

Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research

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Action

Notice; Final Policy Statement

Update: The following update relating to this Notice has been issued:

- [January 11, 2008](#) (NOT-OD-08-033) - Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research.

Summary

The National Institutes of Health (NIH) announces its policy on enhancing public access to archived publications resulting from NIH-funded research. Beginning May 2, 2005, NIH-funded investigators are requested to submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript upon acceptance for publication, resulting from research supported, in whole or in part, with direct costs¹ from NIH. The author's final manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process.

This policy applies to all research grant and career development award mechanisms, cooperative agreements, contracts, Institutional and Individual Ruth L. Kirschstein National Research Service Awards, as well as NIH intramural research studies. The policy is intended to: 1) create a stable archive of peer-reviewed research publications resulting from NIH-funded research to ensure the permanent preservation of these vital published research findings; 2) secure a searchable compendium of these peer-reviewed research publications that NIH and its awardees can use to manage more efficiently and to understand better their research portfolios, monitor scientific productivity, and ultimately, help set research priorities; and 3) make published results of NIH-funded research more readily accessible to the public, health care providers, educators, and scientists.

This final NIH Public Access Policy (the "Policy") reflects modifications and clarifications to the proposed policy released September 3, 2004, in the **NIH Guide for Grants and Contracts** and September 17, 2004, in the **Federal Register** and the more than 6,000 public comments received through November 16, 2004. The most significant change in the Policy from that originally proposed is to provide more flexibility for authors to specify the timing of the posting of their final manuscripts for public accessibility through PMC. The proposed policy indicated a six-month delay of posting through PMC. The Policy now requests and strongly encourages that authors specify posting of their final manuscripts for public accessibility as soon as possible (and within 12 months of the publisher's official date of final publication). The Policy also clarifies that the publication date is the publisher's official date of final publication.

Effective Date: May 2, 2005

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I. Background

It has long been NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. Principal Investigators (PI) and grantee organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large.² It is estimated that the results of NIH-supported research were described in 60,000 – 65,000 published papers in 2003.³ We believe that widespread access to and sharing of peer-reviewed research publications generated with NIH support will advance science and improve communication of peer-reviewed, health-related information to scientists, health care providers, and the public.

As part of on-going efforts to gather perspectives on the issue of public access to research publications, the NIH held a series of meetings to hear and consider the opinions and concerns of publishers, scientists, patient advocates, and representatives of scientific associations and other organizations. The meetings were designed to ensure that discussions of stakeholder issues could occur. The NIH extended invitations to a broad base of participants to ensure balanced representation of opinions. In many cases, a participant represented more than one perspective, such as a scientist who was also a journal editor and reviewer of scientific manuscripts.

After carefully considering the views of publishers, patient advocates, scientists, university administrators, and others, the NIH published its proposed NIH Public Access Policy in the **NIH Guide for Grants and Contracts** on September 3, 2004, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-064.html> and in the **Federal Register** on September 17, 2004, <http://a257.g.akamaitech.net/7/257/2422/06jun20041800/edocket.access.gpo.gov/2004/04-21097.htm> for public comment. During the comment period, the NIH received over 6,000 comments via web, fax, mail, and e-mail. Many comments were received from organizations representing multiple constituents. The NIH developed Questions and Answers to clarify the proposal as issues were raised regarding it; these are available at: http://www.nih.gov/about/publicaccess/publicaccess_QandA.htm.

This final Policy reflects consideration of public comments received on the proposed policy through November 16, 2004, i.e., 60 days from the date of publication of the proposed policy in the **Federal Register**.

The Policy is intended to: 1) create a stable archive of peer-reviewed research publications resulting from NIH-funded research to ensure the permanent preservation of these vital published research findings; 2) secure a searchable compendium of these peer-reviewed research publications that NIH and its awardees can use to manage more efficiently and to understand better their research portfolios, monitor scientific productivity, and ultimately, help set research priorities; and 3) make published results of NIH-funded research more readily accessible to the public, health care providers, educators, and scientists.

II. Public Comments and NIH Responses

A. Need for the Policy

The public comments were largely supportive of the proposed policy to enhance public access to archived publications resulting from NIH-funded research. Comments noted that this policy provides equal and timely access to all via the Internet and that this accessibility should improve individual health outcomes. Many scientists appreciated that the policy would improve the visibility of their work. A large number of comments suggested that publicly-funded research publications should be made accessible to the public in full-text version in a timely

manner. Many commenters expressed support for the policy given their concerns about the high and rising cost of subscriptions to scholarly journals, especially in the areas of science, technology, and medicine.

Other commenters questioned the need for the policy and considered it redundant to existing information sources and systems. Some questioned the added value of the policy and noted that journals increasingly are making full-text articles available immediately upon or within one year of publication through a variety of sources. Commenters noted that many of these articles are already linkable through the NLM PubMed web-based literature retrieval system that contains citations and abstracts from thousands of journals, dating back to 1950.⁴ A significant number of comments also questioned why the NLM could not simply provide a link to the publisher's website, or work with existing vendors to broaden offerings to include peer-reviewed publications not associated with NIH funding.

The primary purpose of the NIH Public Access Policy is the creation of a stable archive to ensure the permanent preservation of vital, peer-reviewed research publications resulting from NIH-funded research findings now and for future generations. While links exist to journal articles that are publicly accessible, these are not sufficient because publishers' websites are not permanently available nor consistently maintained. Additionally, the formatting of journal articles may vary significantly among publishers' websites. The Policy addresses this deficiency in that all articles in PMC, regardless of their original format, are converted into a single, explicit, and well-specified data format. This format is known as the NLM Journal Article Extensible Markup Language (XML) Document Type Definition (DTD). Further, as new needs arise, and as technology and applications change, there is a single, uniform base upon which to build.

Preservation of the biomedical literature is a responsibility that is specifically mandated in NLM's authorizing legislation, found at 42 U.S.C. 286(b)(1), and one that has successfully been carried out by the NLM since 1836. It is logical in this electronic era to expect libraries, and particularly national libraries, to continue this vital function, including keeping pace with the ever-changing technology surrounding document preservation. Updating the data formats to keep up with the changes in technology and the needs of biomedical research requires an ongoing investment in research and development, which is within the NIH mission. As the electronic article increasingly becomes the authoritative and most useful document for researchers and as scientists are actually computing on the contents of these documents - the text itself as well as the associated data - the impermanence of the publishers' websites presents a substantial risk. Creating such an archive is a historical and necessary NIH responsibility.

NIH believes that the NIH Public Access Policy will effectively advance its stated goals. By storing research publications from diverse sources in a searchable, electronic archive with a common format, PMC facilitates greater integration with related resources in other NLM databases such as DNA and protein sequences, protein structures, clinical trials, small molecules (PubChem), and taxonomy thus providing the opportunity to develop unprecedented scientific search and analysis capabilities for the benefit of science. One of the primary goals of PMC is the creation of a permanent, digital archive of journal literature, which by definition, means the full text must be deposited in PMC. This searchable archive will enable NIH program officials to manage their research portfolios more efficiently, monitor scientific productivity, and ultimately, help set research priorities. This strategy also will enable NIH to advance its goal of creating an end-to-end, paperless grants management process. Finally, it will make the publications of NIH-funded research more accessible to and searchable for the public, health care providers, educators, and scientists.

A few commenters asked NIH to strengthen the proposed policy to make submission to PMC a requirement instead of a request. We believe that the voluntary nature of the final policy is preferable to a "one size fits all" requirement, as it permits sufficient flexibility to accommodate the needs of different stakeholders and leaves the ultimate decision in the hands of our scientific investigators who are the best to judge the scientific circumstances and the time frame under which their work may be made accessible to the public at large. It is worth clarifying that NIH does not require or expect that PMC be the sole repository for NIH-funded research publications. Others may choose to post and/or archive peer-reviewed publications resulting from NIH-funded research, subject to applicable laws or permission from any copyright holders.

B. Scope of the Policy

The NIH Public Access Policy applies only to peer-reviewed research publications that have been supported, in whole or in part, with direct costs from NIH. Numerous comments reflected misunderstandings about the scope of the policy as it was proposed. Some comments sought to broaden the Policy to include publications from non-NIH-supported investigators, and others asked that it include publications that did not contain original research findings, e.g., book reviews.

The Policy does not apply to contributed book chapters, editorials, reviews, or conference proceedings. Although PMC does contain articles from non-NIH-supported research, the Policy is focused on final, peer-reviewed manuscripts and publications that result from research supported, in whole or in part, with direct costs from NIH.

C. Potential for Public Misunderstanding of Research Findings

A number of comments questioned the lay public's ability to understand fully original research publications, and expressed fear that potential harm could result from misinterpretation of them.

We believe that individuals who seek to read publications concerning a particular disease, health condition, or treatment should not be denied access because of the possibility that they will misunderstand the publications. Rather, NIH encourages such individuals to become educated consumers about their health care and related research, and to consult with health care professionals for specific guidance. It is important that NIH-supported research publications be made more readily available to provide credible information and to improve public understanding of the benefits of scientific research. The public demand for credible health information is clear. About 93 million Americans searched for at least one of 16 health topics online within the past year.⁵ In a 2003 survey, 58 percent of Internet users said they brought information obtained from the Internet to their doctor's office.⁶

The NIH is strongly committed to conveying the importance of the research it funds to the public. Each NIH Institute and Center has an active staff that produces high-quality educational and informational materials on various health and research topics, many of which highlight the publications of NIH-funded researchers. Institute and Center staff, often with the assistance of third parties and patient advocacy groups, works diligently to develop, review, and disseminate these products. For example, the National Library of Medicine's consumer health site, Medline Plus (<http://www.nlm.nih.gov/medlineplus/>) houses extensive information on over 650 health conditions. NIH believes that these products effectively advance NIH's strong commitment to improving public health through research.

The Policy specifically relates to original research publications. NIH needs to compile these publications into a single archive in order to manage its research portfolio better and monitor its funding choices. NIH recognizes that providing public access to this electronic archive, may also help scientists, policymakers, doctors, patients and the lay public to understand better the research that NIH funds.

D. Version Control and Quality of Manuscripts

Some commenters raised concerns about potential confusion resulting from differences between the author's final manuscript within PMC and the published version of the corresponding article at journal-sponsored websites. Others questioned how corrections, retractions, and other post-publication changes will be accommodated.

Through this Policy, NIH is requesting that NIH-funded investigators submit an electronic version of the author's final manuscripts resulting from research supported, in whole or in part, with direct costs from NIH, after all changes resulting from the peer review publication process have been incorporated. A growing number of journals are currently posting final author manuscripts to provide timely access to their subscribers prior to final publication of the publisher's copy edited version. In addition, under the Policy, the final manuscript will not be made available to the public through PMC until after the copyedited version is published by the journal. Corrections and other necessary revisions of author's final manuscripts will be accommodated. Furthermore, when publicly available, the published article on the journal-sponsored website and the author's final manuscript in PMC will be appropriately linked through PubMed. Corrections and post-publication comments referring to a publication are currently identified and linked in PubMed, and this capability will be linked to the corresponding manuscript in PMC. If publishers wish to provide PMC with the publisher's final version, this version will supersede the author's final manuscript in PMC.

E. Potential for Acceleration of Medical Cures

A few commenters questioned whether the proposed policy, and enhanced access to NIH-funded publications, will facilitate scientific progress and accelerate research for medical cures.

We believe that improved access through PMC to peer-reviewed, final manuscripts of NIH-supported investigators will facilitate scientific progress because it will enable NIH to manage better its research portfolio and funding choices. The NIH encourages the sharing of ideas, data, and research findings to help accomplish its important public mission to uncover new knowledge that will lead to better health for everyone. As such, we envision that the PMC resource will have widespread and varied uses for the research community. It will create a stable, permanent, and searchable archive of peer-reviewed research publications that NIH and the public can access, without a fee, to review scientific productivity, monitor the state-of-the-science, and apply such knowledge in other ways to accelerate medical research. Greater interconnectivity and functional integration between the multiple and large research data bases (e.g., Genbank and PubChem) and an archive of NIH-funded publications has the potential to enhance research in novel ways.

F. Potential Economic Impact on Journal Publishers

Commenters contended that NIH had not carefully considered the potential adverse economic impact of its proposed policy on publishers, in particular, not-for-profit professional and learned societies and associations that rely on subscriptions to cover costs. The consequences of the proposed policy for many small journals, as well as bimonthly and quarterly journals, were of particular concern to some. Concern also was raised that relative to commercial publishers, not-for-profit publishers would be more disadvantaged because they often support highly specialized areas that tend to draw greater representation by NIH-funded researchers. Others questioned the fairness of allowing publishers to continue to profit by restricting access to health-related information.

Publishing patterns vary from year to year and from one journal to another. Using 2003 data, NLM estimates that, on an annual basis, publications resulting from NIH-funded research represent approximately 10 percent of the articles in nearly 5,000 journals indexed by PubMed. In addition, for only one percent of these journals do NIH-funded articles account for more than half of the total published articles.⁷ As such, it is unlikely that scientists and libraries would use the NIH Public Access Policy as the rationale for replacing their journal subscriptions. If they did, they would be able to access only a fraction of a journal's content. It also is important to note that there are many other journal offerings, such as science news, industry information, literature reviews, job announcements, functional websites, and other time-sensitive products that bring value to the reader but are not a part of the PMC archive. Access to journal articles through the NIH archive might increase Internet traffic to those journals, by both the scientific community and the general public.

The NIH supports the current publishing process by providing its funded investigators with an estimated \$30 million⁸ annually in direct costs for publication expenses, including page and color charges and reprints. In addition, NIH provides funds, through indirect costs, to research institutions for library journal subscriptions and electronic site licenses. NIH also supports the current process by encouraging publication of NIH-supported original research in scientific journals.

NIH has made modifications to the proposed policy to provide greater flexibility to accommodate the range of business models represented by large commercial publishing houses through the smaller specialized journals of learned societies. The most significant change is to allow authors to specify the timing of the posting for public accessibility through PMC of their final manuscript. The NIH intends to maintain its dialogue with publishers and professional and learned societies as experience is gained with the Policy.

A NIH Public Access Advisory Working Group of the NLM Board of Regents⁹ will be established. The Working Group will be composed of stakeholders that will advise NIH/NLM on implementation and assess progress in meeting the goals of the NIH Public Access Policy. Once the system is operational, modifications and enhancements will be made as needed with the Working Group, or a permanent subcommittee of the Board, providing ongoing advice on improvements.

G. Potential Impact on Journal Peer Review

NIH recognizes the enormous value and critical role that peer-reviewed journals play in the scientific quality control process. Only peer-reviewed articles accepted for publication will be posted in PMC. Some commenters asked if scientific integrity would be compromised if journals were to go out of business, thus significantly narrowing journal options for authors. A few commenters feared that the NIH proposed policy would limit an author's freedom to publish how, when, and where he or she chooses.

We do not believe that the Policy will compromise scientific integrity or significantly narrow journal options for authors. While NIH encourages investigators to publish and share the results of the research that it funds, NIH does not dictate the means of publishing the research it supports. This Policy is designed to preserve the critical role of journals and publishers in peer review, editing, and scientific quality control processes. It is not intended to alter in any way the manuscript submission process, investigator choice of journal for publication, or existing publication process.

NIH highly values traditional routes of research information dissemination through publication in scientific, peer-reviewed journals. Peer review is a hallmark of quality for journals and is vital for validating the accuracy and interpretation of research results. Publication in peer-reviewed journals is a major factor in determining the professional standing of scientists; institutions use publication in peer-reviewed journals in making hiring, promotion, and tenure decisions. NIH also values the communities of research created by scientific organizations and the journals they publish. By not mandating but instead requesting from our investigators that access be provided to the public within a range of acceptable delays extending from 0 to 12 months, the NIH believes that its Public Access Policy addresses the concerns raised by both for-profit and not-for-profit publishers and will ensure that peer review of scientific articles is preserved. The NIH believes that archiving and making publicly accessible NIH-funded biomedical and behavioral literature after a reasonable time delay can preserve the critical role of journals and publishers in peer review, editing, and scientific quality control. The policy should have no effect on the author's choice of journal. We expect that greater access to research publications will increase the impact of the publicly-funded research. For example, there is emerging evidence that easier access increases impact as measured by the number of times a paper is cited.¹⁰

H. Potential Impact on Scientists

A number of comments expressed the concern that researchers would be adversely affected by the proposed policy if publishers experienced a decline in subscriptions and subsequently chose to increase charges to authors. It was suggested that higher charges would disadvantage disproportionately researchers with more limited resources. In addition, some researchers were concerned that the proposed policy would create an additional burden on them.

NIH-funded investigators are expected to make the results and accomplishments of their activities available to the research community and to the public at large. Consequently, NIH considers publication costs, which include fees charged by a publisher, such as color and page charges, or fees for digital distribution, to be allowable charges to NIH research awards.

Concerning burden, public access submissions will provide NIH-supported investigators with an alternate means by which they can meet and fulfill the current requirement to provide a copy of each publication in their progress reports and other application and close-out procedures. It is anticipated that investigators applying for new and competing renewal support from the NIH will utilize this resource by providing links in their applications to their PMC - archived information. NIH, therefore, anticipates that this process may reduce, rather than increase, burden for investigators.

It is also worth noting that the development of a searchable archive of published findings from NIH-supported research will be a rich resource for all scientists. Access to such information not only will make it easier to investigate a specific area of research, but also may lead to identification of new research questions.

I. Open Access Publication and the NIH Public Access Policy

Some commenters believed that the NIH Public Access Policy constitutes an open access model of publishing. The NIH Policy is not a form of publishing; rather, it creates a stable archive of peer-reviewed research publications resulting from NIH-funded research. In addition, the Policy does not dictate the means of publishing but is compatible with any publishing model that authors and journals choose to employ. For example, some subscription journals already allow free electronic access to published manuscripts directly from their websites after an embargo period. In addition, one survey reports as many as 92 percent of journals allow authors to self-archive either a postprint (79 percent) or preprint (13 percent) of the article on personal websites or on their institution's website¹¹. Copyright to all material deposited in PMC remains with the publisher, individual authors, or awardees, as applicable. PMC currently includes a copyright notice alerting the public to the rights of copyright holders and will continue to post this notice as it has done in the past.

J. Waiting Time to Public Access

The proposed policy published in September 2004 indicated that with the author's permission, the NIH would make the author's final manuscript available to the public no later than 6 months after the date of official publication as determined by the publisher. Many commenters considered the 6-month waiting time to be a reasonable compromise, though some believed the waiting time should be considerably shortened. Some recommended that the waiting time be 12 months or longer, particularly because 12 months rather than 6 months is currently the prevailing model among journals that already provide free, delayed, full-text access. Some commenters also noted that the vast majority of journals currently offer no free public access at all, thus arguing that a 6-month waiting time is too aggressive.

The NIH has tried to balance the legitimate needs of journal publishers with its interest in creating a permanent archive of peer-reviewed research publications resulting from NIH-funded research. There is a wide range of time-to-access policies within the publishing world. Some of the variables that affect time-to-access include differences among scientific fields (e.g., clinical versus basic research), and variability in business models determined by a range of issues including number of article submissions, acceptance rate and subscription base.

After considering the views of scientists, publishers, patient advocates, librarians, research administrators, professional societies, and others, the final Policy provides authors with the ability to specify when their final manuscript will be made available to the public through PMC. Posting for public accessibility through PMC is strongly encouraged as soon as possible (and within twelve months of the publisher's official date of final publication). This Policy provides greater flexibility for participation. Further, it addresses the agency's interest in establishing a permanent archive of peer-reviewed research publications resulting from NIH-funded research in a timely manner.

K. Politicization of Science

Some commenters suggested that a centralized, government-operated repository could compromise the integrity of the scientific record, be subject to government censorship, and be susceptible to the politicization of science and the variability of funding levels and changes in agency management.

Congress assigned to the NLM the responsibility to acquire, organize, disseminate, and preserve biomedical information for the benefit of public health. As part of this responsibility, the Policy will create a stable archive of peer-reviewed research publications resulting from NIH-funded research to ensure the permanent preservation of these vital published research findings. Agency policy is not to restrict or suppress the content of PMC.

L. Implementation Costs

Many commenters expressed concern that the costs associated with archiving NIH-funded manuscripts in PMC have not been clarified, or that costs are understated. Some publishers reported spending on the order of hundreds of millions of dollars over the past decade to improve online access to their journal offerings, which led to skepticism about the validity of NIH's estimates. These commenters are

concerned that allocating funds for an expanded PMC archive would compete with funds available to support original research. Other commenters expressed concern that continued funding for the system may not be available in the future.

By building on an existing information technology infrastructure housed at the NLM, the NIH Public Access Policy can be an exceptionally cost-effective means to accomplish its goals of archiving, facilitating program management, and enhancing accessibility. Estimates of \$2-\$4 million per year reflect incremental costs to create and then maintain a website for submitting authors' final manuscripts and for Extensible Markup Language (XML) tagging of the manuscripts into PMC's archival format. These estimates reflect PMC's experience with a back-scanning project which has generated and tagged electronic versions of more than 200,000 printed articles in the last year. The roughly 50,000–70,000 manuscripts a year for the new NIH Policy will be tagged in a similar manner and incorporated into PMC using a single, consistent digital format. The NIH is committed to maintaining and enhancing the existing PMC infrastructure to achieve the agency's goals.

Some questioned if additional support will be provided to investigators to cover potential increases in publication costs. The NIH awards direct costs to many investigators who request publication costs in their proposed budgets. The NIH estimates that it pays over \$30 million annually in direct costs for publication and other page charges in grants to its investigators. Generally, page charges for publications in professional journals are allowable, if the published paper reports work supported by the grant and the charges are levied impartially on all papers published by the journal, whether or not they are submitted by government-sponsored authors. As with all other costs, NIH expects its investigators to be careful stewards of Federal funds and to manage these resources appropriately. Grantees may rebudget funds to support these costs, but NIH will consider all other options to ensure that budgets are not affected unduly which should be achievable given the voluntary nature of this request.

M. PMC's Capacity and Functionality

Comments supporting the proposed policy noted that online access was desirable because it was centralized, cheaper than accessing a print version, and easier to access. Some comments expressed limited confidence in PMC's ability to keep pace with the current volume of publications, or to handle a large influx of additional manuscripts. Several comments requested that PMC add more functionality to address the increased amount of content.

NLM's National Center for Biotechnology Information supports many large production services, including GenBank, PubMed, and PMC, handling over 3 million queries daily from more than 1.2 million unique users. Since PMC went live in 2000, there have been no delays for any active production PMC journal due to production lags or technical problems at PMC. In addition to incorporating content provided by publishers, the PMC back-scanning project has generated and tagged electronic versions of more than 200,000 printed articles in the last year. The roughly 60,000 manuscripts a year for the new NIH Policy will be tagged in a similar manner and incorporated into PMC using a single, consistent digital format.

A commercial service monitors PMC's website performance and reliability. Based on over 22,000 measurements in a recent two-week period, articles were successfully returned for 98.5 percent of the requests to PMC. This compared during the same two-week period to a 92 percent average success rate for 40 of the largest commercial websites monitored by the same service. The average response time to download a PMC article has been 2.8 seconds.

Another key advantage of PMC is that the articles returned by a PMC search are automatically linked to a variety of research-related resources in other NLM databases, such as DNA and protein sequences, protein structures, clinical trials, small molecules (PubChem), and taxonomy. These databases also provide linkage to a broad collection of other biological and health-related information resources. Investigators applying for new and competing renewal support from the NIH can also utilize this resource by providing links in the applications to their PMC-archived information.

N. Domestic and International Coordination

A number of commenters urged the NIH to coordinate with other scientific agencies in the United States and internationally, while others countered that providing unrestricted access to non-U.S. individuals would represent a subsidization of scientific knowledge outside the United States that disadvantages American scientists.

We believe that American scientists and global health will benefit from greater access to research publications leading to increased collaborative efforts worldwide. In an increasingly interdependent world, the United States and nations around the globe not only share the risk of diseases, but also the challenge to respond. This can best be accomplished in an environment in which rapid communication is possible, wherein scientific knowledge is readily available to all, and where research is conducted based on partnership. This environment will also foster continued U.S. leadership in science.

O. Timing of the Policy's Implementation

Many commenters sought to delay the Policy's implementation, expressing strong concerns that the proposed policy had not been adequately analyzed for short- and long-term impacts. Commenters called for more dialogue and consideration. Others called for more formal studies before Policy implementation.

The request for investigators to submit the authors' final manuscripts to PMC is not a requirement. The NIH instead is providing guidance to conform to a long-standing NIH policy that the results and accomplishments of NIH-funded research activities should be made available to the public. The Policy encourages voluntary cooperation of investigators, and it does not penalize investigators who choose not to use PMC to submit pre-print hard copy versions of their manuscripts as part of their progress reporting requirements.

Timely implementation of the Policy will allow NIH to manage more efficiently and to understand better its research portfolio, monitor scientific productivity, and ultimately, help set research priorities. Also, because many commenters highlighted the public's desire for enhanced access to scientific publications in a timely manner, NIH is confident that this Policy will not only advance science but will benefit the scientific community, the public, and the NIH.

This Policy is subject to periodic review based upon lessons learned in the course of its implementation. Issuance of this Policy is the beginning of a process that will include refinement as experience develops, outcomes are evaluated, and public dialogue among all the stakeholders is continued.

A NIH Public Access Advisory Working Group of the NLM Board of Regents¹² will be established. The Working Group will be composed of stakeholders that will advise NIH/NLM on implementation and assess progress in meeting the goals of the NIH Public Access Policy. Once the system is operational, modifications and enhancements will be made as needed with the Working Group, or a permanent subcommittee of the Board, providing ongoing advice on improvements.

P. Legal Issues

NIH received several comments and objections of a legal nature.

1. Request vs. Required: Some commenters argued that the proposal is mandatory, even though the proposal requests, rather than requires, submission of final manuscripts to NIH. As evidence, they note that NIH plans to monitor submissions as part of the grants close-out process and that the proposal states that the submission will fulfill the current requirement to submit one copy of each publication in the annual or final progress reports. One commenter also asserted that reading the proposal as a requirement would be consistent with House Appropriations Committee Report language in H.R. Rep. No. 108-636.

The final Policy reiterates that submission of the electronic final manuscript is voluntary and that it can serve as an alternate means for meeting current progress reporting requirements as well as application and close-out submissions in the future. The monitoring referred to in the proposed policy referred to determining whether the final manuscripts had already been submitted electronically. We have removed that language from the final Policy to avoid any confusion. The House Appropriations Report did propose requiring submission; however, the NIH Policy requesting, rather than requiring, submission is consistent with the final report language found on page 1177 of the Joint Explanatory Statement in H.R. Rep. No. 108-792¹³.

2. Copyright: NIH received comments that the proposal infringes on copyright interests of Federal grantees. These commenters argued that copyright interests are well-established under Federal law, that NIH has no authority to alter them, and that the proposal is not consistent with controlling Department of Health and Human Services (HHS) regulations. They believe the proposal fails to recognize the need for copyright permission from authors and/or publishers. They argue that neither the principle of fair use, nor the Federal purpose license, can be used by NIH to implement the proposal. Finally, they argue that the PMC "open access" submission agreement constitutes a forced license and undermines copyright.

The Policy explicitly recognizes and upholds the principles of copyright. First, submission of final manuscripts is voluntary rather than mandatory; the voluntary submission to NIH by authors and institutions under the Policy constitutes permission to post the manuscripts on PMC and release to the public after the submitter's specified post-publication delay time. The fair use exemption to copyright infringement does not apply to the government's request for the manuscripts. It applies to the public use of the manuscripts as posted on PMC and provides a limitation on such use consistent with the terms of that exemption.

NIH does not need to seek permission from journals who may acquire copyrights from authors or institutions because any copyright transfer or assignment is currently subject to the government purpose license pursuant to 45 C.F.R. 74.36. Although the NIH is relying on permission, rather than the government purpose license, as the basis for its Policy, the government purpose license is fully available as a legal authority under which manuscripts could be reproduced, published, or otherwise used for Federal purposes. The comment that the proposal is not consistent with controlling HHS regulations granting copyright is not persuasive, since those same regulations grant the agency its government purpose license.

Finally, authors can indicate what copyright restrictions, if any, apply to their manuscripts when submitting them to PMC and can choose an appropriate PMC submission agreement that recognizes those rights.

3. Government purpose copyright license: NIH received a comment that the government purpose license of 45 C.F.R. 74.36 cannot be used by the government as a basis to post final manuscripts on PMC.

Although the NIH, at this time, is not relying on the government purpose license, it is an available means for NIH to reproduce, publish or otherwise use copyrighted works resulting from NIH funding for Federal purposes, as well as to authorize others to do so. Arguments put forth and cases cited by the commenter as support for the premise that the government purpose license could not be used as a basis for PMC to post the manuscripts are not persuasive. None of the cases address circumstances where a government agency is acting to fulfill its own statutory purposes with regard to publications resulting from its own research funding. Creation of a publicly accessible, permanent archive of NIH-funded research publications is squarely within the statutory authorities of the NIH and the NLM and clearly constitutes a Federal purpose¹⁴.

4. Other intellectual property concerns: One commenter suggested that the proposed policy undermines other aspects of intellectual property because problems would result if the principle that "the taxpayers have already paid for the research" were also applied to patents, pharmaceuticals, and other products of government-funded research.

The NIH Public Access Policy is not based on the principle of delivering a product to the taxpayer in return for research support. The Policy calls for the voluntary submission of final author manuscripts; it does not affect the ability to copyright. Funding recipients may continue to assert copyright in works arising from NIH-funded research, and they may assign these rights to journals as is the current practice. Copyright holders may enforce these copyrights as before. A member of the public viewing or downloading a copyrighted document from PMC is subject to the same rights and restrictions as when copying an article from the library. For example, making a copy of an article for personal use is generally considered to be a "fair use" under copyright law. For uses that fall outside of the fair use principle, permission to reproduce copyrighted materials must be obtained directly from the copyright holders. PMC currently includes a copyright notice alerting the public to the rights of copyright holders and will continue to post this notice as it has done in the past.

5. Bayh-Dole Act: NIH received a comment that the proposal undercuts the Bayh-Dole Act by interfering with technology transfer, because scientific publications are an important component of technology transfer, and the proposal weakens that component. This commenter also suggested the proposal undermines the Bayh-Dole principle that the private sector is the preferable vehicle to move research to the marketplace.

The NIH Public Access Policy serves to establish a permanent archive of NIH-funded research publications. It is not expected to supersede any private sector publication activity or create competition with publishers. Manuscripts that are submitted by authors will be available to the public through PMC after the time specified by the author post-publication. As such, we do not believe that the Policy will interfere with publications as a technology transfer vehicle, or that it will supersede the private sector as a vehicle to move research to the marketplace.

6. Patent application filing concerns: NIH received comments that because final manuscripts as submitted to NIH will be subject to Freedom of Information Act (FOIA) disclosure, they will likely be considered "printed publications" for purposes of the timing of filing patent applications. Commenters suggested this would be a change from current practice, which relies on the date of journal publication.

The NIH Policy requests authors to submit final manuscripts after the peer review process has been completed. Although each research institution must determine the timing of the filing of any patent applications arising from their NIH-funded work, NIH does not believe that submission to PMC under the Public Access Policy will constitute a printed publication, nor otherwise interfere with the timing of filing of patent applications. The manuscripts will not have the indicia of "public accessibility" that are generally relied upon as criteria by which prior art references have been judged. Until the interested public has access to the document, it would not be considered to be available as a printed publication within the meaning of 35 USC §§ 102(a) or (b). The primary journal publication constitutes the date of publication for patent filing purposes, as it has traditionally served.

Courts have found it helpful to rely on distribution and indexing as proxies for public accessibility, and one commenter argued that the final manuscripts will be indexed by PMC prior to journal publication. However, even if indexed in preparation for posting, the publication itself will not be available to the public. Once final manuscripts are posted in the archive, indexing and search capabilities will assist user access.

Other aspects of the process of scientific publication do not establish statutory bars to patentability. For example, processes such as oral presentations at scientific meetings and submission of manuscripts and information to peer reviewers or to a journal for review have not been considered to establish a publication date for patent purposes, because these activities have not been considered to result in public availability. Similarly, there is no reason to believe submission to NIH with the expectation of confidentiality until after publication will be treated differently by the U.S. Patent and Trademark Office.

7. Freedom of Information Act (FOIA): Some commenters expressed concern that the final manuscripts would be subject to disclosure to the public under FOIA prior to journal publication.

NIH believes the manuscript information is protected from release under FOIA by Exemption 4¹⁵. In accordance with HHS FOIA regulations, if NIH receives a FOIA request for such a document, it will notify the submitter of the manuscript of the FOIA request in order to provide an opportunity for the manuscript submitter to object to any potential disclosure of the record. If the final publication is requested after the journal publication date but prior to the posting date on PMC, NIH believes that these publications are not "agency records" subject to FOIA. See 45 CFR 5.5, stating that definition of "record" for purposes of the HHS FOIA regulation does not include "books, magazines, pamphlets, or other reference material in formally organized and officially designated HHS libraries where such materials are available under the rules of the particular library."

8. Administrative Procedures Act (APA) rule-making: Some have commented that the proposed policy constitutes a rule-making under the Administrative Procedures Act (APA) and that NIH lacks legislative authority to adopt this policy because it is without rule-making power. They also argue that the notice and comment opportunity for the proposal was insufficient to meet rule-making requirements.

NIH agrees that authority to adopt new regulations is retained by the Secretary, Health and Human Services, and has not been delegated to NIH. However, the proposed policy is not a rule-making for which APA notice and comment, and other procedural requirements for final agency actions, attach. The APA defines a "rule" as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy describing the organization, procedure, or practice requirements of an agency." 5 USC § 551. Exempt from the formal "rule-making" requirements of the law are matters "relating to agency management..." and matters concerning "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" 5 USC § 553.

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. The Policy will allow the agency to manage better its research award process and will also enable it to advance further its public health mission to support high-quality biomedical, behavioral, and clinical research and improve public health. In order to help it develop the Policy, the agency provided public notice and sought public comment on a draft policy. This notice and comment procedure were not undertaken to comply with the APA rule-making requirements; the agency does not believe that they apply because the Policy is not a rule.

9. Regulatory Flexibility Act: Some commenters asserted that the NIH must comply with the Regulatory Flexibility Act before it implements the proposed policy. The Regulatory Flexibility Act (RFA), 5 U.S.C. § 601 *et seq.*, was enacted to ensure that when adopting regulations, Federal agencies seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public. In particular, in accordance with the RFA, Federal agency regulations should not disproportionately affect small entities. Under the RFA, Federal agencies must determine the impact of their regulations on small entities and consider alternatives to alleviate burdens while achieving the agency's policy goals. By definition, the RFA applies when a Federal agency publishes a general notice of proposed rule-making under 5 U.S.C. § 553(b); in other words, it is triggered when an agency engages in rule-making under the APA. As noted above, this Policy is not a rule-making. Accordingly, the RFA does not apply.

10. Paperwork Reduction Act: Some commenters suggested that NIH must comply with the Paperwork Reduction Act (PRA) and cannot penalize investigators until Office of Management and Budget (OMB) clearance under the law is completed.

The PRA requires OMB review before an agency undertakes a "collection of information," regardless of whether the collection is mandatory or voluntary. Under the regulations implementing the law, a "collection of information" includes "obtaining...information by or for an agency by means of ... identical reporting ... or disclosure requirements imposed on" ten or more people or entities in any given year. 5 C.F.R. § 1320.3. While the request to provide copies of manuscripts or publications may not fall within this definition, even if the definition is met, we need not obtain any new OMB clearance because the Policy falls within the existing, approved information collection activities concerning applications, progress and final reporting, (OMB NO. 0925-0001, Expires 9/2007 and 0925-0002, Expires 6/2005). Furthermore, while some commenters focused their PRA criticism on the fact that the agency would be unable to penalize investigators if PRA review is not conducted, we note that the Policy serves as an alternative to compliance with existing reporting activities and, therefore, a discussion of any new "penalties" is misplaced.

The PRA also requires that agencies ensure the public has timely and equitable access to agency public information. The final manuscripts will be submitted under confidentiality agreements and will be posted on PMC only with the permission of submitting authors. Therefore, NIH does not believe that the final manuscripts submitted by authors constitute "agency public information" within the meaning of the PRA until the terms of the confidentiality agreement are met and an author permits posting on PMC. At that time, NIH expects to ensure timely and equitable access. As discussed above, submission is not expected to constitute a "publication" for purposes of filing patent applications, nor are the documents expected to be available to the public under FOIA. Thus, the absence of public availability prior to author permission does not constitute an improperly restrictive agency arrangement.

11. OMB Circular A-76: Some commenters argued that the agency must undertake a cost-comparison under OMB Circular A-76 to determine that the cost of the plan is less expensive than the cost of the present system of scientific publishing before implementing the

Policy.

This criticism is based on the assumption, in the words of one commenter, that "NIH wants PMC to become an in-house electronic publisher of these final manuscripts." This conclusion misstates the Policy and NIH's goals. The NIH Policy is to maintain copies of final manuscripts in a permanent, public archive so that the published results of NIH-funded research are permanently and readily accessible to NIH and others. This archive will be contained in the NIH's existing, electronic archive for scientific publications, PMC. The PMC archive has provided this service for the agency and others when articles are voluntarily provided to it. Electronic copies of publications are available through PMC in the same way that hard copies of publications are available from the NIH's National Library of Medicine.

The NIH Policy does not create any new obligations under OMB Circular A-76. Insofar as the activities of PMC are subject to the requirements of the Circular and related laws, those activities will continue to be reviewed and all applicable requirements will be met.

The NIH Public Access Policy is to establish a permanent archive of NIH-funded research publications. It is not expected to supersede any private sector publication activity or create competition with publishers.

12. Constitutional concerns/Executive Order (E.O.) 12630: One commenter suggested that the proposal implicates Executive Order 12630, which requires government officials to review actions that may have "takings" implications and to "be sensitive to, anticipate, and account for, the obligations imposed by the Just Compensation Clause of the Fifth Amendment in planning out and carrying out governmental actions"

The purpose of E.O. 12630 is to ensure that government officials do not unintentionally exercise the government's power of eminent domain, resulting in an unanticipated or undue drain on the government treasury. NIH believes that its Policy is consistent with E.O. 12630 and that no additional review is required. The private property at issue is the funding recipient's ability to assert copyright pursuant to 45 C.F.R. § 74.36. The NIH Policy does not interfere with that right, as authors and institutions will be voluntarily submitting copies of final manuscripts to NIH, and copyright may be asserted and enforced as it has been traditionally. Further, the same regulation that allows the funding recipient to assert copyright grants the government corresponding rights to reproduce, publish, or otherwise use the work for Federal purposes and to authorize others to do so. A voluntary request for the same use already allowed to the government by regulation is consistent with E.O. 12630 and does not trigger additional review.

13. Information Quality Act: One commenter asked whether the Federal Information Quality Act (IQAA), 44 U.S.C. § 3516 note, applies to documents contained in the electronic archive of publications created through the NIH Public Access Policy.

The NIH Public Access Policy calls for the centralized storage of NIH-funded scientific publications in PMC, an electronic archive of scientific publications operated by the National Library of Medicine. The NIH will include in its electronic archive a statement explaining that the views contained in the archived publications and manuscripts are those of the authors, and do not necessarily reflect the views of the government. Thus, publication in PMC does not make an article/scientific manuscript subject to the NIH Information Quality Guidelines.

III. Text of Final Policy Statement

The NIH Public Access Policy (the "Policy") on enhancing public access to archived publications resulting from NIH-funded research follows:

Beginning May 2, 2005, NIH-funded investigators are requested to submit an electronic version of the author's final manuscript upon acceptance for publication, resulting from research supported, in whole or in part, with direct costs¹ from NIH. The author's final manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process.

This Policy applies to all research grant and career development award mechanisms, cooperative agreements, contracts, Institutional and Individual Ruth L. Kirschstein National Research Service Awards, as well as NIH intramural research studies. The Policy applies to peer-reviewed research publications, resulting from research supported in whole or in part with direct costs from NIH, but it does not apply to book chapters, editorials, reviews, or conference proceedings.

Under this Policy, electronic submission will be made directly to the NIH National Library of Medicine's (NLM) PubMed Central (PMC): <http://www.pubmedcentral.nih.gov>. PMC is the NIH digital repository of full-text, peer-reviewed biomedical, behavioral, and clinical research journals. It is a publicly-accessible, stable, permanent, and searchable electronic archive.

At the time of submission, the author will specify the timing of the posting of his or her final manuscript for public accessibility through PMC. Posting for public accessibility through PMC is requested and strongly encouraged as soon as possible (and within twelve months of the

publisher's official date of final publication).

The publisher may choose to furnish PMC with the publisher's final version, which will supersede the author's final version. Also, if the publisher agrees, public access to the publisher's final version in PMC can occur sooner than the timing originally specified by the author for the author's final version.

Effective with progress reports submitted for Fiscal Year 2006 funding, this Policy provides an alternative means, via PMC, for NIH-supported investigators to fulfill the existing requirement to provide publications as part of progress reports. Though the NIH anticipates that investigators will use this opportunity to submit their manuscripts, sending electronic copies is voluntary and will not be a factor in the review of scientific progress.

By creating an archive of peer-reviewed, NIH-funded research publications, NIH is helping health care providers, educators, and scientists to more readily exchange research results and the public to have greater access to health-related research publications. As the archive grows, the public will be more readily able to access an increasing number of these publications.

Once the system is operational, modifications and enhancements will be made as needed. An NIH Public Access Advisory Working Group will be established to advise NIH/NLM on implementation and assess progress in meeting the goals of the NIH Public Access Policy.

This Policy is intended to improve the internal management of the Federal government, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.

Additional details for the public and for submitting authors pertaining to the implementation of this Policy are available at: <http://www.nih.gov/about/publicaccess/index.htm>.

Footnotes

¹Costs that can be specifically identified with a particular project or activity. NIH Grants Policy Statement, Rev. 12/2003; http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part2.htm#_Toc54600040.

²NIH Grants Policy Statement, Rev. 12/2003; http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part7.htm.

³These figures are derived from searching the PubMed database for citations with 2003 publication dates that include a reference to a specific NIH grant number. The data provide useful estimates of articles funded by NIH, although individual journal counts may vary slightly if calculations are performed using other sources or search strategies.

⁴PubMed includes links to full-text articles in PMC and to several thousand journal websites. PMC is an electronic archive for full-text journal articles, offering unrestricted access to its contents. Every full-text article in PMC has a corresponding entry in PubMed.

⁵Internet Health Resources, Pew Internet and American Life Project, Washington, DC 2003: http://www.pewinternet.org/pdfs/PIP_Health_Report_July_2003.pdf.

⁶Cybercitizen Health 3.0 Survey, Table 10 (Manhattan Research, New York, 2003).

⁷These data are derived from searching the PubMed database for citations with 2003 publication dates that acknowledge funding from either NIH specifically or from an agency of the Public Health Service (PHS). Because some journal citations do not include a reference to the specific NIH grant number, a broader search was done for citations where the Public Health Service (PHS) is identified as the sponsor of the research. These data provide useful estimates of articles funded by NIH/PHS, although individual journal counts may vary slightly if calculations are based on other sources.

⁸The estimated \$30 million is a conservative figure based on amounts spent on page charges and other publication costs on a sample of R01 grant application budgets, scaled up to provide an estimate of direct costs paid on all research grants.

⁹Established pursuant to 42 U.S.C. 286a, section 466 of the Public Health Service Act, as amended. The Board is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

¹⁰<http://opcit.eprints.org/oacitation-biblio.html>

¹¹<http://romeo.eprints.org/stats.php>

¹²Established pursuant to 42 U.S.C. 286a, section 466 of the Public Health Service Act, as amended. The Board is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

¹³<http://thomas.loc.gov/home/omni2005/index.htm>

¹⁴See, e.g., 42 U.S.C. 241(a)(1); 42 U.S.C. 286.

¹⁵HHS FOIA Regulations, 45 C.F.R. § 5.65(b); available at: <http://www.hhs.gov/foia/45cfr5.html#Subf>.

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