ESTIMATED ANNUALIZED BURDEN TABLE—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
	Adolescent Post test Questionnaire	204	1	30/60	102
	Adolescent Session Evaluation Forms (10 forms).	204	10	3/60	102
Adolescent Revised BodyWorks program comparison group participant.	Adolescent Pre test Questionnaire ..	63	1	30/60	32
	Adolescent Post test Questionnaire	50	1	30/60	25
Trainers of the Revised BodyWorks program.	Facilitator Feedback Forms (10 forms).	22	10	5/60	18
Coalition leaders, members, and site coordinators.	Coalition Pre test Survey	86	1	20/60	29
	Coalition Post test Survey	72	1	30/60	36
Total Hours	.....	.....	.....	.....	755

Dated: February 10, 2009.

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. E9–3439 Filed 2–17–09; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions and Delegation of Authority

Notice is hereby given that I have delegated to the Director, Office of Family Assistance, the following authority vested in me by the Secretary of Health and Human Services in the memorandums dated August 20, 1991, Delegations of Authority for Social Security Act Programs and September 16, 1997, Delegations of Authority for the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Pub. L. 104–193).

(a) Authority Delegated.

Authority under section 116 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 to take action related to the reimbursement of the federal share of overpayments that were recovered from former recipients of the Aid to Families with Dependent Children (AFDC) program.

(b) Limitations.

1. This delegation of authority shall be exercised under the Department's existing policies on delegations and regulations.

2. This delegation of authority excludes the authority to hold hearings.

3. Any redelegation shall be in writing and prompt notification must be provided to all affected managers, supervisors, and other personnel, and requires the concurrence of the Deputy Assistant Secretary for Administration.

(c) Effect on Existing Delegations.

As related to the authorities delegated herein, this delegation of authority supersedes all previous delegations relating to the AFDC program delegated to OFA.

I hereby affirm and ratify any actions taken by the Director, Office of Family Assistance, which involved the exercise of the authorities delegated herein prior to the effective date of this delegation.

(d) Effective Date.

This delegation of authority is effective upon the date of signature.

Date signed: February 5, 2009.

Daniel C. Schneider,

Acting Assistant Secretary for Children and Families.

[FR Doc. E9–3458 Filed 2–17–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Analysis of Comments and Implementation of the NIH Public Access Policy

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

Background

The National Institutes of Health (NIH) Public Access Policy requires investigators funded by the NIH to submit, or have submitted for them, an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication to the National Library of Medicine's digital archive, PubMed Central, to be posted publicly within 12 months after the official date of publication. Congress required the NIH to implement this funding limitation in Division G, Title II, Section 218 of the Consolidated Appropriations Act of 2008 (''Section 218''). The Policy is intended to advance science, provide public access to the published results of NIH-funded research, and improve human health.

The current Public Access Policy is the culmination of years of effort and community interaction. Prior to passage of Section 218, the NIH undertook extraordinary public outreach concerning the issue of public access to the published results of NIH-funded research. These outreach efforts included a review of over six thousand public comments and the establishment of an independent advisory group to review NIH's implementation of a voluntary Public Access Policy. Additionally, as part of the process to implement Section 218 in a transparent and participatory manner, the NIH formally sought public input through an open meeting and a Request for Information (RFI) seeking public comment. This open meeting occurred on March 20, 2008, and was designed to ensure that a discussion of stakeholder issues could occur. The feedback from the open meeting helped define questions for an RFI, which was published on the NIH Web site on March 28, 2008 and in the **Federal Register** on March 31, 2008 (73 FR 16881–16895). The RFI was designed to seek input on the NIH Public Access Policy, as it was revised to incorporate Section 218, and the responses to frequently asked questions (FAQs) concerning it. The RFI was open for sixty days following publication in the **Federal Register**, from March 28 to May 31, 2008.

Overview of Feedback

In response to the open meeting and RFI, the NIH received 613 unduplicated comments from a broad cross-section of the public, including NIH-funded investigators, members of the general public, patient advocates, professional organizations, and publishers. This report summarizes these comments.

Most comments offered broad support for the policy as written. Many comments requested a reduction in the delay period before papers can be made publicly available on PubMed Central. In some cases, commenters expressed concern about the Policy, others asked for clarification, and still others suggested alternatives to NIH's implementation. These questions and concerns fall into several broad categories:

- The potential administrative burden on Program Directors/Principal Investigators and awardee institutions.
- The details of implementing the Policy, including applicability, cost reimbursement, compliance monitoring and enforcement, and publisher support of the Policy.
- Associated issues, such as submission procedures, tracking submitted papers, version of the paper submitted, and managing and protecting copyrights.
- The accordance of the Policy Implementation with copyright law and the Administrative Procedures Act.
- Questions about Policy impact, such as financial impacts on publishers and NIH.

The NIH also received comments describing implementation efforts by numerous awardee institutions and publishers. In some cases, libraries took the lead on educating their faculty and supporting them in interpreting publishing agreements and submitting manuscripts to NIH. In other cases, offices of sponsored research provided guidance on the NIH Public Access Policy disseminated to their faculty community via the Web, memos, seminars, and video casts. Still other institutions described collaborations between libraries, offices of sponsored research, university counsels, and technology transfer offices. Several universities and private groups described the development of new policies on scholarly communications and new publishing forms and addenda that their faculty could use to ensure compliance with the Policy.

NIH Response

The NIH carefully considered the views expressed by publishers, patient advocates, scientists, university administrators, and others in the comments submitted. Throughout the course of its analysis, the NIH undertook various efforts to respond to concerns as it identified them. The agency aimed these actions to clarify the Public Access Policy and to facilitate compliance with Section 218. In May, July, and September of 2008, NIH updated the Public Access Web site to clarify the applicability, goals and anticipated impact of the policy, the available methods to submit papers, and planned methods to document compliance. In June 2008, NIH updated the NIH Manuscript Submission System (NIHMS), the online mechanism for submission of manuscripts to PubMed Central (PMC), to allow Program Directors/Principal Investigators (PDs/PIs) to delegate all aspects of submission tasks to authors, and to allow publishers who submit manuscripts to the NIHMS on behalf of authors to exert greater control over manuscript delay periods. In August, the National Library of Medicine issued a new Web tool to help the scientific community obtain PubMed Central Identifiers in bulk. In September 2008, NIH issued a Guide Notice (NOT–OD–08–119 at *http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-119.html*) reminding awardees about the compliance process and providing details concerning NIH's monitoring plan for fiscal year 2008.

These efforts appear to be working. The NIH estimates approximately 80,000 papers arise from NIH funds each year, and this total serves as the target for the Public Access Policy. During the voluntary policy, from May 2005 to December 2007, the NIH was able to collect a total of 19 percent of targeted papers, from all sources. Under the first five months of the Section 218 requirement (April to August 2008), this rate jumped to an estimated 56 percent of papers per month. While NIH expects to post all of the estimated 56 percent of these NIH papers, most of them will not be publicly available until 2009.

These first few months show the promise of a Public Access Policy requirement, its implementation, and the active support from the academic and publishing communities. However, work still remains as over 40 percent of applicable papers per month remain unsubmitted.

Implementation and process refinement will be continuing in the coming months. The NIH has established voluntary partnerships with many publishers to facilitate deposit of manuscripts and final published papers and expects these partnerships to continue to expand and the percentage of submitted papers to grow. The NIH will also continue to engage the community as we proceed to implement the Policy in the most efficient and effective manner possible.

Policy Overview

The NIH Public Access Policy, announced in January 2008, ensures that the public has access to the published results of NIH-funded research. *See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html.* It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication. To help advance science and improve human health, the Policy requires that these papers be accessible to the public on PubMed Central no later than 12 months after publication.

This Policy implements the Consolidated Appropriations Act of 2008, which directed the NIH to require investigators funded by the NIH to submit, or have submitted for them, an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication to the National Library of Medicine's digital archive, PubMed Central (PMC), to be posted publicly within 12 months after the official date of publication. The Policy builds upon the experience with NIH's voluntary Public Access Policy, which was published in 2005 and has three aims:

1. ARCHIVE. A central collection of NIH-funded research publications preserves vital published research findings for years to come.

2. ADVANCE. The archive is an information resource for scientists to research publications and for NIH to manage better its entire research investment.

3. ACCESS. The archive makes available to the public research publications resulting from NIH-funded research.

Policy History

The original, voluntary Public Access Policy, implemented May 2005 (NOT–OD–05–022, available at *http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html*), encouraged but did not require investigators receiving NIH funding to deposit their peer-reviewed manuscripts into PubMed Central. It was shaped, in large part, through discussion with the extramural community.

The NIH began public discussions on this topic with three town hall style meetings in 2004. From this feedback, the NIH developed a proposal for a voluntary public access policy that would make final peer-reviewed

manuscripts publicly available on PubMed Central within 6 months of publication. The NIH issued the proposed NIH Public Access Policy for comment in September 2004 (*see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-064.html* or *http://a257.g.akamaitech.net/7/257/2422/06jun20041800/edocket.access.gpo.gov/2004/04-21097.htm*). In response to its request for input on the proposed policy, NIH received over 6,200 comments from interested parties, including grantees, publishers and trade organizations. After carefully considering all the comments received, the NIH published a final policy, NOT–OD–05–022, on February 3, 2005 (also published at 70 FR 6891). Though 66 percent of comments favored a six-month delay period, the NIH implemented a voluntary Public Access policy with a 12-month delay period out of deference to concerns from some members of the publishing community.

Implementation of this voluntary policy was marked by continued engagement with multiple stakeholders in order to facilitate participation. The NIH staff met dozens of times and exchanged hundreds of letters with patient advocacy groups, awardee institutions and their representatives, publishers, and scientific societies regarding the Policy. (For a breakdown of meetings and correspondence, *see* slide 12 of NIH Director Elias Zerhouni's presentation at the March 20, 2008, open meeting at *http://publicaccess.nih.gov/comments/Overview_Context.pdf*.) In collaboration with publishers, investigators, grantees, and others, the NIH established systems to make it easy for scientists to deposit their manuscripts directly and for interested publishers to deposit manuscripts on scientists' behalf. For example, the NIH Manuscript Submission System (NIHMS), a Web service built to support the Policy, allows publishers to submit manuscripts on behalf of authors in bulk. The NIH also developed new forms of PubMed Central Journal agreements in collaboration with publishers, which enable publishers to submit final, published articles to PubMed Central from NIH-funded authors, only and/or from authors who pay open access fees to the journals.

Thus, for almost three years, the NIH asked the scientists it supports to deposit their NIH-funded scientific manuscripts in an NIH online system that would make them accessible to the public, freely and in perpetuity. But the compliance rate under the voluntary system demonstrated that it would not achieve the goals of the Public Access Policy. In December 2007, the Consolidated Appropriations Act of 2008 was signed into law, directing the NIH to require submission of manuscripts.

Implementing the Consolidated Appropriations Act of 2008

The Consolidated Appropriations Act of 2008 (Pub. L. 110–161), at Division G, Title II, Section 218, directs the NIH as follows: The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, that the NIH shall implement the public access policy in a manner consistent with copyright law.

On January 11, 2008, NIH issued the Public Access Policy implementing this clear and unambiguous new statute. As described in the *NIH Guide for Grants and Contracts* (NOT–OD–08–033, available at *http://grants.nih.gov/grants/guide/notice-files/NOT–OD–08–033.html*), the Policy restates the statute and offers the following specifics:

1. The NIH Public Access Policy applies to all peer-reviewed articles that arise, in whole or in part, from direct costs [1] funded by NIH, or from NIH staff, that are accepted for publication on or after April 7, 2008.

2. Institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles fully comply with this Policy.

3. PubMed Central (PMC) is the NIH digital archive of full-text, peer-reviewed journal articles. Its content is publicly accessible and integrated with other databases (*see: http://www.pubmedcentral.nih.gov/*).

4. The final, peer-reviewed manuscript includes all graphics and supplemental materials that are associated with the article.

5. Beginning May 25, 2008, anyone submitting an application, proposal, or progress report to the NIH must include the PMC or NIH Manuscript Submission reference number when citing applicable articles that arise from their NIH-funded research. This policy includes applications submitted to the NIH for the May 25, 2008 due date and subsequent due dates.

[1] ''Directly'' funded means costs that can be specifically identified with a particular project or activity. *See* NIH Grants Policy Statement, Rev. 12/2003.

Compliance

Compliance with this Policy is a statutory requirement and a term and condition of the grant award and cooperative agreement, in accordance with the NIH Grants Policy Statement. For contracts, the NIH includes this requirement in all R&D solicitations and awards under Section H, Special Contract Requirements, in accordance with the Uniform Contract Format.

In addition to announcing the Policy, the NIH established a Web site and posted responses to frequently asked questions (FAQs) that provide authors, their institutions, and their publishers with guidance on the implementation of the policy.

As part of the process to implement Section 218 in a transparent and participatory manner, the NIH formally sought public input through an open meeting and a Request for Information seeking public comment. The open meeting occurred on March 20, 2008 (NOT–OD–08–057), and was designed to ensure that discussion of stakeholder issues could occur. The feedback from the open meeting helped define questions for a Request for Information (RFI), conducted from March 28 to May 31 (NOT–OD–08–060). This report summarizes comments received at the meeting and in response to the RFI.

Open Meeting

The purpose of the Thursday, March 20, 2008, meeting was to seek comment from the public on implementation of the NIH Public Access Policy. The meeting was open to all, including NIH-funded researchers, representatives of universities and other NIH grantee organizations, publishers (including commercial organizations, professional societies, and journal editors), patients and public health advocates, and members of the general public. The NIH desired broad participation and commentary.

In particular, the NIH was interested in input concerning the Public Access Policy and the effectiveness of the policy's implementation. Individuals, groups, and organizations were also invited to submit written pre-meeting comments on the NIH Policy.

The NIH made every effort to make the meeting and pre-meeting comments open and transparent. Comments were made public as they were received. The meeting was video cast, and everyone who wished to speak was able to. All meeting materials, including the Guide Notice, **Federal Register** Notice, video cast, transcript, and comments are available at *http://publicaccess.nih.gov/open_meeting_march_2008.htm*.

Comments posted on this site are recorded as submitted and, in some cases, include duplicates.

Request for Information (RFI)

The feedback from the open meeting helped define questions for a Request for Information (RFI), which was published on the NIH Web site on March 28, 2008, and in the **Federal Register** on March 31, 2008 (73 FR 1681–1695) (*see* NOT–OD–08–060). The NIH sought information from the public, including all stakeholders, about the new NIH Public Access Policy and the frequently asked questions developed to assist investigators to implement it. Among other issues, the NIH particularly sought information about the following questions:

- Do you have recommendations for alternative implementation approaches to those already reflected in the NIH Public Access Policy?
- In light of the change in law that makes NIH's public access policy mandatory, do you have recommendations for monitoring and ensuring compliance with the NIH Public Access Policy?
- In addition to the information already posted on the NIH Web site, what additional information, training or communications related to the NIH Public Access Policy would be helpful to you?

Individuals, groups, and organizations interested in responding were invited to do so via a Web site that would record their responses for each question and make those responses publicly available. All comments received via the Web and e-mail related to the Public Access Policy RFI is now available at *http://publicaccess.nih.gov/comments.htm.*

Methodology for Analysis

Consolidating and Categorizing Comments

Comments were posted as they were collected, and commenters had the opportunity to respond to other comments. This was a deliberate effort on the part of NIH to encourage dialogue among stakeholders and to provide a more synthesized set of ideas for analysis. Individuals and organizations were allowed to submit multiple comments, and all comments were treated equally, regardless of the source. Although the NIH requested input on several open-ended questions at the meeting and in the RFI, commenters did not restrict themselves to input on these questions and offered a variety of opinions on other topics, either in addition to responding to the questions or in lieu of responding to them.

Combined, the open meeting and RFI yielded 613 unduplicated comments. The comments include materials entered through the online comment service, transcriptions of in-person statements offered at the March 20 Open Meeting, and e-mails received at the Public Access comments mail box.

Duplicates were identified by finding multiple comments from the same individual that contained identical content. Comments that were entirely off-topic (e.g., SPAM, selling products) were considered nonresponsive and thus not counted. If an individual submitted multiple responses and each submission contained new content, they were not marked as duplicates and were separately counted and analyzed. In addition, if the same comment or information (e.g., a form letter) was received from two or more individuals those comments were counted separately and not marked as duplicates.

All unduplicated comments underwent an initial review to identify the topic(s) addressed and to gain a sense of the relative number of commenters who addressed each topic. This initial analysis helped to identify major themes for inclusion in this report.

The 613 unduplicated comments covered by this report, combining comments from both the open meeting and the RFI, and including PDF comments converted to text using optical character recognition, became available in a single file at *http://publicaccess.nih.gov/comments.htm* in October 2008. We invite our stakeholders to use these resources to conduct independent analyses of these data.

The public comments were largely supportive of the Policy. Comments clustered around several broad themes. We describe them below, followed by NIH's analysis and response where appropriate.

1. Need for the Policy

The most common theme among comments, expressed in a large majority of all comments, was support for the Policy as written. When reasons for support were offered, the most common were as follows: (1) The perceived benefit to patients and their families, (2) the belief that the American public has a right to access papers arising from NIH funds, and (3) the expected potential of the policy to advance scientific discovery. A small minority of comments expressed general disagreement with the Policy and/or felt that increasing access to papers arising from NIH funds was unnecessary.

2. The Length of the Delay Period

The second largest number of comments, second only to general support for the Policy, were comments advocating reducing the period of time before papers are made publicly available on PubMed Central. A large number of commenters argued for a shorter maximum delay period—many suggested 6 months, many no delay period at all, and a few suggested 3 months. Advocates for reducing the period of time explained that doing so would provide greater benefits to the public and to science. Some further claimed, and provided examples of how, shorter delay periods would not harm publisher interests. A few commenters suggested that the maximum delay period should be greater than 12 months. These commenters claimed that a longer delay period was needed to protect journals in certain disciplines.

The NIH appreciates the concerns of all commenters concerning the maximum delay period between journal publications and posting on PubMed Central. The Consolidated Appropriations Act of 2008 specifies the maximum delay period at 12 months. Copyright holders may always post materials with a shorter delay period, at their discretion.

3. Actions Taken by Institutions to Support Implementation

Many commenters shared their efforts to implement and promote the Policy. Several publishers described their efforts to support implementation, either by facilitating submission of papers on behalf of their authors, or by offering new guidance and publishing agreements so that their authors may understand how to comply with the Policy.

A number of awardee institutions offered their implementation strategies as well. In some cases, libraries were taking the lead in educating their faculty and supporting them in interpreting publishing agreements and submitting manuscripts to the NIH. In other cases, offices of sponsored research described guidance on the NIH Public Access Policy disseminated to their faculty community via the Web, memos, seminars, and video casts. Still other institutions described collaborations between libraries, offices of sponsored research, university counsel, and technology transfer offices. Several universities and private groups also described institutional policies on scholarly communication and new publishing forms and addenda that their

faculty could use to ensure compliance with the Policy.

The NIH is interested in the role institutions may play in supporting the Policy and appreciates the efforts of these commenters to both support the policy and share their strategies. In January 2008, the NIH published an article outlining key questions institutions may wish to consider as they implement the Policy (*http://grants.nih.gov/grants/partners/0108Nexus.htm#investigator).* Based on the comments submitted, it appears that the community has developed multiple approaches to issues described in this article, but it is too early in the implementation of the Policy to determine if some approaches are more successful than others.

NIH employees publish several thousand peer-reviewed papers each year, and the NIH has to support the Policy as an investigator institution as well. Our approach to ensure compliance among our own faculty involves support from the NIH Library, a unit of the NIH Office of Research Services; NIH technology transfer representatives; and the NIH Office of Intramural Research. The NIH offers employees guidance on our Web site, a publishing agreement addendum, centralized negotiation of publishing agreements, help desk support for manuscript submission and policy questions, and staff training upon request. *See http://publicaccess.nih.gov/nih_employee_procedures.htm* for more information.

4. Administrative Burden for Institutions and Principal Investigators

Some comments expressed concern that the Policy would create undue burdens on authors, investigators, and institutions. The comments are described below.

A. Negotiating Publisher Agreements

Some comments suggested the Policy required authors and individual investigators to negotiate with publishers directly. They felt individual authors lacked the skills or bargaining power to develop an agreement with a publisher that met their needs under the Policy.

Investigators are central to implementing the Policy and usually are the initial copyright holder of the manuscripts that fall under the Policy. They may need to negotiate the terms of publishing agreements with publishers directly. However, the NIH expects that institutions will support their investigators in complying with terms and conditions of award. The NIH Public Access Policy states ''Institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles fully comply with this Policy.'' The NIH underscores the importance of institutional support throughout the Frequently Asked Questions (FAQ). For example, FAQ C4 addresses publishing agreements or publishers that may not support compliance with the Policy. FAQ C11, released in May 2008 in response to this feedback, addresses another aspect of this concern. In both cases, the NIH encourages authors and investigators to work with their institution's office of sponsored research.

With regard to particular agreement terms, individual copyright arrangements can take many forms, and authors and their institutions should continue to manage such arrangements as they have in the past.

Institutions and investigators may wish to develop particular copyright agreement terms in consultation with their own legal counsel or other applicable official at their institution, as appropriate. As an example, the kind of language that an author or institution might add to a copyright agreement includes the following (as described in FAQ C3):

''Journal acknowledges that Author retains the right to provide a copy of the final peer-reviewed manuscript to the NIH upon acceptance for Journal publication, for public archiving in PubMed Central as soon as possible but no later than 12 months after publication by Journal.''

There are many other potential models, some of which were described in other comments and are available for viewing therein.

B. Ability for Investigators to Publish in the Journal of Their Choice

A few comments expressed concern that some journals would refuse to allow manuscripts to be posted to PMC in accordance with the Policy, and authors would not be able to publish in those journals. They claimed this could occur despite an author's best efforts to negotiate with a publisher.

The NIH agrees that author choice of publication is a very important issue, but if this situation were to occur, an author might have to find an alternate journal. Therefore, the NIH encourages authors to clearly communicate with and address these issues before they may transfer their copyright and potentially lose their ability to comply with the Policy. The Public Access Home page states: ''Before you sign a publication agreement or similar copyright transfer agreement, make sure that the agreement allows the paper to be submitted to NIH in accordance with the Public Access Policy.''

The NIH has also engaged the publishing community in order to minimize copyright concerns when possible. The NIH has established voluntary partnerships with many publishers who agree to facilitate deposit of manuscripts and final published papers. The number of papers submitted via these agreements has grown since the Public Access Policy took effect. The NIH issued guidance to authors to clarify these various arrangements in July 2008. The guidance can be found at *http://publicaccess.nih.gov/submit_process.htm*. Whether because of NIH's direct efforts, clear communication from authors and institutions or because of publisher support for the Policy, NIH did not receive comments indicating that publishers or publishing agreements have actually prevented authors from complying with the Policy. To the best of our knowledge, this concern currently remains a hypothetical risk and not a manifest problem.

C. Cost Reimbursement

Some commenters raised the issue of investigators or awardees needing to pay potential publishing costs and fees associated with the Policy (e.g., fees for posting to PubMed Central, fees to reduce delay periods). Some commenters suggested that the NIH should cover these costs, others requested clarification concerning costs, and still others thought the NIH would offer no financial support to either institutions or publishers. As such, the commenters felt that the Policy was an unfunded mandate that might harm author or publisher interests, with junior authors (new investigators and trainees) being especially vulnerable. However, several commenters thought any unrecovered costs associated with the Policy were worth the benefits, and one commenter even requested that the NIH stipulate that costs not be covered.

As with other costs, the NIH will reimburse publication costs, including author fees, for grants and contracts on three conditions: (1) Such costs incurred are actual, allowable, and reasonable to advance the objectives of the award; (2) costs are charged consistently regardless of the source of support; (3) all other applicable rules on allowability of costs are met. Generally, page charges for publication 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.

D. Compliance Burden

Some commenters expressed concern about the time Program Directors/Principal Investigators (PDs/PIs) and authors will need to spend to submit papers. A few commenters said that a simple submission system was critical to the success of the policy. Among those commenting on the potential burden of the submission process, a portion said the existing NIH Manuscript Submission System (NIHMS) was easy to use, a portion said it was complex and burdensome, and a portion were unaware of how it worked. Some commenters also expressed concern or offered suggestions related to the notification and management of PubMed Central Identifiers (PMCIDs), which are assigned to papers after they are submitted and can be used to demonstrate compliance with policy on applications, proposals, and reports.

The NIH agrees with the need to have a simple manuscript submission process to minimize the time associated with deposit of manuscripts into PubMed Central. NIH has worked diligently since the adoption of the voluntary Public Access Policy in 2005 to develop a streamlined and efficient process. During the voluntary Policy, NIH found it took authors about 10 minutes to deposit a paper in the NIH Manuscript Submission System (NIHMS); the time decreased for submitters as they began to submit more papers and gained experience with the system.

The NIH continues to refine the NIHMS as necessary. For example, starting in June 2008, NIH eliminated the need for PDs/PIs to review each deposit. Instead, the NIHMS now allows authors to complete all aspects of manuscript submission, with the idea that greater flexibility in delegation will minimize PD/PI burden. The NIH gives specific guidance on these submission processes on its Web site at *http://publicaccess.nih.gov/submit_process.htm*. This guidance also describes how authors can delegate some submission tasks to someone in the author's organization (e.g., an assistant or a librarian), or to their publisher, and how all aspects of submission can be delegated to a publisher that participates in PubMed Central.

The NIH has developed Policy compliant alternatives to manuscript deposit that require less author effort. For example, as described at *http://publicaccess.nih.gov/submit_process.htm*, some publishers sign agreements with the NIH to submit final published articles directly to PubMed Central without author involvement. Since the passage of the 2008 Consolidated Appropriations Act, the number of publishers signing such agreements has significantly increased.

The NIH has also made changes to the way it reports PubMed Central reference numbers (PMCID), and how authors and delegates can use the NIHMS system. For example, as described in FAQ C9, issued May 2008, the PMCID is posted in PubMed as soon as an article has been successfully processed by PMC, which usually occurs around the time of publication. PMCIDs are listed in the lower right corner of the Abstract Plus view of PubMed (*http://www.ncbi.nlm.nih.gov/PubMed/*). If the paper is not yet publicly available on PMC, PubMed will also list the date the paper will become available. The NIH provides other methods of obtaining PMCIDs (e.g., *http://www.ncbi.nlm.nih.gov/sites/pmctopmid,* created in August 2008), as do several bibliography management software packages.

E. Collaborations With Institutional Repositories

As a way to relieve compliance burdens on their faculty, a few institutions requested direct feeds from their repositories to PubMed Central or the NIH Manuscript Submission system.

The NIH believes that these are worthwhile suggestions, but it is concerned that they raise important technical and logistical challenges regarding author approval, copyright permissions, quality control, and formats for electronic transfer. The NIH remains open to closer collaboration with institutional archives and will consider this issue as the Policy matures. National Library of Medicine representatives met with representatives from academic communities to discuss this issue in November 2008.

5. Expanding the Scope of the Public Access Policy

Some commenters suggested the Policy be expanded in several ways from investigators and research funded by additional or all Federal research funds to papers published before April 7, 2008, or to the data and unpublished results associated with an award. A few comments suggested a specific alternative approach to expand the scope of the policy to exempt all works arising from NIH/Government funds from copyright protection.

The NIH understands and appreciates the strongly held views of many commenters concerning access to works funded by the NIH and the Government generally. The NIH Public Access Policy implements the Consolidated Appropriations Act of 2008, Division G, Title II, Section 218 (Pub. L. 110–161), a Federal statute that was passed by Congress and signed by the President of the United States. This statute is very specific—it indicates what is to be submitted and when, and when and where submissions are made publicly available.

The NIH's new Access Policy took effect a few months after passage of the law to allow copyright holders to make arrangements to post directly and in accordance with copyright law. Regarding the suggestion that works funded through the NIH should be denied copyright protection, we note that works of Government employees, including NIH investigators, are not subject to copyright protection in the United States (17U.S.C. 105). The works of Government awardees, however, are subject to copyright protection.

6. Issues About the Policy and Its Implementation Requiring Clarification

A number of issues were raised that resulted in NIH providing clarifications.

A. Compliance Monitoring and Enforcement

A number of comments suggested that investigators should include evidence of compliance with the Policy in applications, proposals or reports submitted to the NIH. A few comments simply asked what is the process for enforcing compliance.

It is unclear whether the commenters proposing reference within NIH applications, proposals, or reports were endorsing the Policy as implemented, as it already specifies that investigators should do so, or were unaware of the compliance procedure described in the January 11, 2008 Guide notice. As is made clear therein, the NIH expects that investigators citing their NIH-funded papers subject to the Policy in NIH applications, proposals, or progress reports will include the PubMed Central reference number for each applicable paper.

The NIH clarified the compliance reporting process with an update to the Web site in May 2008 and further clarified the compliance documentation and monitoring processes in a Guide Notice (OD–NOT–08–119 at *http://grants.nih.gov/grants/guide/notice-files/NOT-OD–08–119.html*). FAQ C8, also part of the May 2008 release, clarifies that the Policy reporting requirement for applicants and PDs/PIs only applies to papers that are authored by them or arose from their NIH award and fall under the policy.

Some commenters also asked about consequences for PDs/PIs and institutions if manuscripts are not submitted as required by the law and the Policy. Generally, and as specified in the *NIH Guide for Grants and Contracts,* a grantee's failure to comply with the terms and conditions of award may cause the NIH to take one or more enforcement actions, depending on the severity and duration of the noncompliance. The NIH will undertake any such action in accordance with applicable statutes, regulations, and policies. The NIH generally will afford the grantee an opportunity to correct the deficiencies before taking enforcement action unless public health or welfare concerns require immediate action. However, even if a grantee is taking corrective action, the NIH may take proactive action to protect the Federal Government's interests, including placing special conditions on awards or precluding the grantee from obtaining future awards for a specified period, or may take action designed to prevent future noncompliance, such as closer monitoring. See Enforcement Actions in the NIH Grants Policy Statement (11/03): *http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part8.htm#_Toc54600145*.

B. Preventing Copyright Violations on PMC

The NIH received feedback on the potential copyright implications of posting papers to PubMed Central (PMC), which cluster into two themes. Some comments asked how the NIH will prevent inappropriate posting of materials to PMC without permission of the copyright holder or posting prior to expiration of the delay period specified by the submitter. Other comments, described below, expressed concern about the operation of PMC and the protections it offers copyright holders against inappropriate use of their works.

The comments about inappropriate posting primarily focused on individuals posting content without copyright permission. The NIH manuscript submission system is the only way in which authors may deposit manuscripts to PMC. That process requires the author to confirm he or she has the right or permission for the specific version submitted to be posted to PMC after the specific delay period. Publishers and authors have occasionally disagreed on the terms of their publishing agreements. Publishers have submitted final peer-reviewed manuscripts on behalf of their authors requesting a specific delay period, and in the course of approving the manuscript for posting, authors have selected a shorter delay period. In June 2008, NIH modified the NIH Manuscript Submission System to allow a publisher to fix the delay period when they submit a manuscript on behalf of their authors. Authors now have to contact NIH and their publisher if they wish to change the delay. We expect this more direct communication will result in fewer disagreements about delay periods.

Commenters also asked how NIH safeguards privately copyrighted materials on PubMed Central once it is posted. NIH has eight years of experience in safeguarding copyrighted material on the PMC Web site, the host archive of the Public Access Policy. There are over 1.5 million full-text articles on the Web site. PMC has algorithms to detect inappropriate use, such as bulk downloading, and sites responsible for inappropriate use are warned of the consequences of violating copyright provisions and blocked from further access.

C. Applicability of the Policy

Some commenters asked questions or expressed confusion about the papers to which the Policy applies. Applicability was clarified in the May 2008 FAQ B1. The Policy applies to any manuscript that:

Is peer-reviewed;

- And, is accepted for publication in a journal on or after April 7, 2008.
- And, arises from:
- Any direct funding [2] from an NIH grant or cooperative agreement active in fiscal year 2008, or;
- Any direct funding from an NIH contract signed on or after April 7, 2008, or;
- Any direct funding from the NIH Intramural Research Program, or;
- An NIH employee.

Consistent with the NIH's long-standing interest in developing a full and complete database, however, authors may also submit final peer-reviewed manuscripts accepted before April 7, 2008, that arise from NIH funds, if they have appropriate copyright permission or authority.

D. Version Control

The NIH received comments with questions or concerns about the version of the paper posted to PMC. Some commenters suggested that only final, published versions of articles should be posted as they felt final peer-reviewed manuscripts may contain scientific errors corrected during the copy-editing process. A few commenters expressed concern that the formatting processes that are part of PubMed Central may change the meaning of the paper.

The NIH has been posting final peer-reviewed manuscripts on PMC for years and found them to offer the same scientific information as the final published article. The NIH obtains the permission of the author before each author manuscript is posted to PMC. We ask authors to review the specific document to be posted, and allow them to correct any scientific issues during the approval process and afterwards. To date, we are unaware of uncorrected errors in PubMed Central.

In response to questions about the version of a paper that may be posted on PMC, the NIH issued FAQ D6 in May 2008. It explains that the NIH Public Access Policy is based on a law (Division G, Title II, Section 218 of Pub. L. 110–161) that requires investigators to submit ''their final, peer-reviewed manuscripts'' to PubMed Central. The NIH will accept the final published article in lieu of the final peer-reviewed manuscript, provided that the submitter has the right to submit this version. Some journals post final published articles directly to PMC. *See http://publicaccess.nih.gov/submit_process_journals.htm* for more information.

Papers need to be converted into the PMC Archival format in order to be posted. This process does not change the meaning or the content of the paper. However, it does further the goals of the Public Access Policy and is a fundamental feature of the PMC database. Once posted to PubMed Central, results of NIH funded research become more prominent, integrated, and accessible, making it easier for all scientists to pursue NIH's research priority areas competitively. PubMed Central materials are integrated with large NIH research databases such as Genbank and PubChem, which helps accelerate scientific discovery. Finally, the Policy allows the NIH to monitor, mine, and develop its portfolio of taxpayer-funded research more effectively and archive its results in perpetuity.

The NIH should provide guidance on copyright issues.

Some commenters requested explicit guidance on copyright issues. The NIH provides an example in FAQ C3 (*http://publicaccess.nih.gov/FAQ.htm#c3*), which states that ''* * * Individual copyright arrangements can take many forms, and authors and their institutions should continue to manage such arrangements as they have in the past.''

[2] ''Directly'' funded means costs that can be specifically identified with a particular project or activity. See NIH Grants Policy Statement, Rev. 12/2003.

Institutions and investigators may wish to develop particular copyright agreement terms in consultation with their own legal counsel or other applicable official at their institution, as appropriate. As an example, the kind of language that an author or institution might add to a copyright agreement includes the following:

''Journal acknowledges that Author retains the right to provide a copy of the final peer-reviewed manuscript to the NIH upon acceptance for Journal publication, for public archiving in PubMed Central as soon as possible but no later than 12 months after publication by Journal.''

7. Requests for Additional Information About the Policy and Implementation Procedures.

A. NIH Should Disseminate Information About Publisher Support of the Policy

Some commenters asked for a list of publishers that allow their authors to comply with the policy. NIH has developed and maintains two lists of publishers and journals. Hundreds of journals make the final published version of every NIH-funded article publicly available in PubMed Central within 12 months of publication without author involvement. *See http://publicaccess.nih.gov/submit_process_journals.htm* for a list of these journals. Some publishers will deposit an individual final published article in PubMed Central upon author request, and generally for a fee. See the list of publishers at *http://publicaccess.nih.gov/select_deposit_publishers.htm.* All other publisher policies and procedures require active author involvement to finalize submission, as described in Methods C and D of the Policy Web site (*see http://publicaccess.nih.gov/submit_process.htm*).

B. Frequently Asked Questions

Some commenters specifically highlighted the Frequently Asked Questions as a helpful resource. A few mentioned the Public Access Policy Web site in its entirety as helpful. The NIH also offers additional resources to support training efforts, including complete slide presentations that may be downloaded and adopted for stakeholder use. These are available at *http://publicaccess.nih.gov/communications.htm.*

8. Implementation Alternatives

A. Administrative Procedure Act

Some commenters felt the implementation of the Public Access Policy was in violation of the Administrative Procedure Act. They claimed the NIH should not have implemented the Policy without going through a notice and comment rulemaking and that the January 11 Guide Notice (*http://grants.nih.gov/grants/guide/notice-files/NOT-OD–08–033.html*) was issued inappropriately.

The NIH believes the initiation of notice and comment rulemaking to implement the new statute is unwarranted and contrary to the interests of science and the public health. The mandatory access requirement now adopted in NIH Public Access Policy derives from Public Law 110–161, § 218, a Federal statute that was passed by Congress and signed by the President of the United States. This statutory provision is a clear and unambiguous directive to the NIH Director to require NIH grantees to provide their manuscripts to PubMed Central after the date of publication.

Where, as is true in this case, a statute clearly directs an agency to execute a congressional objective, and Congress has not directed the agency to promulgate implementing regulations, an agency's interpretation or statement of policy or procedure regarding the statute does not trigger a requirement for notice and comment rulemaking. 5 U.S.C. 553(b)(3)(A); *see* also *Shalala* v. *Guernsey Mem. Hosp.,* 514 U.S. 87, 99 (1995); *American Mining Congress* v. *Mine Safety & Health Admin.,* 995 F.2d 1106, 1112 (D.C. Cir. 1993). Further, the only significant difference between the new law and the NIH's former voluntary public access policy is implementation of the legal directive to require provision of the manuscripts; there is no ''gap'' left by Congress that would require a rule to implement the statute. *See Chevron, U.S.A., Inc.* v. *NRDC, Inc.,* 467 U.S. 837, 843–44 (1984). The mechanics of implementing the former policy were widely understood as described in published agency policy and in widely accessible Internet resources maintained by the NIH. Furthermore, the mechanics of implementing the new statute are substantially the same as, and consistent with, the NIH's earlier policy implementation. Agency implementation of a plainly worded Congressional mandate—particularly where consistent with established agency policy—does not require a rulemaking proceeding. *See,* e.g., *Gray Panthers Advocacy Cmte.* v. *Sullivan,* 936 F.2d 1284, 1291 (D.C. Cir. 1991). To the extent the NIH has offered, and continues to offer, interpretative policy guidance or procedural assistance with regard to the new law, such guidance is not of free-standing legal effect but rather is intended to assist grantees to comply with their statutory obligations. See American Mining Congress, 995 F.2d at 1112. The impact of the mandatory submission requirement arises from the statute, and rulemaking is not necessary to implement this statutory requirement.

B. America Competes Act

Some commenters suggested the America Competes Act as an alternative to the NIH's implementation. Relying on dissemination of reports and abstracts as described in the America Competes Act is not consistent with the Consolidated Appropriations Act of 2008.

C. A ''Dark Archive'' or Linking to Publisher or Other Web Sites

A few comments suggested that awardees should submit manuscripts to the NIH for internal NIH reporting and portfolio management, and public access could be provided by links to freely available materials on publisher sites. Some comments suggested that the NIH only provide public access via publisher sites, and not maintain an internal archive at all. Many comments explicitly repudiated these ''dark archive'' or linking approaches and argued that the policy should require deposit to PubMed Central. One comment suggested that the Public Access Policy mandate deposit to institutional archives (i.e., those maintained by universities), and that these repositories could submit papers to PubMed Central.

The Consolidated Appropriations Act of 2008 explicitly states that papers should be submitted to and made publicly available on PubMed Central and the NIH must follow this law. PubMed Central (PMC) is the NIH National Library of Medicine's (NLM) digital repository of full-text, peer-reviewed biomedical, behavioral, and clinical research journals. NLM and its predecessor organizations have been archiving the biomedical literature for over 150 years and are experienced in maintaining a stable archive of scientific information. PMC is currently used by approximately 400,000 users per day.

There are several critical advantages to the scientific community for making papers publicly available on PMC. Once posted to PMC, results of NIH-funded research become more prominent, integrated, and accessible, making it easier for all scientists to pursue NIH's research priority areas competitively. PMC materials are integrated with large NIH research databases such as Genbank and PubChem, which helps accelerate scientific discovery. Clinicians, patients, educators, and students can better reap

the benefits of papers arising from NIH funding by accessing them on PMC at no charge. Finally, the Policy allows NIH to monitor, mine, and develop its portfolio of taxpayer-funded research more effectively, and archive its results in perpetuity.

The Public Access Policy does not state that PMC will be the sole repository for these manuscripts and publications. The NIH has always pointed to journal and publisher sites from PMC and PubMed and will continue to do so. *See http://www.ncbi.nlm.nih.gov/projects/linkout/* for more information. Others may also post and/or archive papers arising from NIH funds at other locations, subject to permission from copyright holders, as appropriate.

9. Copyright Issues

A. Consistency With Copyright Law

The Consolidated Appropriations Act of 2008 requires that the NIH implement the policy consistent with copyright law. Some commenters suggested that that might not be possible.

The NIH disagrees with commenters' suggestions that it will be difficult to implement the new statute in a manner that is consistent with copyright law. To the contrary, the effect of the new statute is merely that an author of a work that was funded by grants from the NIH must retain, from the entire ''bundle of rights'' [3] inherent in a copyrightable work, a right to provide the author's manuscript to PubMed Central for display on its Web site. The author (or his or her employer) could, for instance, address this point in the agreement with the publisher by a simple statement that reserves, on behalf of the assignor, the right to provide the manuscript to PubMed Central for display. Such a reservation of rights by the author is clearly consistent with copyright law and the Consolidated Appropriations Act of 2008.[4]

U.S. Copyright law anticipates the transfer of ownership rights in a copyright by agreement among parties or by operation of law (17 U.S.C. 201(d)). Publishers do not own any portion of a copyright in a work that is not transferred to them by the author, or, if it is a work for hire, under an employment agreement with the employing institution. Similarly, the Federal Government, through OMB Circular A–110, grants federally funded institutions the right to retain intangible property (including copyright) as part of the terms and conditions of a Federal grant. Congress could, if it wished, require grantees to assign all rights to intangible property to the Federal funding agency, as indeed was the case for patent rights prior to the Bayh-Dole Act of 1980. However, in recognition of the public interest in having biomedical scientific publications widely accessible, Congress has required only that NIH-funded authors reserve the right to post works on PubMed Central. As one among dozens of conditions imposed on a grantee by Congress in return for taxpayer support of the grantee's work, the reservation of this small sliver of the entire bundle of rights inherent in the work is completely consistent with U.S. Copyright law.

B. Value of Publisher-Held Copyrights if Other Aspects of Copyright Are Retained by Authors

A few comments indicated concern that posting the final peer-reviewed manuscript to PubMed Central undermines the value of all other aspects of copyright that a Publisher may have obtained under the Policy.

As described above, it is acceptable from a copyright perspective for investigators to ensure their papers can be posted to PubMed Central. However, the NIH Public Access Policy applies to awardees, not publishers. The NIH implemented the Public Access Policy prospectively to ensure that publishers have the ability to refuse to publish any paper they wish, for any reason they wish, including not obtaining all the rights they may prefer from authors of papers arising from NIH funds. The 12-month delay period and the ability of NIH awardees to cover publication-related costs from their awards are important aspects of the Policy created specifically to address concerns of some publishers and ensure their interests are protected.

These comments concerning loss of value of the copyrighted work were not supported by data and run contrary to NIH's experience. The voluntary support of hundreds of journals to collect papers under the Policy is, perhaps, a reflection of publisher protections in the Public Access Policy. A significant number of journals support their authors by volunteering to submit manuscripts, and many more go beyond the policy by submitting final published articles. Hundreds even deposit final published articles that do not arise from NIH funds. Many of these journals also permit their papers to be posted to PubMed Central before the 12-month maximum delay period. The NIH appreciates the efforts of all these journals to support the Policy.

C. Section 201(E) of the Copyright Act

One comment raised a concern that Section 201(e) of the Copyright Act prohibits a requirement for NIH awardees to retain a right to deposit in PMC. Section 201(e) of the Copyright Act states that when an individual author's ownership of a copyright has not previously been transferred voluntarily by that individual author, no action by any governmental body purporting to seize copyright shall take effect.

Section 201(e) does not apply to the PMC situation for many reasons. First, the works at issue here are for the most part works in which the author has already expressly agreed how copyright will be handled through the employment agreement with their employing institution (see 201(b) works made for hire). Second, the employing institution will have previously accepted, as a term and condition of the grant, the obligation to submit a work created under the grant to PMC. Third, Congress did not require an involuntary transfer of rights, or otherwise ''seize'' rights. Rather, it required submission of the manuscript to PMC. One way of complying with this requirement would be for the author to retain the right to post, rather than transfer that right to a third party. Such retention by the author does not constitute a seizure or involuntary transfer of rights. Copyrighted material on PMC remains

[3] *See* 17 U.S.C. 106.

[4] Copyright in a manuscript vests initially with the author and remains with the author unless the rights are expressly assigned. 17 U.S.C. 201(a). Of course, the author may be hired to write the manuscript or may otherwise enter into an arrangement that assigns the rights to an employer, making the employer the author for purposes of the Copyright Act. 17 U.S.C. 201(b). Nevertheless, the author owns all of the rights in the manuscript, and a potential publisher owns no rights, unless and until they are conveyed by the author to the publisher. A publisher that subsequently obtains copyright to the work can continue to hold and enforce all of the rights transferred by the author, subject to the principles of the fair use doctrine, as are all copyrights. PubMed Central includes many copyrighted works, and public use of a work on PubMed Central is constrained by copyright, including the principles of fair use, just as it would be if a member of the public viewed the publication in a library, for example. Further, the public is alerted that the works they are viewing may be subject to copyright, with the following statement: ''This site also contains resources such as PubMed Central, Bookshelf, OMIM, and PubChem which incorporate material contributed or licensed by individuals, companies, or organizations that may be protected by U.S. and foreign copyright laws. All persons reproducing, redistributing, or making commercial use of this information are expected to adhere to the terms and conditions asserted by the copyright holder. Transmission or reproduction of protected items beyond that allowed by fair use (*http://www.copyright.gov/fls/fl102.html*) as defined in the copyright laws requires the written permission of the copyright owners.'' [*http://www.ncbi.nlm.nih.gov/About/disclaimer.html*]

fully subject to copyright, and copyright owners may fully enforce their rights. Fourth, to the extent that the PMC requirement can be read as a Government-retained interest, Congress often requires funding agencies to retain certain rights in the public interest in tangible and intangible property first produced with public funds. To read the patent or copyright laws as preventing such action would overturn many long-standing provisions of OMB Circular A–110 as well as the Federal Acquisition Regulation (F.A.R.) (e.g., rights in data first produced in its procurement contracts, rights in inventions, rights in computer software).

D. International Copyright Issues

A few comments suggested that copyright concerns stem from making materials available on the Internet, and therefore internationally available. The NIH appreciates that the scientific community is truly global and interchange among scientists worldwide is essential for professional and scientific advancement. The Policy applies to all NIH-funded investigators, including those in foreign countries. The PMC archive is available through the Internet, and therefore globally. Copyrights on works displayed in PMC are fully enforceable by the copyright owners in the U.S. and abroad. The NIH notes that many publishers post materials to their Web site, which also makes them globally available.

One comment raised specific concerns about the Berne Convention and the World Trade Organization (WTO) TRIPS provision. The Berne Convention's provisions require that member countries provide protection for literary and artistic works, including scientific publications. Such protection is of course provided in the United States by its Copyright Act. The PMC deposition requirement does not undermine copyright protection of the grantee's work. Copyrights on works displayed in PMC are fully enforceable by the copyright owners. Article 2(1) of the Berne Convention is consistent with the widespread practice of reservation of rights in works by the funders of those works, which is essentially what Congress did when it required, as a condition of a grant award, the reservation of the right to place a grantee's manuscript in PMC. The concern about the Public Access Policy and potential conflict with Article 13 of the WTO TRIPS is unwarranted because the requirement does not interfere with the author's commercial use of the work. Article 13 directs member countries to confine limitations on exclusive rights to special cases that do not conflict with the normal exploitation of the work. But the deposition requirement makes no limitation on the exclusive rights attached to the work. It merely requires, as a reasonable and mutually agreed condition of the grant award, that the author or its institution reserves the right to display the author's manuscript on PMC. If the PMC deposition requirement violates TRIPS, then any Government procurement contract that secures rights to works made under the contract would also violate TRIPS. No compelling argument for that proposition has been presented to the NIH.

10. Evaluation and Impact

A. Costs to the NIH

Some commenters asked about the operation and implementation costs of the policy. By building on an existing information technology infrastructure housed at the NLM, the NIH Public Access Policy is an exceptionally cost-effective means to accomplish its goals of archiving, advancing science, and enhancing accessibility. At full compliance, Public Access would cost the NLM $4.5 million per year (i.e., submission of 80,000 articles per year). Costs may decrease as a greater portion of journals submit papers directly to PMC. The NIH spent an additional $250,000 in fiscal year 2008 in policy-related staffing costs and contracts, the Request for Information issuance, and the March 20 Open Meeting. These costs will reduce once implementation is complete. The NIH does not have estimates on the cost of compliance and monitoring per grant for NIH staff. Compliance monitoring may add a few minutes to managing active projects for a subset of NIH extramural staff and, as such, cannot be assigned to a specific Public Access cost center.

B. Potential Impact on Publishers

Many commenters touched on potential financial impacts of this Policy on publishers. Some claimed that the Policy would be harmful. A subset of these commenters further argued that if journals are adversely affected by the Policy, it would harm peer review as a whole. No data demonstrating harm to journals or peer review was submitted.

Some commenters claimed the Policy would not be harmful to publishers. A few publishers described their experience making papers publicly available at 12 months or less, both on and off PubMed Central, without adverse financial impact.

The NIH recognizes the enormous value and critical role that peer-reviewed journals play in the scientific quality control process. Only peer-reviewed papers accepted for publication will be posted in PMC. This Policy is designed to preserve the critical role of journals and publishers in peer review, editing, and scientific quality control processes.

As described in FAQ F10, released September 2008, the NIH is not aware that there will be a substantial impact of the policy on Publishers. An increasing number of journals already provide the public with free access to the published article immediately or within one year of the publication.

The NIH Public Access Policy does not affect authors' freedom to choose the vehicle or venue for publishing their results. The NIH expects that its awardees will continue to publish the results of their research consistent with their professional autonomy and judgment in order to advance science as efficiently and comprehensively as possible.

The NIH has posted thousands of papers to PubMed Central under the NIH Public Access Policy without evidence of harm to scientific publishing or to journals. Only a portion of articles published in scientific journals result from research funded by the NIH. Of these articles, only the final peer-reviewed manuscript is required to be posted, and it need not be made publicly available for up to 12 months post publication. Further, the NIH continues its practice of allowing publication costs, including author fees, to be reimbursed from NIH awards (*see http://publicaccess.nih.gov/FAQ.htm#e3* for more information).

C. Impact on Science

Many commenters supported the idea that the policy will support the advance of science. A few asked for measurement of these impacts. The NIH will consider exploring this issue as compliance rates rise and more NIH funded papers become available on PubMed Central. The NIH also encourages the scientific community to explore this issue independently.

Changes to Date

In response to the feedback received, the NIH communications and procedures regarding the Public Access Policy have evolved. These changes are summarized chronologically below.

May 2008

On May 2, 2008, NIH made the changes listed below to the NIH Public Access Policy Frequently Asked Questions (FAQs). These changes

provide clarifications and do not signify any changes in policy.

• Questions C7, C9, and C10 are new and reflect improvements to PubMed. These clarify and simplify how awardees can comply with the fifth specification of the NIH Public Access Policy, which states: ''Beginning May 25, 2008, anyone submitting an application, proposal, or progress report to the NIH must include the PMC or NIH Manuscript Submission reference number when citing applicable articles that arise from their NIH-funded research. This policy includes applications submitted to the NIH for the May 25, 2008, due date and subsequent due dates.''

• Questions A4, B10–B12, C8, C11, D5, E4, E5, F5, and F6 were developed based on questions received by NIH.

• NIH has responded to a number of questions about issues already addressed by the January 11, 2008, version of the FAQs and has made a number of small changes to many of these FAQ questions to improve their clarity. The biggest changes are in the wording of FAQs B1–B5.

• The January 11, 2008, FAQ uses the term ''article'' as a generic word for a peer-reviewed scientific publication and all its versions. At the March 20, 2008, Open Meeting, some stakeholders commented that ''article'' could be confused with the term ''final published article.'' Therefore, this FAQ uses the term ''paper'' instead of ''article.'' The Web site will be updated to reflect this change as well.

June 2008

The NIH updated the NIH Manuscript Submission System (NIHMS) in two ways:

• Authors, and not Program Directors/Principal Investigators (PDs/PIs), now approve manuscripts for posting. This change reduces the effort for PDs/PIs who are not authors of papers that arise from their award. It also allows these PDs/PIs to more effectively delegate submission duties to the author who is most familiar with the paper. PDs/PIs are now notified by e-mail when a manuscript is linked to one of their awards via the NIHMS.

• The NIH modified the NIHMS to allow publishers to fix the delay period when they submit a manuscript on behalf of their authors. Authors now must contact the NIH and their publisher if they wish to change the delay. The NIH expects this direct communication to result in fewer disagreements about delay periods. In response to concerns from NIH employee authors, the NIH developed procedures its employees can use to ensure any manuscripts they write will be submitted in compliance with the Public Access Policy. These procedures are accessible at *http://publicaccess.nih.gov/nih_employee_procedures.htm*.

July 2008

The NIH made several updates to the NIH Public Access Web page to clarify the submission process. The Web site explains that there are four methods to ensure that a manuscript is submitted to PubMed Central in compliance with the NIH Public Access Policy. These methods vary based on the version of the paper submitted, and the actions undertaken by the author and publisher.

Method A: Publish in a journal that deposits all NIH-funded final published articles in PubMed Central (PMC) without author involvement.

Method B: Make arrangements to have a publisher deposit a specific final published article in PubMed Central.

Method C: Deposit the final peer-reviewed manuscript in PMC yourself via the NIH Manuscript Submission System (NIHMS).

Method D: Complete the submission process for a final peer-reviewed manuscript that the publisher has deposited in the NIH Manuscript Submission System (NIHMS).

August 2008

In response to questions and advice about identifying PubMed Central Identifiers (PMCIDs), the National Library of Medicine created a new utility (*http://www.ncbi.nlm.nih.gov/sites/pmctopmid*) that uses PubMed IDs (PMIDs) to look up PMCIDs, and vice versa. Users can enter PMIDs manually or from their PubMed clipboard. The utility will provide a table of PMIDs with corresponding PMCIDs. For example, an author could look up all his/her publications in PubMed, save them to the clipboard, and use the utility to see which ones have PMCIDs.

September 2008

The Request for Information analysis indicated that a number of FAQs developed in support of the previous voluntary policy remained relevant under the new Policy requirement. Accordingly these were slightly modified and reposted to the FAQs. They are:

A5. What are the benefits of posting peer-reviewed papers to PubMed Central?

F7. Why should there be a public resource of published peer-reviewed research findings of NIH-funded research?

F8. Rather than archive manuscripts in NIH's PubMed Central, why not provide links to other Web sites?

F9. Aren't scientific abstracts, which are currently freely available, sufficient? Why does the public need full-text articles?

F10. Will NIH's Public Access Policy harm scientific publishing?

F11. Will the NIH Public Access Policy harm the quality of peer review?

NIH also issued a Guide Notice NOT–OD–08–119 (*http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-119.html*) informing PDs/PIs and Institutional Business Officials that they may receive e-mails from NIH staff if their applications, proposals, or reports appear to be noncompliant with the NIH Public Access Policy. The Guide Notice also provides reminders about the instructions for citing literature in key NIH forms (*e.g.*, the PHS398, SF424, PHS2590) and through eSNAP.

Current Status

The NIH Public Access Policy requirement took effect April 7, 2008, during the Request for Information, and after the Open Meeting. The NIH made a number of improvements based on the feedback it was receiving; the results of these efforts appear promising. The months following April 7, 2008, have been marked by increased participation from both publishers and authors, which has led to increased collection rates for eligible papers.

The NIH estimates that approximately 80,000 papers arise from NIH funds each year, and this total serves as the target for the Public Access Policy. One can gauge the progress of the implementation of the mandatory Policy by comparing the percentage of NIH-funded papers collected in the period April 2008 to August 2008 with the rate that was achieved under the voluntary Policy (May 2005 to December 2007).

As described at *http://publicaccess.nih.gov/submit_process.htm*, the NIH provides four methods for submitting papers under the Policy. With two of these (methods A and B) publishers voluntarily submit final published articles directly to PubMed Central. With the other two, (methods C and D) authors and publishers can submit final peer-reviewed manuscripts to PMC via the NIH Manuscript Submission System (NIHMS). As Figure 1 indicates, the estimated percentage of final published articles submitted directly to PubMed Central (methods A and B) has more than doubled under the new requirement as compared to the earlier voluntary policy. Rates rose from 12 percent to 26 percent.

The percentage of manuscripts collected via the NIH Manuscript Submission System (NIHMS, using methods C and D) more than quadrupled, from 7 percent under the voluntary policy to an estimated 30 percent under the requirement.

Overall, the Public Access success rate rose from 19 percent of all NIH-funded papers to 56 percent of all NIH-funded papers after the requirement took effect. These first five months show the promise of a Public Access Policy requirement, though the NIH and its awardees remain over 40 percent short of their statutory obligation to make NIH-funded papers available on PubMed Central. Also, while the NIH expects to post all 56 percent of these NIH papers, most of them will not be publicly available until 2009.

Future Activities

The NIH expects to continually monitor and refine the communications and procedures surrounding the NIH Public Access Policy. These changes will be governed by advice and feedback from stakeholders, questions to the help desk, and paper collections rates.

The NIH is exploring ways to enhance the utilities on PubMed and integrate them with bibliographic information on the eRA Commons Profile. For example, NLM just updated its search management tool (*http://www.ncbi.nlm.nih.gov/sites/myncbi/*). This service could eventually provide a way for PDs/PIs and other authors to track their papers that arise from NIH funds, associate them with NIH awards, and automatically obtain PMCIDs as they become available.

The NIH also is exploring ways to facilitate the reporting of papers arising from NIH awards by NIH project number. These services will help investigators and their institutions monitor compliance policy.

The NIH looks forward to continued interaction and advice from the many public access stakeholders. Comments and questions may be directed to *PublicAccess@NIH.gov*.

Note: a full version of this report is available at *http://publicaccess.nih.gov/analysis_of_comments_nih_public_access_policy.pdf*.

Dated: February 10, 2009.

Raynard S. Kington,

Acting Director, National Institutes of Health.

[FR Doc. E9–3442 Filed 2–17–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ELSI Microbiome.

Date: February 27, 2009.

Time: 1:30 p.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Richard A. Currie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1108, MSC 7890, Bethesda, MD 20892, (301) 435–1219, *currieri@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Cardiovascular Devices.

Date: March 2, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 W. Mission Bay Drive, San Diego, CA 92109.

Contact Person: Roberto J. Matus, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7854, Bethesda, MD 20892, 301–435–2204, *matusr@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Disease Models, Astrocytes, and Neurodegeneration.

Date: March 3–5, 2009.

Time: 3 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joanne T. Fujii, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7850, Bethesda, MD 20892, (301) 435–1178, *fujiij@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Applications for Nursing Sciences.

Date: March 6, 2009.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ellen K. Schwartz, EDD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3168, MSC 7770, Bethesda, MD 20892, 301–435–0681, *schwarte@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: AIDS and Related Research Integrated Review Group, AIDS-associated Opportunistic Infections and Cancer, Study Section.

Date: March 9, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Eduardo A. Montalvo, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435–1168, *montalve@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Technology Centers for Networks and Pathways.

Date: March 9–10, 2009.

Time: 8 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Kabuki, 1625 Post Street, San Francisco, CA 94115.

Contact Person: Marc Rigas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5158, MSC 7849, Bethesda, MD 20892, 301–402–1074, *rigasm@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict Special Emphasis Panel.

Date: March 9–10, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rass M. Shayiq, Ph.D., Scientific Review Officer, Center for