

Request for Information: Public Access to Peer-Reviewed Scholarly Publications Resulting from Federally Funded Research

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We welcome the opportunity to address several issues raised by the questions laid out by the Task Force on Public Access to Scholarly Publications. Specifically, we would emphasize that expanding public access to federally funded, peer-reviewed scholarly articles would help respond to the well-considered recommendations of the Institute of Medicine's report on *The U.S. Commitment to Global Health: Recommendations for the Public and Private Sectors*. In particular, Recommendation 3-3 is noteworthy:<sup>1</sup>

The U.S. research community should promote global knowledge networks and the open exchange of information and tools that enable local problem solvers to conduct research to improve the health of their own populations.

- (A) Funders of global health research should require that all work supported by them will appear in public digital libraries, preferably at the time of publication and without constraints of copyright (through open access publishing), but no later than six months after publication in traditional subscription-based journals. Universities and other research institutions should foster compliance with such policies from funding agencies and supplement those policies with institution-based repositories of publications and databases.
- (B) The U.S. government, universities, and other research institutions should develop new methods—such as simplified web-based procedures for executing agreements like materials transfer and nondisclosure agreements—to expedite the sharing of information and research materials with researchers in low- and middle-income countries.
- (C) Scientists, clinicians, advocates, and other personnel involved in defined areas of global health should develop trustworthy websites that aggregate published literature, incorporate unpublished databases or clinical trial information, promote digital collaboration, and disseminate news and other information about common interests.
- (D) Universities and other research institutions that receive federal and philanthropic funding to conduct research should adopt patent policies and licensing practices that enable and encourage the development of technologies to create products for which traditional market forces are

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<sup>1</sup> Institute of Medicine. *The U.S. Commitment to Global Health: Recommendations for the Public and Private Sectors*. Washington, DC: National Academies Press, 2009.

not sufficient, such as medicines, diagnostics, and therapeutics that primarily affect populations in low- and middle-income countries.

The U.S. National Institutes of Health is the leading global funder of neglected disease research. Nearly 40% of neglected disease funding in 2010 came from the NIH.<sup>2</sup> Of course, the value of NIH research for global health extends well beyond just the work funded on neglected diseases. The Report of the UN Secretary General prepared for the High-Level Meeting on Non-communicable Diseases this past September highlighted: “Death and disease from non-communicable diseases now outstrip communicable diseases in every region except Africa, where the rate of such diseases is quickly rising. By 2030, non-communicable diseases are projected to cause nearly five times as many deaths as communicable diseases worldwide, including in low- and middle-income countries.”<sup>3</sup> So we would underscore the importance of publicly funded research for both U.S. and non-U.S. research institutions working on global health issues.

In keeping with the Institute of Medicine report recommendation, there would be no appropriate embargo period after publication before the public is granted free access to the full content of peer-reviewed scholarly publications resulting from federally funded research. As the IOM report recommends, “funders of global health research should require that all work supported by them will appear in public digital libraries, preferably at the time of publication and without constraints of copyright (through open access publishing), but no later than six months after publication in traditional subscription-based journals.” There would be no economic justification to have an embargo period on such publicly funded research in journals not specializing in coverage of neglected diseases, where the publication of occasional articles on these topics could be made available, without embargo, to the public without any risk to the subscriber base of the journal.

An embargo period of no more than six months would be consistent with requirements set by the European Research Council, the Wellcome Trust, and the Howard Hughes Medical Institute.<sup>4,5,6</sup> In complying with Division G, Title II, Section

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<sup>2</sup> PolicyCures. *Global Funding of Innovation for Neglected Diseases (G-FINDER)*. Sydney and London: PolicyCures, 2011. Available at:

<http://www.policycures.org/downloads/g-finder%20summary%202011.pdf>

<sup>3</sup> *Prevention and control of non-communicable diseases: Report of the Secretary-General*. Sixty-sixth session, United Nations General Assembly, A/66/83, 19 May 2011. Available at:

[http://www.un.org/ga/search/view\\_doc.asp?symbol=A/66/83&Lang=E](http://www.un.org/ga/search/view_doc.asp?symbol=A/66/83&Lang=E)

<sup>4</sup> European Research Council. 2007. *ERC Scientific Guidelines for Open Access*.

Available at:

[http://erc.europa.eu/sites/default/files/document/file/erc\\_scc\\_guidelines\\_open\\_access.pdf](http://erc.europa.eu/sites/default/files/document/file/erc_scc_guidelines_open_access.pdf)

218 of PL 110-161 (Consolidated Appropriations Act, 2008), the NIH’s Public Access Policy currently allows journal articles “to be made available no later than 12 months after the official date of publication.” Efforts to reduce further the delay to access to U.S. publicly funded research would be most welcomed.

The U.S. Copyright Act of 1976 prevents government employees from claiming copyright (or assigning it to journals) to publications they author, whether scholarly, peer-reviewed research or not. Yet public access—even to such journal articles written by government employees—might be improved through centralized approaches to managing public access. For example, we conducted a preliminary analysis of publications in PubMed.gov by three government agency heads—Dr. Francis Collins, Director of the U.S. National Institutes of Health, Dr. Margaret Hamburg, Director of the U.S. Food and Drug Administration, and Dr. Carolyn Clancy, Administrator of the Agency for Health Research and Quality—in the years 2010, 2011 and so far in 2012. Of the citations posted on PubMed.gov, we found that overall, full-text availability of journal publications by these three government agency heads only was accessible 42% of the time through the one-click away icon of “Free PMC Article” or “Free Article”.

We are not suggesting that these outstanding public servants bear responsibility for ensuring that their publications are one-click away on PubMed Central, but that PubMed Central be provided the resources it needs to do this with greater regularity as a centralized approach to managing both peer-reviewed scholarly publications that are publicly funded and also as a source for full-text publications authored by government employees.

	Year of Publication	No. of abstracts on PubMed	No. of abstracts on PubMed with article readily available*	% of abstracts with article readily available in PubMed
Francis Collins, NIH	2012	2	1	50%
	2011	17	6	35%
	2010	23	17	74%
	<b>Totals:</b>	<b>42</b>	<b>24</b>	<b>57%</b>
Margaret Hamburg, FDA	2012	0	0	N/A
	2011	2	1**	50%
	2010	4	4	100%

<sup>5</sup> Wellcome Trust. 2007. Conditions under which a Grant is Awarded. Available at: [http://www.wellcome.ac.uk/stellent/groups/corporatesite/@sf\\_central\\_grants\\_admin/documents/web\\_document/wtx026668.pdf](http://www.wellcome.ac.uk/stellent/groups/corporatesite/@sf_central_grants_admin/documents/web_document/wtx026668.pdf)

<sup>6</sup> Howard Hughes Medical Foundation. 2007. Public Access to Publications. Available at: <http://www.hhmi.org/about/research/sc320.pdf>

	<b>Totals:</b>	<b>6</b>	<b>5</b>	<b>83%</b>
Carolyn Clancy, AHRQ	2012	2	0**	0%
	2011	13	1	8%
	2010	11	1	9%
	<b>Totals:</b>	<b>26</b>	<b>2</b>	<b>8%</b>
<b>Overall totals:</b>		<b>74</b>	<b>31</b>	<b>42%</b>

\*By “readily available,” we refer to the PubMed.gov feature of flagging some journal articles with one-click away access, either as “Free PMC Article” or “Free Article”. Some of the articles are available on-line for free, but several clicks away. Others are not obviously accessible to non-subscribers to the journal.

\*\*These articles are reportedly “in process” in PubMed.

The White House RFI also calls for “analyses that weigh public and private benefits and account for external market factors, such as competition, price changes, library budgets, and other factors.” In so doing, we would suggest that such analyses be viewed through the lens of several key policy considerations: 1) the context of how much public funding has gone into the research that led to the publication compared to the value added editing done by the journal (noting, of course, that peer review is usually done at no cost to the journal, apart from organizing such review); 2) the potential costs of delayed publication, including the scenario whereby life-saving treatment options might not become known to patients or health care providers in a timely way when publicly funded research might otherwise have made such options known; 3) the value added that might result from creating collections of publicly funded research--absent the transaction costs of seeking copyright permission from multiple journals--for republishing or providing links to public access versions, particularly for those in resource-limited health care settings (e.g., a specialized collection on the diagnosis and treatment of a neglected tropical disease); and 4) the alternative policy option that public funding, now supporting journal subscription costs, could be directed to supporting open access institutional repositories and open access journals.

We have argued elsewhere that:

This calculus of ‘pay now or pay more later’ might guide where the public ought to direct its investments to maximize the returns to the healthcare system. For example, in the value chain of scientific journal publication, paying the publication fees for open-access journals is one way of supporting a business model that encourages the sharing of knowledge. Going further, the U.S. government could develop a system of supporting open-access journals that publish peer-reviewed, publicly funded research. For those open-access journals that charge publication fees, it could build support into

the direct or indirect cost structure of grants. For those open-access journals that do not charge fees, it could provide direct or indirect subsidies. Either way, it could support journals that provide open access rather than impose subscription fees on patients, providers, and universities. This support could factor in transition costs, the citation impact factor of the journal in that field, the rejection rate, and the number of publicly funded research articles published by the journal.<sup>7</sup>

Finally, we would flag concerns raised over access to building blocks to knowledge more generally. Just as the private sector focuses on copyright, patents and trademarks as an incentive for investment, the public sector also should consider the strategic use of intellectual property rights in ensuring an enabling environment for innovation. These concerns have been reflected in the adoption of the Bermuda Rules, whereby leading funders of the Human Genome Project required research centers to deposit the sequencing of every 1000 base pairs on-line into the GenBank within 24 hours of completion. This purposefully prevented the patenting of our human genetic endowment through defensive publishing of prior art.<sup>8</sup> Along similar lines, the NIH issued “Principles and Guidelines for Sharing of Biomedical Research Resources” in December 1999. This guidance counseled against exclusive licensing or even patenting if the government-funded research yielded “a broad, enabling invention that will be useful to many scientists, or multiple companies in developing multiple products, rather than a project or product-specific resource.”<sup>9</sup> And most recently, the *New England Journal of Medicine* piece on “Copyright and Open Access at the Bedside” reminds us that protecting building blocks of knowledge for broad public use must extend to copyrighted tools, like the Mini-Mental State Examination.<sup>10</sup> That a newer cognitive screening tool—the Sweet 16—could be removed from being available on an open access basis from the Internet because of a copyright dispute makes this case especially worrisome. This incident serves as a useful warning of the need for the U.S. government to take strong and strategic action to ensure fair returns from publicly funded investments and an enabling environment for innovation.

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<sup>7</sup> So AD, Stewart E. “Sharing Knowledge for Global Health,” in *The US Commitment to Global Health: Recommendations for the Public and Private Sectors*, Institute of Medicine Committee on the U.S. Commitment to Global Health. 2009, page 271.

<sup>8</sup> Marshall E. “Bermuda Rules: community spirit, with teeth.” *Science* 2001; 291: 1192.

<sup>9</sup> National Institutes of Health, U.S. Department of Health and Human Resources. “Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice,” *Federal Register* 1999; 64(246): 72090-72096.

<sup>10</sup> Newman JC, Feldman R. “Copyright and Open Access at the Bedside,” *New England Journal of Medicine* 2011; 365: 2447-2449.