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**Comments of The American Association of Immunologists
Regarding the Implementation of the NIH Public Access Policy
Notice Number: NOT-OD-08-057
March 14, 2008**

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 regarding the implementation of the National Institutes of Health’s (NIH) Public Access Policy.

AAI has strong concerns about the implementation of the NIH Public Access Policy. 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.*”

AAI continues to believe that the NIH Public Access 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 also concerned that the information that NIH has provided to investigators and institutions 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.

AAI has significant concerns about the legality of NIH’s implementation plans. As AAI pointed out in a legal brief commissioned by AAI and the American Physiological Association (APS) in 2004 when NIH proposed a mandatory program (see AAI’s position and the full legal brief at http://www.aai.org/News_Board/CommentsNIHPublicAccess.pdf), the following questions, among others, must be addressed before any implementation plan is adopted:

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

Even if NIH addresses the above concerns, AAI needs additional information regarding NIH’s implementation plans in order to be able to submit thoughtful comments in response to NIH’s upcoming Request for Information (RFI) on the NIH Public Access Policy (see NOT-OD-08-057). Therefore, AAI respectfully requests that NIH respond to the following questions before the RFI is published:

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 NIH Public Access Policy in 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 3 questions, please report the costs 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 PubMed Central 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 articles
 - 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
 - f) it complies with copyright law by ensuring that an article cannot be posted before the journals' 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.