recent results. I have attached a summary of this work, which has been conducted mostly in the last couple of years. I hope this information is useful.

I am copying to Dr. Erick Motta, who collaborated with me on this work.

Yours sincerely,

Nancy Moran

Nancy A Moran
Warren J & Viola Mae Raymer Chair, Professor
Integrative Biology, UT Austin
Austin TX 78712

From: [Susi Sheridan](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Wednesday, July 14, 2021 12:23:55 AM

The only effective way to prevent "improper political interference in the conduct of scientific research and the collection of data" and "the suppression or distortion of findings, data, information, conclusions, or technical results" is for the government to cease all funding of science and to stop making pronouncements about it.

The government has no business in the field of science and should not support "scientists and researchers of all genders, races, ethnicities, and backgrounds" nor advance "the equitable delivery of the Federal Government's programs."

Susi Sheridan, member of the public
Minnesota

From: [Sea ImpEx](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [WARNING: UNSCANNABLE EXTRACTION FAILED][EXTERNAL] Dangerous goods and defence goods total transport service
Date: Friday, July 9, 2021 10:00:42 AM

A Very Good day to you

Dear Sirs,

We would like you to give us the opportunity to introduce ourselves:
Sea ImpEx DK is a company specialized in the Transport.

Of: Industrial Equipment

Heavy-Lift units, Oversized units, Project Cargo,
high technology and defense equipment.

IMO Class Explosives and munition cargoes by Road, Sea and Air.

We have behind us a specific experience of more than 40 years.

Being an independent entity Sea ImpEx enjoys the confidence and support of ship' Owners
Managing cargo ships with a range in size that goes from 1.000 DWAT up to 25.000 DWAT
multipurpose ships and with own gear lifting capacity In excess of 500 metric ton per single
unit.

As well as Aircraft Charter of any size.

In our baggage experience there is the total transport and support in the estimation phase of
CIF

Cost for the supplier or from the EX-WORKS basis for the buyers / Receivers.

This for defense equipment and IMO Class 1 cargo munition, explosives for many Producers
and Governmental entities.

We would, therefore, very much have the opportunity to assist you in these types logistics.

We would appreciate to be put in contact with the department and / or person(s) within your
organization to start, hopefully, a successful dialogue.

IT IS THIS PROFESSIONALISM AND EXPERIENCE THAT WE CAN MAKE
AVAILABLE TO YOU AND YOUR
ORGANIZATION.

Looking forward to hearing from you,

remaining at your disposal for any further information You may require

Best regards,

Saverio Sears 



(Visit US web: www.sea-impex.com OR <https://www.army-technology.com/contractors/logistics/sea-impex/>

Sea ImpEx DK

From: [ASTRO SPACE EDUCATION CO Intl](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Thursday, July 15, 2021 11:41:34 PM

15 july 2021

In our now truly endangered society and planet. SCIENCE has been pushed aside n denied by those zealots who are hell bent on destroying democracy... They in their mob rule and violence and absurd baseless political maneuvering are in fact fighting to destroy the very planet they too must live on.

You politicos, legislators and also state governors know perfectly well who you are as you align into this self destructive anti everything mob rule. You choose to ignore that you in your insane zeal are destroying your own society and planet we all must share n cherish n respect in peace.

So, I - AS A CITIZEN OF PLANET EARTH DEMAND THAT YOU STOP THIS CONTRIVED ABSURD SELF DESTRUCTION NOW. IF YOU REFUSE. YOU AND ALL OTHERS and YOUR CHILDREN WILL NEEDLESSLY SUFFER THE DESTRUCTION OF DEAR and PRECIOUS IREPLACABLE LIFE DREAMS. ALONG WITH THE RUIN and DESTRUCTION OF OUR SOCIETY and PLANET...

From: [Katie Hughes](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Katherine Hughes public comment SI-FTAC RFI
Date: Friday, July 23, 2021 9:53:10 AM

We need a stable, educated voice not tainted by short lived opinions but rooted in scientific fact to guide us.

Climate change is real and we MUST act now to prevent disaster.

I wholly endorse the benefits of regenerative agriculture to lock Carbon into the soil. Nice spongy, healthy soil absorbs water, helps filter pollutants and reduces flooding. Any climate action plan that doesn't include pushing quickly for a healthy soil to lock Carbon in the ground will fail, because we must get rid of the carbon that has been building up, not just reduce what we emit this year.

Please ensure there is funding to promote healthier soil and to educate land owners, farmers, and the public sector on this issue.

Tilling is bad news for the soil.

Farmers need to use no till planters and plant cover crops at a minimum but these changes cost money for equipment

Thank you for your time.

Regards,

Katherine Hughes PhD

From: [Avi Dey](#)
To: [MBX OSTP Scientific Integrity RFI](#); [Avi Dey](#)
Subject: [EXTERNAL] Avi/Cafe T --Unable to attend virtual listening sessions --interested in submitting My PDF Document before July 28, 2021 Deadline
Date: Tuesday, July 20, 2021 8:55:15 AM

07/19/2021

Good Morning,

I would like more clarification on the value and benefits of submitting my short visual enhanced PDF Document I developed recently for "community wealth building" that appears to be a "good fit" to this announcement I received for Weave Newsletter, which had a presentation on your "listening sessions" follow up titled "Scientific Integrity and Evidence-Based Policymaking.

Avi/Cafe T Conversation: Titled "Coming Homebased emerging community service project, , social fabrics developmentAgain", my "virtual team" project for fairfax/N.Virginia community will be anchored with community tv media here. With "Twin" "social fabrics" development for our own community of 2 million + residents out of Virginia's 8 million with 2 key goals help our neighbors, friends, and family aspire and know more about
(01) healthy eat in daily life styles-- bring value of the latest scientific discovery, for example, gut-brain axis
(02) "Music is Medicine", for example, soundhealth.net initiative & nationwide network recently announced for all USA citizens.

Can you please help me to determine if my PDF "Community wealth building" Community TV anchored "weavenet Fairfax-N.VA" community service project would be a "good fit" to your initiative ?

And if I decide to submit this document for your agency's consideration if allowed to do so by your guidelines & procedures ?

Avi Dey

> _____

My Community Service EMAIL 02: [Avi Deu](#)

=====

Working ON ---Journey to Equity & Opportunity Community Wealth with Weave Proj Wisdom at N.Va Social Web_Cafe Twin Healthy Fx

=====

Scientific Integrity and Evidence-Based Policymaking

Those unable to attend the virtual listening sessions or who would like to provide additional information for consideration by the Task Force are welcome to submit a response to the [Request for Information \(RFI\) to Improve Federal Scientific Integrity Policies](#) that was issued on June 28, 2021 in the Federal Register. Responses to the RFI should be submitted to ScientificIntegrityRFI@ostp.eop.gov by Wednesday, July 28, 2021.

From: [bob costa](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Contact ASQ (amer. Society for quality) and "the Deming institute"
Date: Friday, July 9, 2021 7:11:43 PM

Sent from my iPhone

From: [Adam Wildavsky](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Wednesday, July 28, 2021 12:37:14 PM

From: Adam Wildavsky, a member of the public

Thank you for soliciting my opinion!

The goal “to help improve the effectiveness of Federal scientific integrity policies to enhance public trust in science” presumes that the first will positively affect the second. I don’t believe this to be the case. When science is funded by a government, the population suspects, usually rightly, that the research will tend to a direction that supports the government’s agenda. No regulation can surmount the verity that “He who pays the piper calls the tune.”

My view, I hope accurately representing Ayn Rand’s, is that government has no business in the field of science. The best and proper way to improve public trust would be for the government to stop funding science and stop making pronouncements about science. Science is a method, not an authority.

President Eisenhower noted his concern in his farewell address:

“The prospect of domination of the nation’s scholars by Federal employment, project allocations, and the power of money is ever-present and is gravely to be regarded.

Yet, in holding scientific research and discovery in respect, as we should, we must also be alert to the equal and opposite danger that public policy could itself become the captive of a scientific-technological elite.”

When Orwell warned us about a Ministry of Truth, he was not concerned that such a department would promulgate falsehoods, but rather that it is not the proper function of the executive or legislative arms of the government to determine truth or falsity.

I don’t expect my view to be influential, but I don’t know how to make a less radical suggestion that would still be effective.

Page 1 of 1

From: [E.G. Elias](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Climate and human health
Date: Tuesday, July 27, 2021 5:23:11 PM

The study of the Climate should not be conducted by a club. It is a global problem and should be handled by World Health Organization (WHO). A club of few nations cannot dictate on large and very populated countries such as China, India, Russia and others including industrial countries to follow on such club recommendations. We must also realize that the existing situation developed over decades and not overnight. It will take us decades to correct diplomatically over long time. The WHO should have a CLIMATE Service with a scientific board to decide priorities for their approach, e.g., if emission is the priority, it should be dealt with immediately even if will cost us loss of some the speed. Another example, they can recommend and encourage the development of electric cars.

The club in France has over \$61 Billion and is expected to go over \$100 Billion. Such money should doted to WHO to support the Climate section and not used for devious other services and lost.

Regards,
E. George Elias, MD, PhD.
Retired, Professor of Surgery. University of Maryland.

From: info1@micky-7.top on behalf of [semmy wu](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Hollow shaft motor
Date: Monday, July 26, 2021 2:08:48 AM

Hi Buyer,

Zozhi manufactures **Hollow & Solid Shaft Motor** for high pressure pump such as **AR,HAWK,INTERPUMP...** with good quality and pretty competitive price.

Please check our product link:

[>https://zz-pump.en.alibaba.com/product/1600057366919-812752926/best_choice_2hp_gear_motor_hollow_shaft_electric_motor.html?spm=a2700.shop_plgr.41413.16.ca72a6e1C8jiCz<](https://zz-pump.en.alibaba.com/product/1600057366919-812752926/best_choice_2hp_gear_motor_hollow_shaft_electric_motor.html?spm=a2700.shop_plgr.41413.16.ca72a6e1C8jiCz<)

THREE PHASE 4 POLES 1500RPM 50Hz

FRAME	POWER		RPM	COSf	EFF.%	VOLT	AMPERE
	KW	HP		P.F.		V	A
112M2-4	5.5	7.5	1430	0.82	84	400	12.1
112M3-4	6.2	8.5	1425	0.82	84	400	13.5
112L-4	7	9.5	1430	0.80	85	400	13.8
132S1-4	5.5	7.5	1430	0.82	84	400	11.7
132S2-4	7.5	10	1430	0.84	84	400	15.4
132M1-4	9.2	12.5	1430	0.90	85	400	17.8
132M2-4	11	15	1430	0.90	87	400	21.3
132M3-4	12.5	17	1430	0.88	84	400	26
160M1-4	15	20	1450	0.86	89	400	29
160M2-4	18.5	25	1450	0.86	90	400	34

Yours sincerely,

Semmy Wu
Sales Director

Add:No.155 Shangcun Qinxiyang Industry Zone,Fuan city,Fujian,China

From: [Critical Situation](#)
To:
Subject: [EXTERNAL] URGENT LETTER TO HIS EXCELLENCY MISTER THE PRESIDENT: CRITICAL SITUATION.
Date: Sunday, July 25, 2021 3:57:25 PM

URGENT LETTER TO HIS EXCELLENCY MISTER THE PRESIDENT.

Dear your Excellency Mister the President;

I have the honor to write you my request and I hope that you are fine.

The situation is critical and very difficult and outside of all the standards of ethics and human values.

I sent a lot of requests to the concerned United States authorities to obtain records, documents and information about my case and obtain information and payment of my assets; but unfortunately, no one answers me and at the same time people in Algeria attack me and poison me with harmful substances and with diabolical manner to make me crazy and liquidate me to prevent me from obtaining documents and my rights as assets to restore my life and protect myself.

The United States authorities and a lot of authorities around the world know that Allah (God) sent a lot of miracles and warnings and still because of me, Allah (God) defend me, so any hostilities against me is automatically considered hostilities against Allah (God).

I never harmed anyone and never interfered in the affairs of others; all what I did and do is defending myself, my nation and the humanity.

I did a lot of good to the international community and people around the world as the United States people and I sacrificed for the safety of all of them; I deserve respect and special care.

Dear your Excellency Mister the President;

I request you to issue an order to the United States authorities to give me, as soon as possible; records, documents about me and my case and information and payment of my assets
IMMEDIATELY

I am convinced that you respect Allah (God) and his will, please do not let wrath of Allah (God) happen because the misconduct of some people, they fight Allah (God) without they know that or maybe they know that.

Allah (God) can harm all, I do not want that; I pray for peace, safety and good for everyone.

Please help me, as soon as possible and save the American values.

Please Dear your Excellency Mister the President; accept the assurances of my kind regards.

Comments on U.S. food production and distribution

David G. Fisher

Department of Sustainable and Regenerative Living
Maharishi International University, Fairfield IA

July 24, 2021

Bio - MS and PhD in botany (University of Wisconsin); Alexander von Humboldt Fellow, Universität Göttingen, Germany; funded by the USDA and the Leopold Institute for Sustainable Agriculture for research in potato breeding; 20 publications in botany and crop breeding. Taught botany, environmental science, and sustainability (including organic agriculture) for about 40 years; lifelong avid gardener.

Introduction

Alarmed by the Covid-19 outbreak, I was inspired to write a book promoting a revival of the WWII victory gardens. That, in turn, led me to compare home gardens to the industrial food system point by point, from taste and nutrition to cost, safety, and yield. To my utter surprise, and contrary to what I had routinely taught in my environmental science courses, I found that pound for pound of food production, home gardens are vastly more efficient than the industrial food system while delivering far superior health, social, economic, and environmental outcomes. I expanded on this finding my book, *Just Grow It Yourself – Home Gardens Outshine Industrial Food*, due out August 10. I wrote it for both gardeners and policymakers, as each needs to understand the other's perspective in order to generate a much-needed gardening boom.

Industrial food has prohibitive external costs, unlike home gardens

The industrial food system's extraordinary inefficiency is mostly due to the enormous external costs it generates but doesn't pay for. Various estimates put these costs in multiples of \$trillions:

- \$12 trillion per year – Food and Land Use Coalition
- \$3 trillion per year in environmental costs alone – TruCost study for the UN
- \$4.97 trillion in externalities for U.S. industrial agriculture – Iowa State University
- External costs = 224% of industrial food's \$1 trillion in revenues – KPMG Global
- \$2.6 trillion: annual cost of wasted food to U.S. economy – *Food Fix*, Mark Hyman
- At least \$3.2 trillion: the true cost of U.S. food – Rockefeller Foundation

By contrast, home gardens generate no such externalities, and few internal costs. And even at average yield rates they can deliver more food per unit area of land than the industrial system, in which 40% of food production is wasted, as is 50% of fresh fruits and vegetables.

Home gardens' enormous efficiency advantage over industrial food has everything to do with thinking through innovative solutions to come up with new evidence-based policymaking. For the last sixty years the government, industry, and food scientists have advanced the false narratives that the industrial food system is a marvel of efficiency, safety, and precision, and that home food production has little or no potential to meet significant, let alone much or even most of our food needs.

Contrary to what might be expected, lawns—conveniently already the largest irrigated crop in America—have more than enough area when converted to home gardens to feed the country. They could provide a healthy diet complete in everything except Vitamin B12, which could be derived from a couple egg-laying hens per household. Densely populated areas with few lawns per capita would need to depend more on local food systems (see below), but even the largest cities have many unused lawns, empty lots, and rooftops that could be converted to food gardens.

Obviously, home gardens will not duplicate the meats, grains, dairy products, sweeteners, and soy that make up 85% of the American diet, primarily in the form of ultra-processed, low-nutrition commodities. But those are precisely the foods that have largely resulted in now 70% of the population being overweight and 43% obese, with nearly 50% either diabetic or prediabetic, not to mention incurring chronic illness from other diet-driven deficiencies. Something new and more effective than current policies is needed to address a truly drastic public health challenge.

Despite industry promises to become sustainable or regenerative, it is unlikely to transition to a form that will truly serve the public good. This is because the current food system depends on an ecologically extractive and socially exploitative business model deeply geared to deliver the cheapest food in the world (in proportion to income), with the lion's share of profits going to a small group of multinational corporations with inordinate amounts of control over the economy.

That said, attempting to switch overnight to home gardens as the principal source of food is also unrealistic. Rather, a well thought-out, evidence-based policy would favor transitioning to a three-tiered system in which home gardens are the anchor, supplemented by local foods such as farmers markets, CSAs, and urban food hubs. These, in turn, would be backed up by a third tier – a much reduced (and thus more easily sustainably reconfigured) distant form of industrial food. The relative sizes of these tiers would gradually shift as the populace begins to understand how much it has to gain. As an aside, the first and second tiers would not replace purely industrial uses of food crops such as corn and soy for fuel.

Home gardens also have much lower internal costs

Food system experts are generally aware of the many problems with industrial externalities, yet they've evidently missed the also substantial internal efficiencies of home gardens, whose per pound production of food incurs far less:

- Use of fossil fuels (because the energy expended is mostly human-generated)

- Carbon emissions (since very little in the way of fossil fuels is needed)
- Land use (as little as 1-2% of the 3 acres/American that industrial food requires)
- Soil erosion and organic matter loss (home gardens typically increase healthy topsoil)
- Synthetic chemicals (home gardeners usually avoid chemical pesticides and fertilizers)

With both external and internal costs vastly lower than those of the industrial food system (per pound of production), the far greater efficiency of home gardens is not surprising.

The extraordinary leverage of home gardens

To date, the principal strategies for achieving sustainable, healthy, and affordable food involve attempts to: 1) “sustainabilize” the industrial system while retaining its largely centralized control by a few corporate players; or, to 2) transition to an alternative system composed of decentralized, small local farms / community food webs. Both would continue to rely on farms to produce food and middlemen to distribute it (farmers markets notwithstanding), and proponents of both contend that with enough engineering, their favored model would be sustainable.

By contrast, home and community gardens do without farms and middlemen. As a result, they enjoy an extraordinary degree of efficiency-derived leverage—and thus the power to produce timely, “massified” results—that is lacking in the industrial, and to a lesser degree, local systems. The same could be said when comparing home gardens to hybrid strategies that adopt varying degrees of both industrial and local systems. Thus of all the proposed routes to food sustainability, home gardens are the:

Quickest

Eliminating industrial food’s externalities is such a formidable goal it would require a “generational” time scale to accomplish, even if the prohibitive transition costs and drastic changes to its business model could somehow be managed. Local food systems are better positioned, as they have already largely internalized their costs, but they have not been able to attain even 1% of the U.S. food supply so far. New farms, equipment, buildings, and supplies would still have to be financed, and an army of new farmers would have to be trained on a far larger scale and at a much faster rate than has happened to date.

By contrast, it has already been demonstrated that home gardens have the capacity to ramp up quickly, even with amateur gardeners. In World War II, 20 million victory gardens were started virtually overnight, providing 40% of the nation’s vegetable supply. Moreover, the ratio of home gardens to population today is 0.13, very near the ratio of 0.15 during the era of victory gardens in 1944. However, today’s home gardens produce only 6-8% of the country’s vegetables, which together with industrial produce supply only about 15% our calorie intake. So what would be needed is an evidence-based national campaign, similar to the quickly-rolled-out effort by the USDA in WWII, to inspire substantially increased home food production.

Gentlest

Home gardens are the least threatening alternative to the existing food system primarily because the industry will not at first perceive a threat to its near-total domination. That will allow home gardeners to accelerate production gently enough (though still relatively quickly compared to the other strategies) to avoid unduly disruptive shock waves. Then, once industry does recognize their broad public appeal, it will be more inclined to accommodate than fight it, which will paradoxically further ease its way.

Most powerful

The principal reason home gardens, per pound of food production, are so powerful is that they have so much unused potential. The amazing productivity of the WWII victory gardens provide one line of evidence, and Nigeria's production of 50% of its vegetables in home gardens on only 2% of its cropland is another. Why continue to waste all that unused potential? Especially when it brings so many additional benefits along with it (e.g., much needed exercise, exposure to nature, increased freshness and nutrition, greater food safety).

Easiest to implement

Compared to what it would take to transform the industrial system into a truly sustainable one (i.e., to fully internalize its costs by drastically redesigning its business model, then to educate the public about why resulting prices are so much higher), or to increase the capacity of local food well beyond its current 0.4% of food production, home gardens require by far the least amount of social and physical infrastructure upgrades required to produce much to most of the nation's food. This is because 33% of all households already have a food garden, 67% of all adults either have a food garden or are planning to start one, and a national infrastructure to deliver seeds, gardening, and canning supplies already exists. It's just a matter stepping up the already substantial participation of gardeners and production of supplies, which has been done before in a timely manner (again, the example of victory gardens).

Most economical

As indicated above, if industrial food were serious about becoming fully sustainable, it would simply internalize all its external costs. Except it isn't simple, as it would require a highly complex, gargantuan effort and hundreds of billions of dollars, which would drive up the cost of food well beyond what people have been conditioned to believe is reasonable. Internalizing any remaining external costs for local foods would be less challenging, but so far they have resulted in higher average food prices than what most people are willing to pay (cf. the stigma attached to higher prices for organic). By contrast, home gardens bypass virtually all the internal and external costs of producing industrial food, as well as most of the costs of local food production. The result is lower real costs for food.

Most enticing

Approached in the right way (with self-sufficient empowerment), home gardens are easily the most enticing way to inspire people to implement large-scale production of healthy food. This is because gardens are 1) driven by enjoyable activity with 2) relatively quick, satisfying results that 3) benefit gardeners and their families in a number of tangible ways. And given that sales of seeds, gardening, and canning supplies have gone through the roof in the spring of both 2020 and 2021, a gardening boom is already underway. Evidently the challenges of the pandemic, unemployment, and social disruption have made more people open to the advantages of self-producing a ready supply of healthy food.

Least likely to be undercut by predatory business practices

The reason industrial food has slipped into the habit of offloading far more than half of its production expenses onto other segments of society comes back to a fundamental failure of capitalism as we know it: the so-called “invisible hand” of modern economics. An unfettered marketplace and buyer short-term, financial self interest were supposed to automatically work for the good of all, but they never have. Although not all business players are unethical, enough are to set the operating tone of our entire economic system. That allows predatory practices to subvert fair and equitable competition, resulting in short-term benefits for some at the longer-term expense of many, or even all. That is what generates the \$trillions of industrial food’s external costs, with its massive, out-of-control exploitation, damage, and waste.

Local food systems, to their great credit, avoid the most destructive hegemonies of industrial food. However, even the locals are strongly impacted by it, as they must compete with conventional food in a culture that’s been conditioned to see artificially low prices as a good thing. That puts local food sources at a distinct disadvantage, which is likely a leading reason why they’ve never been able to get more than a tiny foothold in the food market.

Home gardens, by contrast, basically avoid predatory business practices, as they don’t engage in business in the usual sense at all, other than minimally depending on industrially produced seed, gardening, and canning supplies. That gives them an edge that even local systems can’t match.

Home Gardens: The most reliable way to ensure national food security

Precisely because home gardens have the greatest leverage to establish a new food system, they also have the greatest potential to ensure national food security in a timely manner. There are currently a number of threats to the U.S. food supply that have ultra-thin regional, national, or global safety margins, exacerbated by the increasing frequency of catastrophes. To wit:

The most immediate threats

- Continued or new pandemics (note the recent rise of the Delta variant)
- Extreme heat waves in the NW and NE, leading to mega-fires in the West

- Global supply chain disruptions such as the Ever Given blocking the Suez Canal
- Power losses like that in Texas this past winter
- Ransomware attacks that can shut down large companies and public services
- “Just-in-time” restocking: supermarkets typically have only a three-day supply of food
- Destructive winds and floods caused by storm events like derechos (e.g., the Midwest in 2020), hurricanes, tropical depressions, and mega-storm systems like Sandy
- Severe water shortages caused by extreme heat, droughts, and over-draught of aquifers

Ongoing threats

- Increasing frequency of food recalls
- Livestock diseases such as those that recently wiped out millions of chickens and pigs
- Rapidly increasing incidence of overweight (now 70 percent of the population) obesity (43 percent), and people who are diabetic or prediabetic (almost 50 percent).

Larger, overarching threats

- Climate change exacerbating the threats above, and others such as sea level rise
- Continued loss of topsoil 10-17 faster than it’s being replaced
- An overdue megaflood in the Central Valley of California

National policymakers generally know about these threats, but few are aware of the megaflood that is overdue for California’s Central Valley. This breadbasket, home to 7 million people, 230 crops, and 5 million cattle, supplies over half of the fruits, vegetables, and nuts produced in the U.S., and 8% of the nation’s total agricultural output. The last time it experienced a megaflood was in 1861-62, when it was inundated with 15-20 feet of water (immediately followed by a brutal drought). Geological records indicate that it also experienced megafloods at some point during the periods 1235-60, 1395-1410, 1555-1615, 1750-70, and 1810-20, about every 100-200 years. As 160 years have elapsed since 1861, it’s definitely overdue for another one, especially in view of the increasing turbulence of extreme weather events because of climate change.

Given these kinds of threats to the food supply, it makes sense as a matter of national security for evidence-driven policymakers to step up and promote the expansion of existing home food gardens, the starting up of substantial numbers of new gardens, and the establishment of community gardens for those who lack appropriate garden space (see below). These gardens are literally our most reliable hedge against sudden widespread food shortage.

Home Gardens: Greater Potential for a Reliable and Permanent Source of Food for the Hungry

No country can honestly call itself food secure when 18 percent of its citizens are chronically hungry; it’s an even more immediately alarming threat to national security than those mentioned

above. Even before Covid-19, the USDA estimated that 39 million Americans were food insecure, a number that has ballooned by at least 20 million in the pandemic, and families with children are being hit the hardest. Altogether, that's 18% of the U.S. population. It is not a matter of insufficient production; we produce far more than enough to feed the country, although much of it is rendered into high-calorie, low-nutrition food, or wasted. The problem is that many millions do not have adequate access to it.

The current system addresses food insecurity with assistance programs such as SNAP (whose recipients are often guided by heavy industry advertising toward junk food) and food warehouses and pantries. These band-aid programs are at best temporary and stigmatized sources of often unhealthy food, and tens of millions continue to go hungry in spite of them. How much better it would be if the food insecure were supplied with plots in community gardens, along with the support, know-how, tools, and the voluntary option to put them to use, with the goal of establishing permanent, healthy self-sufficiency. This would call for a well-thought-out national campaign to respectfully entice and empower people desperate for food to start growing their own – a great opportunity for a cadre of innovative, energized, evidence-driven policymakers. Given the enormous efficiencies of home gardening discussed above, it would likely cost far less than the \$92 billion the USDA annually spends on food and nutrition assistance.

Home gardens - Walking my (and our) talk

It's one thing to talk about how efficient home gardens are; it's another to demonstrate their efficacy firsthand. So borrowing from Morgan Spurlock's 2004 documentary "Super Size Me," in which he ate only at McDonald's for 30 days, recording the effects on his body, last year I ate only vegetables grown in my garden for the same amount of time. Like him, I arranged a physical exam before and after, and kept a journal documenting my experiences. I also recorded every ounce of the eight different vegetables I consumed, and exactly how much area was required to grow them. Based on that, and the fact that I was able to stay healthy and well fed throughout the month, I calculated that with a 35' x 40' garden I could sustain myself for a year. This year's garden of that size is now well underway (see illustrations below). It remains to be seen if my calculations will pan out; the results will be described on my author and garden website <https://justgrowityourself.com/> once the total harvest is in late this fall. An interim progress report is already there.

That represents the first level of food self-sufficiency—an individual model garden. The next level model is being constructed by two groups of food entrepreneurs here in Fairfield, Iowa (population 10,000). We are applying for grants to begin a network of community gardens in the city, with special attention to serving the low income and to offer them the option to not only start growing their own food, but to become permanently self-sufficient, or as close to that as feasible. A local food relief organization, The Lord's Cupboard, is cooperating with us toward that end. Coming up will be expansions to regional-, state-, and national-level demonstrations of the heretofore grossly underestimated efficacy of home gardens.



From: [Andrea Calilhanna](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] Notes Session 2 Science and Education
Date: Thursday, July 29, 2021 10:36:08 AM
Attachments: [White House session Andrea Mary Calilhanna.docx](#)

Dear Laurie,

Ahead of the meeting Session 2 Science and Education, I have attached some ideas for policy planning. There won't be time to discuss all of the ideas at the session so I include them here for inclusion in discussion by anyone interested in music and mathematics education. The ideas are listed in dot points as a snapshot of some of the infrastructure theory in the work I am doing for my PhD.

Best regards,

From: [polinfo](#)
To: [MBX OSTP Scientific Integrity RFI](#)
Subject: [EXTERNAL] SI-FTAC RFI
Date: Wednesday, July 28, 2021 2:30:27 PM

In response:

1. Stop lying.
2. Stop lying.
3. “follow the science” should ACTUALLY follow the science. The false agenda of mandating masks that are PROVEN ineffective against a virus from multiple studies is the classic example.
4. Stop lying about being able to control the weather/climate, like some later day King Canutes.
5. Stop lying about CO2 being the driver of global temperature.
6. Stop lying about the mRNA experimental inoculations (that are NOT “vaccines” by definition) and their supposed effectiveness.
7. Stop lying about PM2.5 so you can increase your fiefdoms while stealing tax money from other good causes.

And finally – stop lying! Even the low information types are catching on. That’s how bad your lying is.

From: [Greg Undeen](#)
To:
Cc: [EXTERNAL] SI-FTAC RFI
Subject: Wednesday, July 28, 2021 2:20:23 PM
Date:
Attachments:

To whom it may concern;

Attached is a comment submitted by Greg Undeen, a Journalist/ Public Interest Communicator, Organizer with The Climate Mobilization, and Advocate with LSEN AAAS. It is a fictional model of an organization that might better facilitate the communication of the climate emergency and lead administrators in the transition to mitigate climate change.

Sincerely,

Greg Undeen
Public Interest Communicator