



The NIH Public Access Policy

There and back again

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Today's conversation

- ❑ Where we are
- ❑ How we got here
- ❑ What we've learned along the way
- ❑ What our next steps will be

Where we are: the final policy says (1)

- ❑ 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 costs from NIH.
- ❑ Electronic submission will be made directly to the NLM's **Pub Med Central (PMC)** digital repository of full-text, peer-reviewed, biomedical, behavioral, and clinical research journals found at: <http://nihms.nih.gov/>
- ❑ At the time of submission, the **author** will specify the timing of the posting for public accessibility.
- ❑ NIH **strongly encourages** authors to post for public accessibility **as soon as possible** (and within twelve months of the publisher's official date of final publication).

Where we are: the final policy says (2)

The policy applies to:

- ❑ Peer-reviewed publications resulting from research supported in whole or in part with direct costs from NIH
- ❑ All research and career development award mechanisms, cooperative agreements, contracts, NRSA grants, and NIH intramural research studies
- ❑ Author's final manuscripts resulting from:
 - **Currently funded** NIH research projects OR
 - **Previously supported** NIH research projects if they are accepted for publications on or after May 2, 2005.

Where we are: the final policy says (3)

The policy does not apply to:

- ❑ Book chapters, editorials, reviews, conference proceedings
- ❑ Publications resulting from non-NIH-supported research projects

Author's final manuscript = final version accepted for journal publication and includes all modifications from the publishing peer review process.

How we got here

- ❑ Background/context
- ❑ Brief history
- ❑ NIH's goals
- ❑ The path we took

How we got here: background/context

□ External drivers

- New developments in information technology tools
- Increasing public use of internet for biomedical information and need for credible information
- Congressional interest

□ Internal drivers

- NIH needs and objectives

House Appropriations Committee said:

*“The Committee is **very concerned** that there is **insufficient public access to reports and data resulting from NIH-funded research**. This situation, which has been exacerbated by the dramatic rise in scientific journal subscription prices, is contrary to the best interests of the U.S. taxpayers who paid for this research.”*

*“The Committee is aware of a proposal to make the complete text of articles and supplemental materials generated by NIH-funded research available on PubMed Central (PMC), the digital library maintained by the National Library of Medicine (NLM). The Committee supports this proposal and **recommends that NIH develop a policy, to apply from FY 2005 forward, requiring that a complete electronic copy of any manuscript reporting work supported by NIH grants or contracts be provided to PMC upon acceptance of the manuscript for publication in any scientific journal listed in the NLM's PubMed directory.**”*

*“NLM would commence making these reports, together with supplemental materials, **freely and continuously available six months after publication, or immediately in cases in which some or of the publication costs are paid with NIH grant funds.**”*

NIH needs to engage the public in medical research



To protect the public trust, we must:

- ❑ Manage our scientific portfolio
- ❑ Have transparent management practices
- ❑ Encourage scientific communication with the public

To improve participation in clinical trials, we must reach out to:

- ❑ Community-based physicians
- ❑ A diverse public

Internal drivers: Public Access Policy Challenges

- ❑ 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.
- ❑ Secure a searchable compendium of these peer-reviewed research publications that will make it easier for:
 - scientists to mine medical research publications
 - NIH to monitor **scientific** productivity, and ultimately, help inform research priorities.
- ❑ Make published results of NIH-funded research more readily **accessible** to the public including health care providers, educators, and scientists.

The path we took

We sought input and have been listening to our constituents.

- **Public meetings**
 - **Publishers and Associations (July 2004)**
 - **Investigators (August 2004)**
 - **Health advocacy groups (August 2004)**
 - **Notice in *NIH Guide for Grants and Contracts* – draft policy**
 - **September 3, 2004**
 - **Notice in *Federal Register* – draft policy**
 - **September 17, 2004**
 - **6,249 comments received**
 - **Talks, visits, interviews, letters, e-mails**
 - **Final policy (February 3, 2005)**
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Key provisions of proposed policy

Proposed Policy, September 2004

The draft policy **requests**, but **does not require**, that NIH-supported investigators submit electronically to the NIH the final, **peer-reviewed author's copy** of their manuscripts upon acceptance for publication.

The manuscripts will be archived in PubMed Central (PMC).

The author's copy will be made available freely to the public through PMC **six months after the study's publication**.

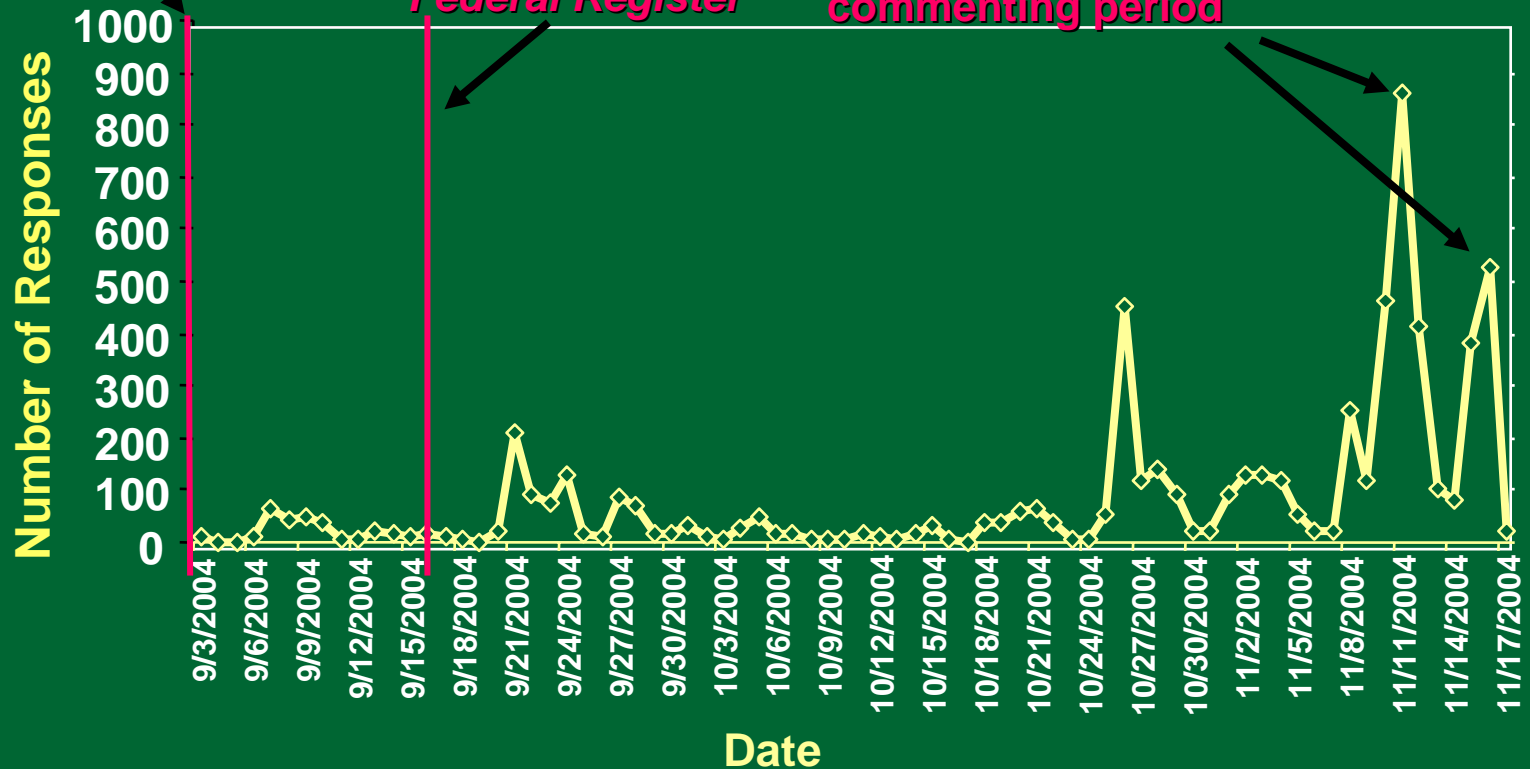
What we've learned along the way

Cumulative – 6,249 Responses

Announcement
in *NIH Guide*

Announcement in
Federal Register

Universities and Researchers
and final submissions before end of
commenting period



What we've learned: examples of public comments -- Pros

- ❑ Public should have access to research results in timely manner.
- ❑ Enhanced access to information strengthens and expands impact of research.
- ❑ Policy provides equal access to less wealthy individuals, institutions, and countries.
- ❑ Online access to information is less expensive and easier to obtain.
- ❑ Public's concern that access not be drive by business models of publishers.
- ❑ Without policy, government favors publishers at publics' expense.
- ❑ This policy will improve the visibility of an author's research.

Examples of public comments - Cons

- ❑ Policy will harm financial stability of publishers.
- ❑ Policy will adversely impact peer review of research prior to publication.
- ❑ Overall implementation of this plan is too costly.
- ❑ This policy may lead to an increase in cost for publications or an increase in costs for researchers to submit work.
- ❑ The proposed policy does not adequately address copyright issues.
- ❑ Policy will hurt learned societies and the efforts that they support.
- ❑ Regardless of enhanced access, general public does not understand research.

The Final Public Access Policy Outcome

In response to feedback, NIH revised the proposed policy in February 2005 to:

- ❑ Emphasize the **voluntary** nature of authors' submissions.
- ❑ Clarify “**NIH-funded investigators**” to mean those supported with “**direct costs**” from NIH.
- ❑ Provide **authors with flexibility to specify the timing of the posting** of their final manuscript for public availability through PMC thus addressing the “one size fits all” issue.
- ❑ **Strongly encourage posting** for public accessibility through PMC **as soon as possible** and within twelve months of the publisher's official date of final publication.
- ❑ Recognizing and clarifying that “**publication date**” is **publisher's official date of final publication.**
- ❑ **Public Access Policy Web site:**
<http://www.nih.gov/about/publicaccess/>

We are still listening to our constituents – common questions and misconceptions (1)

Is the policy voluntary?

- ❑ Yes. It is **voluntary**, but NIH **expects** authors to submit their manuscripts.
- ❑ We are urging maximum participation by providing maximum flexibility for authors to specify the timing of the posting of their final manuscript.

We are still listening to our constituents – common questions and misconceptions (2a)

Does the policy violate copyright law?

- ❑ No. The Policy is consistent with copyright law.
- ❑ Authors and journals can continue to assert copyright in NIH-funded scientific publications, in accordance with current practice.
- ❑ While individual copyright arrangements can take many forms, NIH encourages investigators to sign agreements that specifically allow the manuscript to be deposited with NIH for public posting on PubMed Central **as soon as possible** after journal publication.

We are still listening to our constituents – common questions and misconceptions (2b)

Does the policy violate copyright law?

- ❑ The author owns the copyright to his/her manuscript and can choose to establish agreements with publishers to retain certain rights.
- ❑ 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 manuscript to NIH upon acceptance for Journal publication or thereafter, for public archiving in PubMed Central as soon as possible after publication by Journal.”

We are still listening to our constituents – common questions (3)

Time of public accessibility?

- ❑ **Immediately to twelve months.**
 - ❑ The Policy is the result of NIH's consideration of more than 6,000 public comments from those who advocated faster release to those wanting longer delays for accessibility due to concerns with potential negative impact on certain journal types.
 - ❑ NIH decided to provide a more **flexible approach** to allow authors to determine the time of public release ranging from immediately to 12 months from the official date of final publication in a journal.
 - ❑ NIH **strongly encourages** authors to provide **immediate** public access **following the official date of final publication.**
 - ❑ NIH expects that only in limited cases will authors deem it necessary to select the longest delay period.
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We are still listening to our constituents – common questions (4a)

What manuscripts should authors submit for posting on PMC?

- ❑ The Policy applies to **peer-reviewed, original research publications** that have been **supported in whole or in part with direct costs from NIH**, but it does not apply to book chapters, editorials, reviews, or conference proceedings.
- ❑ The NIH Public Access 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.

We are still listening to our constituents – common questions (4b)

What manuscripts should authors submit for posting on PMC?

- ❑ Manuscripts resulting from:
 - **currently funded** NIH research projects or
 - **previously supported** NIH research projects if they are **accepted for publication on or after May 2, 2005.**
- ❑ Publications resulting from non-NIH-supported research projects should **not** be submitted.
- ❑ Submit to the PMC NIH manuscript submission system:
<http://nihms.nih.gov/>

We are still listening to our constituents –
common questions (5a)

How will the author's manuscript be matched with the published article in PMC?

- For publishers with **standing agreement** with PMC to post full text articles:
 - Authors do not need to submit manuscripts if journal releases full text in PMC within 12 mo. of publication.
 - If author's submit, their version will be available on PMC only as .pdf document
 - Publisher's version, once posted, will become the default version (article is integrated with the various PMC databases).
 - The author's version will still be available for viewing.
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We are still listening to our constituents –
common questions (5b)

*How will the author's manuscript be matched with
the published article in PMC?*

- For publishers with **no agreement** with PMC to post full text articles:
 - The author's manuscript will be integrated with the various PMC databases and posted on PMC (a link to the publisher's web site will be given).
 - If the Publisher agrees to allow PMC to post their version of the article then the publisher's version will become the default version shown during a PMC search.
 - The author's version will still be available for viewing.
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Outcomes & Next Steps

- ❑ **Ramping up submission numbers.**
- ❑ **Dialogue with public continues:**
 - **Public Access Policy Working Group** of the NIH National Library of Medicine's Board of Regents established and is composed of stakeholders to advise the Board of Regents on implementation and evaluation of the policy
 - ❑ List of members can be found at:
http://www.nlm.nih.gov/od/bor/workgroup_roster.html
 - ❑ First meeting scheduled: July 11, 2005
 - **Public Access Policy Mailbox:** PublicAccess@nih.gov
- ❑ **Continued outreach to funded investigators and other stakeholders.**

There and back again:

Why Public Access? Because:

ARCHIVE *Keep a central archive of NIH-funded research publications—for now and in the future, preserving vital medical research results and information for years to come.*

ADVANCE SCIENCE *Create an information resource that will make it easier for scientists to mine medical research publications, and for NIH to manage better its entire research investment.*

ACCESS *Provide electronic access to NIH-funded research publications for patients, families, health professionals, teachers, and students.*

The policy is good for the public, science, and NIH.

Public Access Policy Resources

- **Public Access Policy Website:**
<http://www.nih.gov/about/publicaccess/>
 - **NIH Manuscript Submission (NIHMS) System:**
<http://www.nihms.nih.gov/>
 - **Public Access Policy in the *NIH Guide*:**
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html>
 - **Authors' Manual:**
http://www.nih.gov/about/publicaccess/publicaccess_Manual.htm
 - **Questions and Answers:**
http://www.nih.gov/about/publicaccess/publicaccess_QandA.htm
 - **Public Access Policy Mailbox**
PublicAccess@nih.gov
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Thank you kindly for your attention...

