

**Comments of The American Association of Immunologists
In Response to the National Institutes of Health Request for Information:
NIH Public Access Policy (NOT-OD-08-060 -March 28, 2008)
May 30, 2008**

Transmitted via <http://publicaccess.nih.gov/comments2/comments.htm>

The American Association of Immunologists (AAI), a professional association of more than 6,500 research scientists and physicians dedicated to understanding the immune system, and the publisher of *The Journal of Immunology (The JI)*, the world's most cited immunology journal, respectfully submits the following comments in response to the National Institutes of Health's (NIH) March 28, 2008 "Request for Information: Public Access Policy" (RFI) (Notice number NOT-OD-08-060).

AAI has deep concerns about the NIH Public Access Policy ("Policy") and plans for its implementation. The Policy, as enacted by the Consolidated Appropriations Act of 2008 (P.L. 110-161), requires 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."*

While AAI strongly supports - and successfully implements - activities to enhance access to scientific information and publications, we continue to believe that the Policy will duplicate, at great cost to NIH and to taxpayers, publication services which are already provided cost-effectively and well by the private sector. The private sector, including not-for-profit scientific societies, already publishes - and makes publicly available - thousands of scientific journals that report cutting-edge research funded by both NIH and other public and private entities. Rather than creating a new government bureaucracy, a particular burden in this era of severe budget constraints, NIH should partner with these publishers to develop a plan that enhances public access while also addressing publishers' key concerns, which include ensuring journals' continued ability to provide high quality, independent peer review of NIH-supported research.

AAI is concerned that the information that NIH has provided to investigators and institutions is confusing and, in some cases, mischaracterizes the plain language of the federal law. The Consolidated Appropriations Act of 2008 (P.L. 110-161) requires *"(t)hat the NIH implement the public access policy in a manner consistent with copyright law."* And yet, in its Notice and Revised Policy Statement dated January 11, 2008 (NOT-OD-08-033), NIH shifts what is clearly its legislative responsibility to ensure (*i.e.*, that the Policy respects publishers' copyright rights) to institutions and investigators: "Institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles fully comply with this Policy." This is clearly creating concern and confusion among investigators and institutions and must be addressed in a way that eases compliance for authors while respecting publishers' rights. As the NIH deflects this responsibility, it accepts whatever the authors send to PubMed Central (PMC) without confirming the existence of copyright agreements with the publishers. This has resulted in NIH consistently posting material which violates copyright

agreements with publishers, requiring publishers to seek out the violations and bring them to NIH's attention. In addition, a recent NIH directive by Michael Gottesman, Deputy Director of Intramural Research ("NIH Employee Procedures for Complying with NIH Public Access Policy," May 15, 2008), which requires intramural investigators to use NIH submission forms for all journals and to reject the use of publishers' forms (irrespective of whether they comply with the Policy), has created confusion for NIH investigators and an administrative burden for publishers. [Publishers' submission forms often include - in addition to copyright transfer agreements - statements regarding Conflict of Interest and Author Responsibility (*e.g.*, appropriate approval for human and animal use, prior publication history, the availability of unique materials, responsibility for scientific integrity, etc.) that authors are required to sign.]

AAI also has serious concerns about the legality of the Policy. Many of these concerns were addressed in great detail in a legal analysis commissioned by AAI and the American Physiological Society (APS) in 2004, when NIH had proposed a mandatory program (NOT-OD-04-64, September 3, 2004). This legal analysis, which was submitted to NIH on November 16, 2004, and resubmitted via an electronic link in our March 14, 2008 comments (responding to NOT-OD-08-057), addresses legal issues that NIH had dismissed as irrelevant when the NIH plan was initially implemented as a voluntary policy. With the passage of the Consolidated Appropriations Act of 2008 (P.L. 110-161), which made the Policy mandatory, key legal issues raised in this analysis (see http://www.aai.org/News_Board/CommentsNIHPublicAccess.pdf), including the following, must now be addressed:

1. whether NIH has complied with the Freedom of Information Act (and has considered its impact on patent applications);
2. whether NIH has complied with the provisions of the Administrative Procedures Act, including whether the notice provided to the public under this Act, and the opportunity for public comment, has been satisfied;
3. whether NIH has complied with the provisions of OMB Circular A-76;
4. whether NIH has complied with the Regulatory Flexibility Act; and
5. whether NIH has complied with the Paperwork Reduction Act.

Other legal/procedural concerns include the following:

1. NIH moved forward with the implementation of this Policy even as it announced the imminent publication of this RFI. In its March 7, 2008 notice [NOT-OD-08-057], NIH announced that it would issue an RFI later in March and respond to comments after a 60-day comment period. Yet NIH went ahead to implement this Policy with an effective date of April 7, 2008. In addition to the obvious legal flaws with this approach, it creates a sense that the NIH is neither interested in, nor willing to work with, the stakeholders who are deeply affected by this new Policy. NIH should proceed with implementing this Policy only after formal Notice and Rulemaking.
2. There are problems with the implementation guidance on the NIH website. While NIH appears to have corrected many of these errors in early May, there were serious problems for several months, including but not limited to the frequent incorrect use of the phrase "journal article" when it should have used "final peer reviewed manuscript."
3. NIH has created an appearance of favoritism by posting on its website a list of journals which submit authors' articles directly to PMC

(http://publicaccess.nih.gov/submit_process_journals.htm). Authors might perceive these publishers as preferred by NIH, their funding agency, dealing an unfair blow to other publishers who are not submitting authors' articles but who comply fully with the Policy.

In written (March 14, 2008) and oral (March 20, 2008) comments to NIH regarding the implementation of the Policy, AAI identified and requested additional information that stakeholders needed in order to be able to submit thoughtful comments in response to this RFI. This information has not been provided; therefore, AAI again respectfully requests that NIH respond to the following questions and provide stakeholders with an opportunity to comment before the Policy is implemented or enforced:

1. What are the total funds that were expended on implementing the voluntary NIH Public Access Policy (May 2, 2005 – January 11, 2008)?
2. What is the cost anticipated for implementation of the mandatory Policy in Fiscal Year (FY) 2009?
3. How much of the cost anticipated for implementation in FY 2009 will be a one-time implementation cost, and how much will be an annual implementation cost?
4. In responding to the above three questions, please report the cost incurred by the National Library of Medicine (NLM) as well as the various NIH Institutes, Centers, and Offices involved, including:
 - a) the number of FTEs and contracted services used to accommodate this initiative;
 - b) the cost of personnel and administrative services for this program (including associated space for infrastructure and personnel);
 - c) time spent directly on the promotion, management, enforcement and assessment of this program to/by NIH grantees and the public; and
 - d) all costs associated with network infrastructure improvements including but not limited to bandwidth capabilities, server capacity, and equipment.
5. What steps is NIH taking to ensure that it posts only articles that comply with a particular publisher's embargo period?
6. Who will be responsible if the publisher's embargo period (and therefore the publisher's copyright rights) is violated?
7. Who will ensure that NIH complies with a publisher's copyright rights once a manuscript is submitted (*i.e.*, who will make sure that NIH does not transfer a manuscript to any other entity/repository without permission from the publisher)?
8. Who within NIH/the various Institutes will be responsible for determining whether a grantee is in compliance? (Institute directors, Program officers, etc.?)
9. What will be the penalties for non-compliance by a grantee? Will it matter if the non-compliance is intentional or inadvertent?
10. Why won't NIH accept the "Linking Proposal" offered to NIH in 2005 by fifty-seven not-for-profit scientific publishers, which would provide seamless links on PMC to the journals' websites, enable readers to access the full text of any article funded by NIH (and in many instances, the full text of *all* articles published in the journal, irrespective of funding source). This proposal has the following advantages:
 - a) it provides the public with free access to all published articles funded by the NIH;
 - b) it provides access to the final, copy-edited article of record (and any related materials, including corrections);

- c) it is cost effective, since the NIH would not have to create a new repository, educate grantees about compliance and copyright, or monitor for compliance;
- d) it addresses publishers' copyright concerns;
- e) it satisfies the new law; and
- f) it complies with copyright law by ensuring that an article cannot be posted before the journal's embargo period is over.

In subsequent conversations with NIH about this Linking Proposal, publishers offered to consider ways to satisfy NIH's need for a repository of all NIH-funded works, *i.e.* to help NIH populate a "dark archive" for internal NIH use only.

In addition to the above questions, AAI respectfully requests answers to the following questions:

1. How will NIH address allegations of/evidence regarding plagiarism, including issuing corrections and retractions?
2. How will NIH ensure that manuscripts accepted for publication but not ultimately published (due to legal or other issues arising between the date of acceptance and the date of publication) are not posted?
3. How will NIH provide publishers with the data necessary to evaluate the effect of this Policy on their business model (including their subscription base)? Will NIH provide publishers with PMC usage (and other relevant) statistics?
4. Since publishers invest millions of dollars in the publication process (including peer review, editing, design, printing, and posting online), will NIH compensate publishers for their loss of revenue when PMC posts articles within 12 months after publication?
5. How will NIH ensure that it posts only manuscripts eligible for posting under this Policy, and how will NIH ensure the prompt removal of manuscripts which should not have been posted? To date, the burden of ensuring compliance has fallen to publishers who have been forced to expend time and resources monitoring the PMC site and contacting NIH to request removal of articles which have been posted in violation of journals' copyright rights.
6. How will NIH prevent the piracy, alteration, re-publication, or other illegal use of copyrighted material that is published on PMC? Will NIH notify publishers and provide them with the information necessary to protect their copyright?
7. How will NIH prevent "repurposing," *i.e.*, modifications to the manuscript by authors or NIH that result in variations from the original manuscript? This includes inadvertent repurposing (e.g., inserting links to databases or other articles).
8. How will NIH ensure the inclusion of - and protect - publisher and society trademarks and branding? Absence of these proprietary marks may confuse or mislead readers as to the owner of the copyright (or the existence of copyright), and may result in inadvertent misuse.
9. How will NIH prevent the distribution of copyrighted material to sites outside the United States if publishers do not grant approval?
10. Since the law applies to "all investigators funded by the NIH," how will NIH address situations where investigators have minimal NIH funding and depend on another primary funder who objects to submitting to PMC?

11. How will NIH educate Principal Investigators (“PIs”) and their institutions about their responsibilities to ensure that all authors submitting manuscripts based on funds from their grants are aware of, and comply with, the Policy? What will be the penalties to PIs and their institutions for failure to comply? Will it matter if there has been a good faith effort to comply?
12. What is NIH doing to ensure that authors, institutions, and publishers are aware of this Policy and have an avenue for prompt responses to questions arising under it?
13. How will NIH ensure that the law is being followed, particularly the following provision: “*Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law*”?