

# The AMERICAN ASSOCIATION of IMMUNOLOGISTS



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**Via email to: [publicaccess@ostp.gov](mailto:publicaccess@ostp.gov)**

**Re: “Public Access Policies for Science and Technology Funding Agencies Across the Federal Government”**

*Executive Director*

M. Michele Hogan, Ph.D.

The American Association of Immunologists, Inc. (AAI), a professional association of almost 7,000 research scientists and physicians dedicated to understanding the immune system, and the publisher of *The Journal of Immunology (The JI)*, the world’s largest and most cited immunology journal, respectfully submits the following comments on the Office of Science and Technology Policy’s (OSTP) Request for Information (RFI) on “Public Access Policies for Science and Technology Funding Agencies Across the Federal Government.” (Federal Register, Vol. 74, No. 235, Pages 65173-65175, December 9, 2009).

By way of this RFI, OSTP invites the public and the stakeholder community to comment on the promulgation of federal public access policies. As a professional scientific society of biomedical researchers and as a scholarly publisher, AAI has had experience with the National Institutes of Health (NIH) Public Access Policy, both when it was a voluntary policy (2005) and after it became law in 2008. As enacted by the Consolidated Appropriations Act of 2008 (P.L. 110-161), the law 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 strongly supports the goal of increasing access to the results of federally funded scientific research and works to enhance access to such information and publications. However, AAI has significant concerns about the effect of federally mandated public access policies, including the NIH Public Access Policy, and believes that such policies are detrimental to the very publishers whose mission it is to publish and disseminate

research findings. AAI believes that federal access policies like the NIH Public Access Policy duplicate, at great cost to federal agencies and to taxpayers, publication services which are already provided cost-effectively and well by the private sector<sup>1</sup> and weaken federal intellectual law protections which have been the engine of innovation in science and technology. Rather than diverting precious dollars away from research toward a new government bureaucracy of federal agency publishers, federal agencies should partner with private sector publishers to develop a plan that enhances public access while also addressing publishers' key concerns, including ensuring journals' continued ability to provide high quality, independent peer review of NIH-supported research. AAI therefore urges OSTP not to mandate additional public access policies, and to reinstate a voluntary Public Access Policy at the NIH, while exploring ways to foster expanded access through a federal partnership with the private sector.

### ***The American Association of Immunologists (AAI)***

The purpose of AAI is to advance knowledge of immunology and related disciplines, foster interchange of ideas and information among investigators in scientific disciplines related to immunology, and promote an understanding of the field of immunology among research scientists, educators, legislators, and the public. In its pursuit of this purpose, the principal activities of AAI include: disseminating scientific information about advances in immunology through publication of *The JI*; developing and hosting an annual international scientific meeting on immunology (including lectures and symposia on recent discoveries in immunology and related research; workshops on topics such as grant-writing, funding opportunities, the spectrum of scientific careers, and job opportunities; and programs to promote the careers of women and under-represented minority scientists); offering professional development opportunities for immunologists; hosting introductory and advanced courses on immunology; sponsoring an awards program to recognize scientists who have made significant contributions to the field of immunology; offering a summer fellowship program for high school and college science teachers; and interacting with other organizations, government agencies, and legislators to promote the importance of biomedical research and the field of immunology.

### ***The Journal of Immunology (“The JI”)***

*The JI* is a peer reviewed scientific journal that has been owned and published by AAI since 1916. *The JI* publishes original reports from all areas of experimental immunology, and is one of the leading scholarly journals not only in the field of immunology but in all biomedical science.<sup>2</sup> Publishing *The JI* is a central part of the longstanding AAI mission to serve immunologists and advance our scientific discipline.

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<sup>1</sup> 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.

<sup>2</sup> Of the approximately 25,000 scientific and scholarly journals which publish research, approximately 6,600 are ranked by the Institute for Scientific Information (“ISI”); *The JI* is ranked 16th (in the top 0.25%) for number of citations.

*The JI* fosters scientific discourse among immunologists by establishing a forum for the reporting, dissemination and discussion of cutting-edge research in immunology. It also creates an archive of scientific advances in the field of immunology for which AAI is responsible and is dedicated to preserving. *The JI* is so important to the immunology community and the advancement of the field that AAI continued to publish it even during years when it was not financially self-sustaining. Indeed, AAI has published *The JI* for 94 years and plans to do so in perpetuity. As such, AAI is highly motivated to ensure *The JI's* continued vitality and success, and does so by publishing the highest quality research and making those research results - as well as relevant reviews and commentary - available quickly, easily, widely, and at reasonable cost.

As a peer reviewed scientific journal, *The JI* maintains a database of, and relies upon, thousands of volunteer experts to serve as reviewers and editors and to evaluate submitted manuscripts. Currently, *The JI* peer reviews over 4,000 submitted original scientific manuscripts annually, as well as re-reviewing approximately 2,500 revised manuscripts. This effort requires over 10,000 reviews and thousands of editorial decisions by expert scientists. Via a three-tiered review structure, volunteer experts and editors review and critique almost every paper that is submitted. Reviewers' written comments are shared with manuscript authors regardless of whether the manuscript is accepted or rejected for publication.<sup>3</sup> This feedback is invaluable to developing both the writing and research techniques of authors, who must publish in order to receive further grant funding and to advance their career. In addition, voluntary participation with *The JI* (by serving as a reviewer or editor) is considered both a valuable and prestigious credential for any scientist's career.

*The JI's* comprehensive peer review process, like that of many non-profit scholarly scientific journals, also provides a crucial public policy function: ***expert scientists provide, through independent peer review, a validation of the research funded by the federal government***; this enhances Congressional efforts to ensure that federal tax dollars devoted to biomedical research are well spent.

Publishing a journal the size and quality of *The JI* is costly and involves significant administrative and technical support. In addition to the peer review process, *The JI* provides other essential publication services, including copy editing, production services (print and electronic), archiving, dissemination, and author and customer services. AAI and *The JI* also ensure compliance with laws and good standard business practices/reporting; develop and implement editorial policies and oversight; and manage allegations of misconduct and ethical violations related to scientific publishing. To stay competitive and deliver author and reader services, a publisher must keep up with technical advances and innovations; this requires on-going professional education and expert consultations.

Like most publishers of scholarly journals, AAI has only a few sources of revenue to support the significant expense of publishing *The JI*. These sources are primarily subscriptions and reprints, advertising, and author charges. Because author charges alone are insufficient to cover the full cost of publication, publication costs are subsidized significantly by revenues from subscriptions,

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<sup>3</sup> *The JI* accepts approximately 45% of all submitted manuscripts but provides peer review services for all submitted manuscripts.

reprints, and advertising, with subscriptions being the largest source of revenue. If these supplementary revenue sources are lost or eroded, as is likely to result from the adoption of public access policies, authors will have to pay more - or all - of the cost of publishing. This “author pays all” system will obviously result in significantly higher costs to authors.

AAI members receive a subscription (print and/or online) to *The JI* as part of their membership. Non-members and institutions such as libraries purchase subscriptions (print copies and/or electronic access via single and multi-site licenses). While *The JI* has more than 8,000 subscriptions, the number of readers of *The JI* cannot be accurately estimated because many institutional subscribers make the online version available to a wide readership. However, *The JI* online has over 4 million views per year.

Over the years, *The JI* has become increasingly accessible to the general public. AAI provides free, online access (open to the public) to the abstracts of every article immediately upon publication. Public online access to all full text articles (at no charge) is made available 12 months after publication. Further, all articles in *The JI* are available to the public immediately upon publication for a small fee (\$10 per article or \$40 for two weeks’ unlimited access to the complete archive). Print copies of full length articles are available to the general public through subscribing public libraries, universities, and medical schools.

### ***AAI Concerns about the NIH Public Access Policy and Federal Public Access Policies***

AAI has repeatedly expressed concerns about the NIH Public Access Policy through previous submissions – solicited and unsolicited – to NIH. Our concerns have ranged from legal to policy to practical. And yet we have had few answers provided to our many questions. AAI sincerely hopes that OSTP will endeavor to learn the following before retaining the NIH Policy or replicating it at other agencies:

#### **A. Legal Concerns**

1. In developing its Public Access Policy, did NIH comply with the following laws:
  - the Freedom of Information Act (and its impact on patent applications);
  - the Administrative Procedures Act (including providing adequate notice and the opportunity for public comment);
  - the provisions of OMB Circular A-76;
  - the Regulatory Flexibility Act; and
  - the Paperwork Reduction Act?
2. Since the law applies to “all investigators funded by the NIH,” how does NIH address situations where investigators have minimal NIH funding and depend on another primary funder who objects to submitting to PMC?
3. Who is responsible if the publisher’s embargo period (and therefore the publisher’s copyright rights) is violated?
4. Who ensures that NIH complies with a publisher’s copyright rights once a manuscript is submitted (*i.e.*, who makes sure that NIH does not transfer a manuscript to any other entity/repository without permission from the publisher)? How is NIH preventing the

distribution of copyrighted material to sites outside the United States if the publisher does not grant approval?

5. What are the penalties for non-compliance by a grantee? Does it matter if the non-compliance is intentional or inadvertent?

## **B. Policy Concerns**

1. NIH has revealed little regarding the cost of developing and implementing its Public Access Policy. What was the cost of:

- implementing the voluntary NIH Public Access Policy (May 2, 2005 – January 11, 2008)?
- implementing the mandatory Policy in Fiscal Year (FY) 2009? How much of this cost was a one-time implementation cost, and how much will be an annual cost?

2. In regard to the above question, how much was expended by the National Library of Medicine (NLM) and the various NIH Institutes, Centers, and Offices involved, including:

- the number of FTEs and contracted services used to accommodate this initiative;
- the cost of personnel and administrative services for this program (including associated space for infrastructure and personnel);
- the time spent directly on the promotion, management, enforcement and assessment of this program to/by NIH grantees and the public; and
- all costs associated with network infrastructure improvements including but not limited to bandwidth capabilities, server capacity, and equipment.

3. Was the Policy analyzed regarding its relative costs and benefits compared to the dynamic, time-tested free market alternatives, and if so, what were the findings?

4. Since publishers invest millions of dollars in the publication process (including peer review, editing, design, printing, and posting online), is NIH compensating publishers for their loss of revenue when PMC posts articles that violate a publisher's embargo period?

5. 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?

## **C. Practical Concerns**

1. Did NIH unfairly post on its website a list of journals which submit authors' articles directly to PMC ([http://publicaccess.nih.gov/submit\\_process\\_journals.htm](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.

2. How does NIH ensure that it posts only manuscripts eligible for posting under its Public Access Policy, and how does it 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.

3. How is NIH preventing piracy, alteration, re-publication, or other illegal use of copyrighted material that is published on PMC? Does NIH notify publishers and provide them with the information necessary to protect their copyright?

4. How is NIH addressing allegations of/evidence regarding plagiarism, including issuing corrections and retractions?
5. How is NIH ensuring 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?
6. How is NIH preventing “repurposing,” *i.e.*, modifications to the manuscript by authors or NIH that result in variations from the original manuscript?
7. How is NIH ensuring the inclusion - and protection – of 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.

### **OSTP Request for Information – Questions**

As requested by OSTP, AAI responses to the questions posed by OSTP appear below:

*1. How do authors, primary and secondary publishers, libraries, universities, and the federal government contribute to the development and dissemination of peer reviewed papers arising from federal funds now, and how might this change under a public access policy?*

The federal government provides important but partial financial support to many scientists to conduct their research. Financial support for most scientists comes from many sources, including academic institutions, state funds, private foundation and corporate partnerships.

Once research is performed, scientists prepare manuscripts describing aspects of their work. After submission to a scholarly journal, the manuscript undergoes peer review to assess its quality and relevance. If it meets the journal’s standards, it will be published. Most important in this process is peer review as it establishes the value of the research. Scholarly peer review for publication is the most crucial assessment for scientific research available.

The value to the federal government and the public of the peer review and publication by private journals is that it is a process of independent review and assessment of the money spent by the federal government on research. Further, publication in scholarly journals is a major benchmark of research progress and is used by government officials in the assessment and continuance of grant applications. Publication is also a key consideration for employers, particularly academic institutions which base promotion and tenure decision in part on a scholar’s record of publication. **Authors** disseminate their peer reviewed works by reference in lectures, by citation, on their web sites, and in sending reprints (digital or paper).

**Libraries** purchase subscriptions to the official journal of record and make it available to their students, staff, and for some institutions, the public.

The **federal government**, as of May 2005, started a voluntary program posting manuscripts on an NIH website called PubMed Central (PMC). This has been an unnecessary, poorly executed, and costly endeavor. NIH’s repeated rejection of viable alternatives and lack of good faith negotiating alienated the very entities that support and had previously been partners with NIH in the scientific endeavor: the scholarly publishers. Had PMC been a “great idea” or filled a dire

market need, it would have been successful from the start, but the initial launch of PMC was demonstrably unsuccessful. In order to make it work, an act of Congress mandating scientists' compliance was necessary. This policy raises the fundamental question of how the government can require that private entities give over their privately owned content to the government for its distribution and use; the federal government should not use threats and coercion to force a policy that has never been proven to be needed.

**Authors:** Scientists who receive federal funds to support their research report their research findings to their funding agency through regular progress reports, working groups, and special meetings. However, to continue a successful career, scientists must write scholarly manuscripts summarizing their research for the benefit of their peers and to advance their scientific discipline. These manuscripts must undergo a validation process and the only official source for this process is the peer review provided by scholarly journals. The peer review process in society journals is – more often than not – educational in nature and intended to assist the author with his/her research by providing a critique. If accepted, the manuscript is further improved through an editing process that polishes text and figures, and is subsequently published (in print and online). If the manuscript is not accepted, it is returned to the author and may be revised and resubmitted. Not only is publication essential if an author is to receive future federal funding, but it is a key consideration for employers, particularly academic institutions which base promotion and tenure decisions in part on a scholar's record of publication.<sup>4</sup>

Under a public access policy such as the NIH Public Access Policy, authors still submit articles to a journal for peer review and publication. In fact, the NIH policy *requires* that manuscripts submitted to NIH for public dissemination have been peer reviewed and accepted for publication by a scholarly journal. Based on the policy of the publishing journal, authors must either submit the accepted manuscript to NIH themselves or authorize journals to submit the article to NIH on their behalf. The accepted publications are then posted on national and international servers for open public viewing, often in violation of the publisher's embargo period.

**Publishers:** Primary publishers such as The AAI (owner of *The JI*) receive submitted manuscripts, facilitate peer review, publish journals containing the final article in print and online, maintain an archive of all published journals/articles; and enforce copyright related to the journal/article.

The role of professional society publishers in the peer review process cannot be overstated. Society publishers create, maintain and manage large databases of scientists who are willing and able to provide high quality peer review of submitted manuscripts. After receiving a submitted manuscript, the journal solicits reviewers and manages the review process to ensure that reviews are timely and thorough, that submitting authors receive useful critiques, and that published manuscripts satisfy the journal's quality standards. In providing this review and editorial process, *journals are effectively acting as independent evaluators of government-funded research and are ensuring that published manuscripts reporting the results of federally-*

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<sup>4</sup> Furthermore, journals themselves are ranked in a hierarchy of excellence based on high impact articles and use by readers, so *which journal* an author publishes in is also an important consideration. This process of peer review, publication, and journal ranking is a private enterprise which was independent of federal government mandates prior to 2008, and which remains private and independent today.

*funded research are of quality and value. Society publishers are, therefore, critically important partners of the federal government in the review and publishing of the results of federally funded research.*

Society publishers also ensure that a correct and final version of the article is made publicly available as soon as possible, and that it remains so. *The JI*, for example, makes all content available in print and online to AAI members and subscribers to *The JI* immediately upon publication. It makes its online content available to all others immediately upon publication for a small fee (pay-per-view fees for *The JI* are \$10 per article or \$40 for two weeks' unlimited access to the complete archive). All *Ji* content is available at no charge to the public immediately after publication if visiting a subscribing library, and all content published from 1998 to 12 months after publication is available at no charge if searching online.

Other not-for-profit scholarly publishers make their content publicly available at no charge as their business models allow; some do so immediately, while others have varying embargo periods.

Public access policies such as the NIH policy have added additional burdens to the publication process. Primary publishers continue to perform all of the work described above (i.e., peer review, editing, publication, dissemination, etc.). In addition, they must devote staff time to oversight of and corrections to errors in PMC postings; answer author questions regarding the NIH Policy; and divert funds and energy away from their continuing efforts to improve submission-to-publication times, decrease the cost of publication, increase dissemination of their publications to both the scientific and lay communities, and provide innovative features to enhance the reader's experience (for example, by keeping up with technological advances such as mobile devices and by implementing more rapid publication via Publish Ahead of Print).

**Federal Government:** The federal government contributes to the development and dissemination of peer reviewed papers arising from federal funds indirectly. By making federal funds available for research, the federal government supports (in whole or in part) the work of scientists who apply for and receive these grant funds. In addition, the federal government, through these grants, provides some funds to assist grantees with some of the costs of subsequent publication; however, these funds represent only a portion of the cost of publication, and the remainder is paid by the publishing journal. It is important to note that federal dollars allotted for publication fees are neither intended for, nor used as direct support for the research performed by grantees; rather, they partially pay for the purchase of necessary publication-related services, including peer review and editing.

Under a public access policy such as the NIH Public Access Policy, the federal government requires grantees to submit their final, peer reviewed, accepted manuscript to NIH, which then posts the article online at no charge to the public and with no payment to journals which provided the peer review and editing services. Such a policy threatens the viability of the publishing journal by:

- 1) depending on authors to know journal's copyright policy and embargo period



- 2) requiring journals to monitor the NIH website for embargo violators and to contact NIH to take down any non-compliant postings <sup>5</sup>
- 3) posting material owned and/or copyrighted by the publishing journal on a government website
- 4) depending on scholarly journals to perform all the work necessary to ensure the quality of the submitted manuscript (i.e., the peer review/editing process)
- 5) refusing to link from the federal agency to the version of record on the publisher's website, creating potential confusion as to which is the version of record,
- 6) depriving publishers of the website "hits," and
- 7) allowing articles to be posted without ensuring that corrections/retractions made by the publishing journal also appear on the government website

*2. What characteristics of a public access policy would best accommodate the needs and interests of authors, primary and secondary publishers, libraries, universities, the federal government, users of scientific literature, and the public?*

A flexible and voluntary public access policy which fosters innovation by private sector publishers, enabling them to utilize their skill and resources to increase access to their entire journal content, would best accommodate the needs and interests of authors, primary and secondary publishers, libraries, universities, the federal government, users of scientific literature, and the public. It bears repeating that most scholarly, non-profit journals already had successful public access policies in place before the NIH Public Access Policy was implemented.

Most scholarly journals publish content that is 1) funded by federal agencies; 2) funded by state agencies; 3) funded by private foundations/other private sources, and 4) funded by some combination of numbers 1-3, above.

The NIH Public Access Policy requires authors to submit manuscripts resulting from research that is funded in whole or in part by the federal government. It does not require, nor could it require, the submission of state funded or privately funded research. Therefore, the archive created by NIH is inferior to the archive created by the publishing journal as it includes only federally funded research and not the entire body of research published by the journal. If federal agencies worked with scholarly journals to provide links back to the journal website, the public would have access to the entire body of work published by the journal.<sup>6</sup> As these links would be

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<sup>5</sup> 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.

<sup>6</sup> In 2005, fifty seven not-for-profit scientific publishers offered to NIH leadership a "Linking Proposal," which would provide seamless links on PubMed Central (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,

present on the federal site and invisible to any user, the government could serve as a portal to the content it believes the public seeks, while accommodating publishers and alleviating financial threats to them. Such a process is simpler for the author (who would then have to deal only with the publishing journal), addresses the concerns of publishers regarding the government-mandated loss of their content (see #1, above), makes more information available to readers (scientific and lay), and eliminates the need for the federal government to become the publisher of all manuscripts resulting from federally funded research.

A flexible and voluntary public access policy would also:

- ensure that publishers could protect their content as needed to preserve the revenue required for peer-reviewed publication, and
- be least likely to violate the principles of copyright law that have fueled innovation in science and technology since the founding of our nation.

*3. Who are the users of peer-reviewed publications arising from federal research? How do they access and use these papers now, and how might they if these papers were more accessible? Would others use these papers if they were more accessible, and for what purpose?*

The primary users of peer-reviewed publications arising from federal biomedical or other scientific research are research scientists. As the information published is of a highly specialized and technical nature, it is of little (if any) use to the lay public.

Research scientists currently access published manuscripts through subscriptions to the journal(s) of interest and relevance to them. Scientists have access to subscriptions in one of the following ways:

1. they are members of a professional scientific society and receive print and/or online access to the journal(s) published by that society immediately after publication;
2. their place of employment (medical school, research institution, agency, company) purchases a subscription enabling them to access the information immediately in print and/or online;
3. they purchase individual subscriptions, enabling them to access the information immediately in print and/or online;
4. they go to a public library which purchases a subscription and access the information immediately in print and/or online;
5. they can usually purchase any article online, for costs that range by journal (*The JI* is available to the public immediately (on the date of publication) for a small fee (i.e., pay-per-view fees for *The JI* are \$10 for a single article for 24 hours, and \$40 for a 2-week pass to the entire journal content, which permits downloading and PDF printing); or

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irrespective of funding source). This proposal provides the public with free access to all published articles funded by the NIH; provides access to the final, copy-edited article of record (and any related materials, including corrections); is cost effective, since the NIH would not have to create a new repository, educate grantees about compliance and copyright, or monitor for compliance; addresses publishers' copyright concerns; satisfies the 2008 law; and 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 also offered to consider ways to satisfy NIH's desire for a repository of all NIH-funded works, *i.e.* to help NIH populate a "dark archive" for internal NIH use only.

6. they can use available open archives.

Scientists use these publications to advance their understanding of a given field, and to inform their own research. AAI does not believe that non-scientists (i.e., members of the general public) would, except in rare circumstances, use manuscripts published by *The JI* even if the entire journal were made freely available to the public immediately upon publication.

AAI wishes to point out that, although the general public would not benefit from immediate access to articles published in *The JI*, such articles are immediately available through the means listed above, and AAI has no intent or desire to limit distribution of the research results its articles report. To the contrary, AAI works vigorously to reduce the time from manuscript submission to publication and to increase the dissemination of *The JI* as part of its mission to advance the field of immunology and to maintain the journal's prominence in immunology.

*4. How best could federal agencies enhance public access to the peer-reviewed papers that arise from their research funds? What measures could agencies use to gauge whether there is increased return on federal investment gained by expanded access?*

Federal agencies could best enhance public access to the peer reviewed manuscripts that arise from their research funds by providing links back to the journal of record, thus allowing access to the journal's content. This is a simple, streamlined approach that causes no harm to publishers and yet enables the public to access not only federally funded content, but also the publisher's entire journal content.

AAI is not aware of any measures that agencies could use to gauge accurately whether there is an increased return on federal investment gained by expanded access.

*5. What features does a public access policy need to have to ensure compliance?*

Public access policies are at fundamental odds with our federal history of providing protection for creative works in order to foster innovation. To be forced by the federal government to make public one's work, even if that work was supported in whole or in part by federal funding, undermines the notion that while federal dollars support creativity and innovation, the result is owned by the creator, who is entitled to benefit from his/her work.

Ensuring compliance with public access policies would require, therefore, a fundamental change in the public's understanding of and relationship with copyright, patent, and similar legal concepts, all of which have their underpinnings in the U.S. Constitution, and therefore require changes in the law to enable the federal government to require the appropriation of privately owned manuscripts. Agencies would also have to enforce the policies against the very creators of the works which they funded.

*6. What version of the paper should be made public under a public access policy (e.g., the author's peer reviewed manuscript or the final published version)? What are the relative advantages and disadvantages to different versions of a scientific paper?*

AAI believes that the version of record, as published by the journal, is the only version that should be made available to the public. AAI does not believe that a government agency should post the version of record; rather, a government agency should provide links to the publishing journal, allowing the public to access the final article directly from the publisher's website. (See footnote 6) The existence of multiple versions is simply confusing; and the posting on an agency website of an author's peer reviewed manuscript raises serious questions about the agency's ability to address the need for final edits, corrections, deletions, and withdrawals.<sup>7</sup>

*7. At what point in time should peer-reviewed papers be made public via a public access policy relative to the date a publisher releases the final version? Are there empirical data to support an optimal length of time? Should the delay period be the same or vary for levels of access (e.g., final peer reviewed manuscript or final published article, access under fair use versus alternative license), for federal agencies and scientific disciplines?*

Within the biomedical research community, there are a variety of publishing models, all designed to foster the rapid dissemination of important scientific information while ensuring the quality of published papers, the archival needs of the discipline, and the long-term viability of the publishing journal. All *JJ* content is available at no charge to the public immediately if visiting a subscribing library, and 12 months after publication if searching online. Other not-for-profit scholarly publishers make their content publicly available at no charge as their business models allow; some do so immediately, while others have varying embargo periods. As stated above, it is essential that any public access policy adopted be flexible and voluntary, in order to allow individual publishers to select an embargo period that will enable them to preserve the revenue that helps to finance publication. If the limited revenue sources are eroded or lost (subscriptions, reprints, and advertising), authors will have to pay more - or all - of the cost of publication.

*8. How should peer-reviewed papers arising from federal investment be made publicly available? In what format should the data be submitted in order to make it easy to search, find, and retrieve and to make it easy for others to link to it? Are there existing digital standards for archiving and interoperability to maximize public benefit? How are these anticipated to change?*

Peer-reviewed papers arising from federal investment should be made publicly available via the publishing journal. The Internet makes searches for any kind of information rapid and simple; the question facing users is which information is reliable. Scientists already know which sources/journals are reliable; scholarly publishers are willing to identify for the public all articles which result from federally funded research.

*9. Access demands not only availability, but also meaningful usability. How can the federal government make its collections of peer-reviewed papers more useful to the American public? By what metrics (e.g., number of articles or visitors) should the Federal government measure success of its public access collections? What are the best examples of usability in the private sector (both domestic and international)? And, what makes them exceptional? Should those who access papers be given the opportunity to comment or provide feedback?*

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<sup>7</sup> Even if a journal publishes the author version of a manuscript at the "publish ahead of print" stage, the journal, which maintains control of the content, can ensure that any corrections are made.

“Meaningful usability” is a crucial concept. If increased public access does not result in a meaningful use of the articles by the general public, and yet could harm the very publishers who conduct the peer review and editing of the articles, then a cost-benefit analysis must be conducted to weigh any benefit to the public against any harm to the publisher. The federal government needs to exercise the Hippocratic Oath administered to all physicians: “First, do no harm.”

The federal government must determine whether it can accomplish the following critically important tasks through a public access policy, all of which are currently done by private sector publishers: make access simple to not only single articles but also an entire body of work; ensure that there is only one, final version of record and that it has been edited, revised, or withdrawn as necessary; and protect the copyright and therefore the author’s work.

There are – and will always be – many outstanding collections of scientific literature because of the nature of science. This diversity is a strength of the scientific publishing enterprise. Homogenizing the literature is neither necessary nor productive any more than a futile attempt to collect all artwork in the United States into one federal museum.

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