

May 27, 2008

NIH Public Access Staff
National Institutes of Health
Transmitted via <http://publicaccess.nih.gov/comments2/comments.htm>

RE: Request for Information: NIH Public Access Policy
NOT-OD-08-060 (March 28, 2008)

To the National Institutes of Health:

These comments are submitted on behalf of the American Physiological Society (APS). In addition to its views on the policy implications of the NIH proposal, the APS is submitting a legal analysis jointly commissioned by the APS and the American Association of Immunologists (AAI). The legal analysis was originally submitted November 16, 2004, in response to NOT-OD-04-64 (September 3, 2004) and was submitted with our earlier comments on March 17, 2008. In NOT-OD-05-022 (February 3, 2005), NIH dismissed several issues raised in our legal analysis by stating that the points were not relevant since the May 2, 2005 Public Access Plan was voluntary. With the release of NOT-OD-08-057 and now NOT-OD-08-060, the NIH Public Access Policy is no longer voluntary, which now makes certain legal issues raised in the earlier analysis germane.

The APS/AAI legal analysis may be found as Attachment A to the APS comments to NOT-OD-04-64 (September 3, 2004) which are posted at <http://www.dcprinciples.org/responses/index.htm>.

Request for a Rulemaking

On March 7, 2008, NIH announced that it would conduct a public meeting on March 20, 2008, to discuss the agency's implementation of the Revised Policy. That notice also announced that NIH would publish a Request for Information (RFI) in the Federal Register [NOT-OD-08-060 (March 28, 2008)] during the month of March, and that NIH would respond to comments within 120 days after the close of a 60-day comment period. However, that notice states that the Revised Policy will nevertheless go into effect on April 7, 2008.

APS is pleased that NIH has chosen to solicit the public's views regarding the important issues raised by the Revised Policy and looks forward to participating in that process. We believe, however, that NIH's "regulate first, ask questions later" approach not only violates the letter of the Administrative Procedure Act (APA), but that it also violates the spirit of that statute.

The APA requires that regulated entities and the public be given an opportunity to comment on the content of a regulation before it goes into effect, absent emergency circumstances -- an exception that is not relevant here. The APS believes that NIH is obliged to engage in notice and comment rule-making since the courts have held that the failure to engage in notice-and-comment rulemaking cannot be cured by an agency's acceptance of comments after the effective date of a legislative rule such as the Revised Policy. In other words, permitting the submission

of views after the effective date of the policy is no substitute for the right of interested persons to make their views known to the agency in time to influence the rulemaking process in a meaningful way. Consequently, the APS respectfully requests that HHS and NIH stay the effective date of the Revised Policy and grant the rulemaking petition that was submitted to HHS on January 11, 2008 as soon as possible.

The NIH apparently recognized that it might have to comply with the APA in 2005. NOT-OD-05-022 stated:

The Policy does not require investigators to do anything other than what the current rules require. While funding recipients may follow the Policy to fulfill some of their existing reporting requirements they need not do so and may continue to provide hard copies of publications.

Inasmuch as the April 2008 policy now mandates deposit of manuscripts, this removes any flexibility in terms of how to comply. Thus, it is our view that as a mandatory requirement, the proposed policy is a rule-making which means that APA notice and comment and other procedural requirements for final agency actions must be followed.

Recommendations

The APS supports the principle of public access to science but believes that the NIH plan is not the right approach because it is not a collaborative endeavor. The implementation of this policy will come at great cost to the NIH, the research community and the American taxpayer. It will also cause disproportionate harm to not-for-profit societies that publish high-quality journals containing a significant amount of NIH-funded research. This group includes many publishers who have been at the forefront of providing free public access from journal websites within 12 months after publication.

The APS believes that NIH could have achieved greater success 3 years ago had it enhanced the existing MedLine/PubMed web site to enable full text searches of articles on the journals' own websites. Such searches would yield links to finished articles on those websites rather than access to manuscripts as PMC now provides. A number of publishers were interested in this approach, which would have led to the development of a comprehensive search engine that would do for biomedical research what search engines such as Google and Yahoo do for the web as a whole. The APS urges NIH to revisit this approach because it has a number of advantages to all parties. For NIH, this arrangement would make it possible to search the text of all biomedical research articles and not just the 10% that are based on NIH-funded research. Journals, and especially high-quality journals that publish a significant proportion of NIH-funded research, would still be able to determine their own access policies within a 12-month window and based upon their own cost recovery requirements. Finally, and perhaps most importantly, instead of access to manuscripts, this would make it possible to locate the final copy-edited articles of record presented in context with links to related materials such as commentaries and corrections.

Specific Problems with the New Policy

1. **Incorrect terminology**

The policy implements Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008) which states:

SEC. 218. The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.

The Public Access Frequently Asked Questions (FAQs) posted on January 11, 2008, has created confusion because it used the wrong terminology. In numerous places the document refers to journal articles rather than final peer-reviewed manuscripts as stated in the legislation. Specific instances where this occurs may be found in the answers to question 1 under General Information and questions #1 – 7 under Scope of the Policy.

The confusion caused by multiple references to journal articles may encourage investigators to submit final published article to PubMed Central in violation of revised copyright agreements made in good faith by publishers such as the APS that grant NIH funded authors the right to make their accepted manuscripts publicly accessible through PMC 12 months after publication. NIH clearly knows the difference between final peer-reviewed manuscript and the final published article as evidenced by the FAQ response provided under C (“How to Comply With the Policy - #5. What is the difference between a final peer-reviewed manuscript and a final published article?”). **All improper references to journal articles should be replaced immediately with correct references to final peer reviewed manuscripts. Moreover, NIH should draw attention to the correction and monitor information being disseminated by third parties to ensure that the misconception is not perpetuated.**

2. **Scope of the Policy**

The language in Section 218, PL 110-161 suggests that NIH-funded investigators must deposit every accepted manuscript into PMC whether or not the actual research reported in a given manuscript was supported by NIH. This is a significant issue for investigators who might receive funds from multiple sources including private sources. There is an implied threat that failure to do so might jeopardize future requests for NIH grant support. This requirement vastly expands NIH “ownership” of its grantees’ work. The 2005 NIH policy focused solely on the research funded by NIH. **NIH must clarify the scope of the policy to ensure that investigators know with certainty which research manuscripts they must submit. Moreover, it should provide justification for its expansive claim to its grantees’ works.**

The 2005 voluntary policy stated that it did “not apply to contributed book chapters, editorials, reviews, or conference proceedings.” Rather, it applied “only to peer-reviewed research publications.” This was consistent with statements Dr. Zerhouni made during an October 2004 meeting with publishers. During that meeting, Dr. Zerhouni encouraged publishers to maintain the subscription base of their journals by publishing reviews and other non-research materials.

The taking of review articles is against the spirit of the original NIH policy, and NIH is using the following statement to defend this, "The Policy applies to all peer-reviewed journal manuscripts. The Policy does not apply to non-peer-reviewed materials such as correspondence, book chapters, and editorials." Unfortunately, the statement is completely nonsensical. Review articles are peer reviewed just like correspondence and editorials--often just by an Editor or two, often by outside reviewers, and this is all considered peer review. To say that some content in a peer-reviewed journal is peer reviewed, and some is not, is incorrect. The REAL difference is that review articles, and other types of editorials, are commissioned by a publisher. NIH is making the wrong distinction. Also, books are certainly peer reviewed!! Just because they don't use the same systems journal publishers do, does not mean they are not peer reviewed!

The inclusion of reviews under the 2008 mandatory policy breaks Dr. Zerhouni's promise to publishers, confuses the role that publishers play in commissioning these articles, and will undermine the economic viability of these same society journals.

The 2008 policy also threatens to exacerbate problems caused by NLM's flawed implementation of the 2005 policy. The policy that went into effect on May 2, 2005 clearly stated that it "focused on final peer-reviewed manuscripts and publications that result from research supported, in whole or in part, with direct costs from NIH." However, NLM failed to create a system that would screen out submissions that fell outside the scope of the policy. As a result, publishers had no choice but to police the site themselves and request removal of non-compliant articles one-by-one in order to defend their legitimate copyright interests in those items.

Under the 2005 voluntary Policy, investigators only submitted 4% of the NIH-funded manuscripts, with publishers submitting another 20-25% of the eligible manuscripts. Under a mandatory Policy, the volume of investigator submitted manuscripts will increase dramatically and so will the burden on publishers to make sure that authors comply with the terms of their copyright agreements. **It is critically important for NIH to work with publishers to modify the NIH manuscript submission site to ensure that only manuscripts eligible for submission may be uploaded.** As a publisher, the APS is prepared to work with NIH to address these issues.

Another reason why non-compliant uploads may be expected to increase is confusion caused by NIH's failure to make a consistent distinction between peer-reviewed manuscripts and articles in its FAQ. It is therefore all the more urgent that NIH modify its submission site to prevent the upload of non-compliant articles. Absent such action, it is difficult for publishers to believe that the NIH has any meaningful interest in protecting publishers' copyright.

Publishers have asked NIH to help protect publishers' copyrights by creating a database of journal embargo periods as a means of assisting authors to comply. The request was denied because NIH did not want to influence the submission decisions of their investigators. There is a great tradition in scientific publishing that it is unethical for the funding agencies to influence where and how an article was published. However, NIH has now created a list of journals (http://publicaccess.nih.gov/submit_process_journals.htm) that submit articles directly to PubMed Central on behalf of authors. By providing the list, NIH may be perceived as

encouraging authors to publish in a small subset of journals that have established a favorable relationship with the agency.

NLM's Mission

The preservation of the biomedical literature is a responsibility mandated in NLM's authorizing legislation, found at 42 U.S.C. 286(b)(1). While the NLM has done an excellent job of preserving the printed biomedical research literature going back to 1836, it has not devised a suitable plan to do so for digital content. The APS and other publishers have urged NIH to exercise its responsibility to preserve digital journal content in collaboration with journal publishers. Many publishers whose content will be subject to the new policy previously offered to work with NLM to preserve the digital record by depositing the entire content of their journals for use within the NLM. NLM rejected this offer. Instead, the current plan will only preserve articles funded by the NIH, which comprise just 10% of the total biomedical literature.

Many publishers have expressed a willingness to work with NLM on digital preservation and would deposit both NIH and non-NIH funded content to create a digital archive that would fulfill many of the goals of the NIH Public Access Plan. The viability of the archive could be assured through its use on the NIH campus and within the NLM with the understanding that public access would be provided via a link to the publisher's online journal. In so doing, NIH would be able to preserve the scientific literature, maintain an archive for portfolio management, have the ability to search the entire scientific literature, and direct the public to free access available from the publishers. The maintenance of a complete archive by NLM would enable NIH to utilize it to set its research priorities, something that cannot be done with an archive that contains only 10% of the biomedical literature.

The APS as a scientific publisher

The American Physiological Society is a not-for-profit scholarly association founded in 1887 to promote the advancement of physiology. Today the Society has nearly 11,000 members who are scientists involved in physiological research and the teaching of physiology. APS members hold positions at colleges, universities, and medical schools and in industry, government, and independent research institutions. In the fulfillment of its mission, the Society publishes peer-reviewed journals; sponsors scientific meetings and conferences; and provides professional development opportunities for its members as well as educational and mentoring programs to identify, encourage, and train future physiologists. For its efforts in the latter areas, the APS was awarded the 2003 Presidential Award for Excellence in Science, Mathematics, and Engineering Mentoring.

The Society publishes 14 journals that provide venues where research findings are validated through peer review and disseminated to other scientists. In 2007, 8,710 manuscripts were submitted to APS journals for peer review, and 4,642 of those manuscripts were ultimately published. The Society's oldest journal is the *American Journal of Physiology*, which was founded in 1898, and its newest journal is *Physiological Genomics*, which was founded in 1999.

Thank you for considering the comments we have submitted on behalf of the American Physiological Society.

Sincerely,

Handwritten signature of Irving H. Zucker in black ink.

Irving H. Zucker, Ph.D.
President, American Physiological Society

Handwritten signature of Martin Frank in black ink.

Martin Frank, Ph.D.
Executive Director, APS

Enclosure