

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Eye Institute; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, 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: National Eye Institute Special Emphasis Panel; Translational Research Program for Therapeutics.

Date: July 19, 2024.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Jennifer C. Schiltz, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Eye Institute, 6700 Rockledge Drive, Bethesda, MD 20817, 240-276-5864, jennifer.schiltz@nih.gov.

Name of Committee: National Eye Institute Special Emphasis Panel; R38 Applications.

Date: July 19, 2024.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Brian Hoshaw, Ph.D., Designated Federal Official, National Eye Institute, National Institutes of Health, Division of Extramural Research, 6700 B Rockledge Dr., Rockville, MD 20892, 301-451-2020, hoshawb@mail.nih.gov.

Name of Committee: National Eye Institute Special Emphasis Panel; Individual Training Grant Applications.

Date: July 24, 2024.

Time: 10:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Ashley Fortress, Ph.D., Designated Federal Official, Division of Extramural Activities, National Eye Institute, National Institutes of Health, 6700 B Rockledge Dr., Bethesda, MD 20817, (301) 451-2020, ashley.fortress@nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: June 13, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-13360 Filed 6-17-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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: Eunice Kennedy Shriver National Institute of Child Health and Human Development Initial Review Group; Population Sciences Study Section Population Sciences Study Section.

Date: October 25, 2024.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, 7400 Wisconsin Avenue, Bethesda, MD 20814 (In-person Meeting).

Contact Person: Christiane M. Robbins, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Rm. 2121B, Bethesda, MD 20817, 301-451-4989, crobbs@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 12, 2024

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-13310 Filed 6-17-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Request for Information on the National Institutes of Health Draft Public Access Policy**

AGENCY: National Institutes of Health, HHS.

ACTION: Request for information.

SUMMARY: The National Institutes of Health (NIH) is soliciting comments from the public on the NIH Draft Public Access Policy and two supplemental draft guidance documents regarding government use license and rights and costs for publications. The NIH Draft Public Access Policy builds upon NIH's long history of providing public access to scholarly publications resulting from the research it supports and proposes additional steps to accelerate access.

DATES: To ensure consideration, comments must be submitted in writing by August 19, 2024.

ADDRESSES: Comments may be submitted electronically to <https://osp.od.nih.gov/comment-form-national-institutes-of-health-draft-public-access-policy/>. Comments are voluntary and may be submitted anonymously. You may also voluntarily include your name and contact information with your response. Other than your name and contact information, please do not include in the response any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your response. After the NIH Office of Science Policy (OSP) has finished reviewing the responses, the responses may be posted to the OSP website without redaction.

FOR FURTHER INFORMATION CONTACT: Hilary Leeds, J.D., Senior Policy Analyst for Public Access, Office of Science Policy, at (301) 496-9838 or SciencePolicy@od.nih.gov.

SUPPLEMENTARY INFORMATION:

Background

Increasing access to publications resulting from NIH funding offers many benefits to the scientific community and the public who funded the underlying work. The ability for patients, families, and members of the public to access published findings resulting from NIH funding enables them to better understand and address the most critical public health concerns facing their communities. It also allows researchers, students, and health care

providers in all communities to have equitable access to such content. This access can accelerate future research, lead to collaboration, and allow interested readers and patients to keep up more closely with critical advances. Importantly, these goals also reflect NIH's commitment to responsible stewardship of the Nation's investment in biomedical research by improving transparency and accessibility of taxpayer-funded research.

The NIH Public Access Policy,¹ in effect since 2008, requires that NIH-supported researchers submit their final peer-reviewed manuscripts to the PubMed Central® digital archive of full-text biomedical literature upon acceptance for publication. NIH makes manuscripts freely available to the public after an allowable embargo period of not more than 12 months after the official date of publication. The 2008 Policy implements Public Law 110-161² and has, to date, resulted in more than 1.5 million articles reporting on NIH-supported research being freely available to the public in PubMed Central.

On August 25, 2022, the Office of Science and Technology Policy (OSTP) released updated policy guidance (2022 OSTP Memorandum³) in an effort to further promote equity, advance trust in science, and continue to advance American scientific leadership. Following the 2022 OSTP Memorandum, NIH released its *Plan to Enhance Public Access to the Results of NIH-Supported Research* (hereinafter "NIH Public Access Plan" or "Plan") in February 2023.⁴ The NIH Public Access Plan provided a roadmap for how NIH proposed to accelerate access to scholarly publications, consistent with the expectation to remove the currently allowable 12-month embargo period before public availability. Informed by public comments in response to the Plan, the NIH Draft Public Access Policy accommodates novel elements of the 2022 OSTP Memorandum related to scholarly publications.

Overview of Public Comments

A total of 143 written public comments⁵ were received on the NIH

Public Access Plan, released in 2023. In addition, NIH hosted a public listening session on the Public Access Plan in April 2023,⁶ and in November 2023, NIH sponsored a workshop held by the National Academies of Science, Engineering and Medicine (NASEM) on Enhancing Public Access to the Results of Research Supported by HHS.⁷ Commenters and attendees came from academic institutions, including institutional officials and researchers at various career stages, and professional associations (many of whom also publish academic journals). They also importantly included representatives of non-profit research organizations, general members of the public, publishers, patient advocates, health care organizations, advocacy organizations, and biotechnology/pharmaceutical companies.

NIH considered all feedback to inform and develop a new NIH Draft Public Access Policy. Upon finalization, the new Policy will replace the current 2008 NIH Public Access Policy. Notably, commenters and attendees were generally supportive of updating the 2008 Policy to remove the embargo period, allowing for accelerated access to the results of NIH-funded research.

Discussion of Public Comments and Key Provisions of the NIH Draft Public Access Policy

A discussion of the public comments on the NIH Public Access Plan and how they were incorporated into the NIH Draft Public Access Policy is provided below. This section outlines the 2008 Public Access Policy's approach on each issue, proposals in the NIH Public Access Plan, followed by Public Comments on the NIH Public Access Plan, and finally the approach proposed in the NIH Draft Public Access Policy.

Definition of "Article"

Current Public Access Policy: The current Public Access Policy does not have a general term or definition to describe the versions produced in the various stages of writing and publishing.

NIH Public Access Plan: The Plan did not propose a term or definition to describe the versions produced in writing and publishing.

Public Comments: Several commenters suggested clarity was needed to distinguish the official published version of a manuscript from previous draft versions, though no

comments suggested a specific definition or term to refer to these various versions.

NIH Draft Public Access Policy: The NIH Draft Public Access Policy includes a definition of "article" to describe, in general, the versions from the creation of the manuscript through the final published article.

Definition of "Official Date of Publication"

Current Public Access Policy: When determining the timing of public release of an article, NIH bases the official date of publication on the issue or "print" publication date.

NIH Public Access Plan: For consistency with expectations under the NIH Policy for Data Management and Sharing (NIH DMS Policy) and to reflect current practice in scholarly communications, NIH proposed to interpret "Official Date of Publication" as the date on which the publisher first makes an article available, either online or in print. This is consistent with a relevant Frequently Asked Question (FAQ)⁸ on the NIH DMS Policy.⁹

Public Comments: There were no public comments on the definition of "Official Date of Publication." Many commenters noted the importance of easing burden and providing clarity on methods of compliance.

NIH Draft Public Access Policy: The NIH Draft Public Access Policy proposes to define "Official Date of Publication" as "the date on which the article is first made available in final, edited form, whether in print or electronic (*i.e.*, online) format," which is slightly modified from the proposal in the NIH Public Access Plan to be more precise. Consistent understanding about what is meant by an official date of publication between the NIH DMS Policy and NIH Public Access Policy will provide clarity to those complying with both policies. NIH notes that NIH's proposed implementation of public availability without embargo will take into account processing time that may be needed before public availability in PubMed Central.

Scope of the Public Access Policy

Current Public Access Policy: The current Public Access Policy's scope includes the concept of "direct" funding by NIH. The scope of the current Public Access Policy is also not limited to manuscripts reporting research findings. Rather, the Policy's requirements apply

¹ <https://sharing.nih.gov/public-access-policy/public-access-policy-overview#public-access-policy-details>.

² <https://www.congress.gov/110/statute/STATUTE-121/STATUTE-121-Pg1844.pdf>.

³ <https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf>.

⁴ <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-091.html>.

⁵ https://osp.od.nih.gov/wp-content/uploads/2023/06/NIH_Public_Access_to_the_Results_of_NIH-Supported_Research_RFI_FINAL_508.pdf.

⁶ <https://osp.od.nih.gov/events/virtual-listening-session-on-the-nih-public-access-plan/>.

⁷ <https://www.nationalacademies.org/our-work/enhancing-public-access-to-the-results-of-research-supported-by-the-department-of-health-and-human-services-a-workshop>.

⁸ <https://sharing.nih.gov/faqs#/data-management-and-sharing-policy.htm?anchor=56773>.

⁹ <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html>.

to any peer-reviewed manuscript that arises from direct funding from the NIH and is accepted for publication in a journal on or after April 7, 2008. For example, a peer-reviewed manuscript that describes an infrastructure project that was NIH funded may be subject to the Policy, even if not reporting research findings.

NIH Public Access Plan: The Plan did not discuss the proposed scope of the NIH Draft Public Access Policy regarding “direct” funding or other related details.

Public Comments: Some public comments requested clarification on situations where NIH funding does not directly support the research reported in a publication or where researchers use NIH resources without NIH funding. Other comments suggested that only awardees above a certain funding threshold or level of contribution on a grant be subject to the Public Access Policy.

NIH Draft Public Access Policy: The NIH Draft Public Access Policy proposes to adopt the current NIH Public Access Policy’s scope and is intended to make available knowledge generated from NIH-supported discoveries. Accordingly, the NIH Draft Public Access Policy applies to any Manuscript¹⁰ accepted for publication in a journal that results from funding by NIH in whole or in part. NIH intends to clarify in FAQs that using NIH resources, such as datasets available through NIH repositories and physical resources and infrastructure supported by the NIH, when no NIH funds were used for the work upon which the Manuscript is based, does not subject a resulting Manuscript to the NIH Public Access Policy. However, NIH notes that some programs at NIH and specific agreements may add in such a requirement independent of the NIH Public Access Policy’s scope.

The NIH Draft Public Access Policy also applies regardless of whether non-NIH funds contributed to developing or writing the Manuscript. The applicability of the NIH Draft Public Access Policy depends on whether the Manuscript is the result of NIH funding in whole or in part and is not dependent on the funds that contributed to the writing of the Manuscript itself.

Finally, the NIH Draft Public Access Policy, like the current Public Access Policy, does not limit its scope to Manuscripts reporting only on research (it can include, for example, a peer-reviewed manuscript that describes an

infrastructure project that was funded by NIH).

Timeline of Public Access Policy Applicability

Current Public Access Policy: Neither the current Public Access Policy nor the law that the Policy implements specifies an end date to the Policy’s applicability to Manuscripts within scope of the Policy.¹¹ This approach is consistent with publishing practices, in which publication often happens after the end of an award.

NIH Public Access Plan: The Public Access Plan did not indicate how long the Public Access Policy would be applicable to Manuscripts.

Public Comments: There were no public comments on the Public Access Policy’s potential applicability to publications arising after the closeout of the award. Some commenters requested guidance on how to comply with the Policy when NIH-supported researchers submit articles for publication long after their NIH funding has ended.

NIH Draft Public Access Policy: NIH is not proposing an end date for applicability to Manuscripts arising out of awards. Non-compliance with the NIH Public Access Policy may be considered by NIH regarding future funding decisions for the recipient institution.

Policy Effective Date

Current Public Access Policy: The current Public Access Policy became effective for manuscripts accepted for publication on or after April 7, 2008; and which arose from direct funding from an award active in FY 2008 or beyond, a contract signed on or after April 7, 2008, or from intramural research or an NIH employee.

NIH Public Access Plan: The NIH Plan indicates “NIH plans to update the NIH Public Access Policy no later than December 31, 2024, with an effective date no later than December 31, 2025,” adhering to an expectation from the 2022 OSTP Memorandum.

Public Comments: Some public comments on the proposed effective date, noted in the NIH Public Access Plan, argued for a two-year delay in the effective date to allow time for publishers (particularly smaller society-based publishers) to adjust. Some also suggested that the timeline for an effective policy was too aggressive but did not specify or suggest a specific delay. There were no comments regarding how the effective date should align with the NIH award cycle.

NIH Draft Public Access Policy: Consistent with the current Public Access Policy, the NIH Draft Public Access Policy is proposed to become effective for Manuscripts accepted for publication on or after October 1, 2025. This approach has the benefit of capturing all Manuscripts accepted for publication regardless of whether the award or contract is new or ongoing. NIH is committed to working with the research community to prepare for implementation of the final Policy.

The proposed effective date, October 1, 2025, will follow the expectations of the 2022 OSTP Memorandum to be no later than the end of calendar year 2025.

Rights in Manuscripts

Current Public Access Policy: Currently, the FAQs to the Public Access Policy describe how and when rights in manuscripts accrue and what may be transferred. NIH provides sample language an author or institution might add to a copyright agreement with a journal. In addition, authors submitting Manuscripts to PubMed Central must agree to the NIH Manuscript Submission (NIHMS) Statement¹² that, in part, allows the Manuscript to be appropriately tagged and made available on the PubMed Central website. This ensures that Manuscripts are available in machine-readable formats that support accessibility¹³ and facilitate text mining.¹⁴

NIH Public Access Plan: In the Public Access Plan, NIH said it would clarify how NIH-supported investigators may retain sufficient rights to NIH-supported peer-reviewed manuscripts. NIH proposed to develop language that NIH-supported investigators may use for submission with their peer-reviewed manuscripts to journals to retain rights to make the peer-reviewed manuscript available in PubMed Central without an embargo period.

Public Comments: There were numerous public comments on rights retention. These comments ranged from suggesting that NIH require authors to retain rights to all versions of research products (including the preprint, the author-accepted manuscript, and the journal version of record) to advocating that NIH not provide guidance or sample language on rights retention as it will interfere with publisher practices. The most frequently observed responses referred only to the author accepted

¹² <https://support.nlm.nih.gov/knowledgebase/article/KA-05252/en-us>.

¹³ <https://www.ncbi.nlm.nih.gov/pmc/about/accessibility/>.

¹⁴ <https://www.ncbi.nlm.nih.gov/pmc/tools/amdataset/>.

¹⁰ Note that defined terms are capitalized throughout.

¹¹ <https://www.congress.gov/110/statute/STATUTE-121/STATUTE-121-Pg1844.pdf>.

manuscript (to be submitted to PubMed Central) and argued that either (1) NIH require authors to retain rights via the most open licenses (e.g., Creative Commons [CC] BY) or (2) NIH should not mandate rights retention or specific licenses but should allow authors to decide whether and how to retain their rights in the manuscript. Many comments were in favor of NIH publishing guidance around rights retention, including some suggestions to ease administrative burden by providing template language to be submitted alongside manuscript submission to the publisher.

NIH Draft Public Access Policy: NIH proposes to focus on achieving the Policy's goals regarding rights in Manuscripts through minimally burdensome pathways. First, the NIH Draft Public Access Policy proposes to clarify that government use rights are given to NIH upon acceptance of funding. A statement granting NIH rights to make Manuscripts publicly available in PubMed Central upon the Official Date of Publication is proposed to be incorporated into Notices of Award and applicable contracts. This ensures it is understood that NIH's rights are automatically established at the acceptance of funding, without requiring funded recipients to take additional steps.

Secondly, the NIH Draft Public Access Policy proposes that those submitting Manuscripts to PubMed Central will provide a license to NIH that mirrors the Government Use License as part of a revised Manuscript Submission Statement, granting NIH the right to (1) make Manuscripts publicly available in PubMed Central upon the Official Date of Publication and (2) make Manuscripts available in machine-readable formats to support accessibility and facilitate text mining, consistent with current practice.

Beyond these measures, NIH does not propose requiring authors apply a particular license to their Manuscripts. A particular license is not needed to achieve the Policy's goal of making Manuscripts available without an embargo.

In the Draft Guidance on Government Use License and Rights, NIH encourages authors to clearly communicate NIH's rights through a statement in the Manuscript itself. In this Guidance, NIH has proposed standardized language authors may choose to place in their Manuscripts.

Publication Costs

Current Public Access Policy: According to the current NIH Public Access Policy FAQs, "Publication costs,

including author fees, may be charged to NIH 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."¹⁵ Importantly, even if such costs were not incurred during a specific period of performance of an award, an award may still be charged before its closeout for publication costs.

NIH Public Access Plan: NIH stated in the Public Access Plan the intent to continue to allow reasonable publication costs for all NIH-supported or authored scholarly publications consistent with current policy and guidance. NIH proposed to continue monitoring trends in publication fees and policies to ensure that they remain reasonable and do not disproportionately burden one or more segments of the NIH-supported community, and that opportunities to publish are equitable and consistent with NIH's strategic priorities.

Public Comments: Many respondents argued that removal of the embargo would drive publishers to business models that charge fees to make articles openly and immediately available, and that as these fees rise, so will inequity for lower resourced institutions and investigators. Some publishers suggested that these models are the only way forward as subscriptions diminish. Others sought assurances that authors would be able to comply with the revised NIH Public Access Policy without cost through repository deposition models. Some publishers suggested that removal of the embargo and subsequent diminished subscriptions could have a significant negative effect on their operations, leading to limited choices of where to publish, which would limit accessibility.

Many comments favored monitoring the costs of publications. Some suggestions included examining application budgets and annual reports to the NIH, working with publishers to understand publishing model and/or discipline specific requirements, and exploring currently existing cost assessments. Some suggested that any appearance of dictating business models would be inappropriate and could interfere with a publisher's ability to remain in business.

Several respondents perceived fees to make articles openly and immediately available to be too high and to lack

transparency. Some of these comments encouraged NIH to cap publication-related costs. Several publishers argued that cost-capping could lead to an increase in "predatory" publishing.

Many argued that NIH should define which publication costs would be permissible under regulations and the Grants Policy Statement (GPS). Some suggested that it would be helpful to define "reasonable" costs, while others suggested that such definitions would be entirely context dependent and would necessarily evolve.

NIH Draft Public Access Policy: In the NIH Draft Public Access Policy, NIH clarifies that compliance with the Policy is free. While allowable publication costs may be budgeted, as publishing itself may incur costs, NIH maintains a free pathway for compliance with the NIH Draft Public Access Policy by submission of the Manuscript to PubMed Central. This free pathway for policy compliance helps to support the goals of equitable public access. Additionally, the benefits of eliminating costs and delays in access to publications will likely be greatest for lower resourced institutions, researchers, and the public.

The NIH Draft Public Access Policy notes that if authors are asked to pay a fee by a third party for submission of Manuscripts to PubMed Central, the NIH Draft Public Access Policy would not permit this fee to be paid from NIH funds because it is not a legitimate publication expense. The NIH Draft Public Access Policy indicates reasonable costs associated with publication that are allowable may be requested in the budget for the project as direct or indirect costs.

The Draft Guidance on Publication Costs contains examples of unallowable costs, based on existing cost principles and existing sections of the GPS. Regarding the ability to pay publication costs after an award has ended, NIH cannot pay publication costs after closeout of an award (as recently affirmed in revisions to 2 CFR 200.461¹⁶). Points to Consider are provided for authors and institutions to inform whether a publication cost is reasonable.

NIH will continue to consider appropriate methods to monitor costs for potential impacts on relevant communities once the final Public Access Policy has been implemented and any downstream effects are more readily apparent.

¹⁵ <https://sharing.nih.gov/faqs#/public-access-policy?anchor=50507>.

¹⁶ <https://www.federalregister.gov/documents/2024/04/22/2024-07496/guidance-for-federal-financial-assistance#sectno-reference-200.461>.

Compliance and Enforcement

Current Public Access Policy: The current NIH Public Access Policy notes that the awardee institution is responsible for complying with the terms and conditions of the award. Compliance may be achieved through submission of the Manuscript or through journals submitting Final Published Articles to PubMed Central based on existing agreements. NIH may take one or more enforcement actions, depending on the severity and duration of the non-compliance, in accordance with applicable statutes, regulations, and policies.

NIH Public Access Plan: The Public Access Plan did not specify enforcement actions but rather outlined the pathways to compliance of submission of the Manuscript or Final Published Article.

Public Comments: Many commenters requested that compliance with the NIH Public Access Policy be as simple as possible and not place undue burden on investigators. There were no public comments on the consequences for non-compliance.

NIH Draft Public Access Policy: The NIH Draft Public Access Policy minimizes burden by proposing to adopt the same pathways to compliance as under the current Public Access Policy. It also reinforces the requirement to properly communicate and acknowledge federal funding in Manuscripts. Importantly, the NIH Draft Public Access Policy states that non-compliance with the requirement to properly communicate and acknowledge federal funding is itself a violation of the terms and conditions of award and also may result in non-compliance with the NIH Public Access Policy. It notes that non-compliance may delay non-competing award processing and potentially affect future funding for the institution.

Accessibility and Understandability

Current Public Access Policy: NIH currently makes content in PubMed Central available in accessible and machine-readable formats. In addition, NIH currently has multiple ways to make research and research results available to the public,¹⁷ including through press releases, the Public Health Relevance Statement in grant applications, and the Outcomes section in RePORTER.

NIH Public Access Plan: The Public Access Plan proposed to continue making articles available in formats that

allow for machine-readability and through assistive devices.

Public comments: Public comments indicated that making information available is necessary but not sufficient to meet goals concerning equitable access. Consumers of the information resulting from NIH-supported studies need to be able to process and understand what they are reading. Many public comments supported NIH's goals to make information machine-readable and available on assistive devices, but there were also comments about the need to enhance understanding, such as by translating articles into multiple languages and accompanying articles with plain language summaries.

NIH Draft Public Access Policy: Accessibility of PubMed Central content is paramount and NIH will continue to make content accessible for those using assistive technologies. NIH appreciates comments noting that to make discoveries truly accessible to the public, information should be disseminated in ways that are meaningful and digestible. While NIH does not currently plan to require that authors develop or submit plain language summaries of Manuscripts or translate their content into languages other than English, as supporting technologies continue to develop, NIH will consider additional approaches to increase understanding of NIH-funded scientific research.

NIH Draft Public Access Policy

Purpose

Increasing access to publications resulting from NIH funding offers many benefits to the scientific community and the public who funded the underlying work. The ability for patients, families, and members of the public to access published findings resulting from NIH funding enables them to better understand and address the most critical public health concerns facing their communities. It also allows researchers, students, and health care providers in all communities to have equitable access to such content. This access can accelerate future research, lead to collaboration, and allow interested readers and patients to keep up more closely with critical advances. Importantly, these goals also reflect NIH's commitment to responsible stewardship of the Nation's investment in biomedical research by improving transparency and accessibility of taxpayer-funded research.

Per the NIH Public Access Policy, effective October 1, 2025, NIH is requiring Manuscripts to be submitted to PubMed Central upon acceptance for

publication, for public availability without embargo upon the Official Date of Publication.

Definitions

Manuscript: The author's final version that has been accepted for journal publication and includes all revisions resulting from the peer review process, including all associated tables, graphics, and supplemental material

Final Published Article: The journal's authoritative copy, including journal or publisher copyediting and stylistic edits, and formatting changes

Article: A general term that encompasses the versions resulting from writing and publishing, from creation of the manuscript through final published article in a journal

Journal: A periodical publication that is either (1) included in the "journal" section of the National Library of Medicine (NLM) Catalog¹⁸ or (2) meets all of the following criteria:

- Requirements for ISSN assignment;
- Content is issued over time under a common title;
- Is a collection of articles by different authors; and
- Is intended to be published indefinitely.

Official Date of Publication: The date on which the article is first made available in final, edited form, whether in print or electronic (*i.e.*, online) format

Scope and Effective Date

The NIH Public Access Policy applies to any Manuscript accepted for publication in a journal, on or after October 1, 2025, that is the result of funding by NIH in whole or in part through:

- A grant or cooperative agreement, including training grants
- A contract,
- An Other Transaction,
- NIH intramural research, or
- The official work of an NIH employee.

The NIH Public Access Policy applies regardless of whether the NIH-funded principal investigator or project director is an author and regardless of whether non-NIH funds contributed to developing or writing the Manuscript. Upon the effective date, this Policy replaces the prior 2008 NIH Public Access Policy.

Requirements

The Public Access Policy requires:

- Submission of an electronic version of the final peer-reviewed Manuscript to

¹⁷ <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.100-how-to-use-the-application-instructions.htm#6>.

¹⁸ <https://www.ncbi.nlm.nih.gov/nlmcatalog/journals?term=periodical%5BPublication+Type%5D+AND+open%5BPublication+Status%5D>.

PubMed Central upon its acceptance for publication, for public availability without embargo upon the Official Date of Publication;

- An acknowledgment in the Manuscript and Final Published Article that satisfies the requirements in the NIH Grants Policy Statement regarding communicating and acknowledging federal funding,¹⁹ as well as analogous requirements for acknowledging federal funding as incorporated into Other Transactions and applicable contracts; and

- When a Manuscript is submitted to NIH,²⁰ providing NIH with a standard license that mirrors that of the Government Use License at 45 CFR 75.322(b),²¹ or its successor regulation, explicitly granting NIH the right to make the Manuscript publicly available through PubMed Central without embargo upon the Official Date of Publication.

Government Use License and Rights

- By accepting NIH funding, the recipient grants to NIH, as the funding agency, a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for federal purposes, and to authorize others to do so. This includes making Manuscripts publicly available in PubMed Central upon the Official Date of Publication. A statement that conveys this point is incorporated into Notices of Award and applicable contracts.

- NIH encourages inclusion of a statement in the Manuscript that indicates it is subject to the NIH Public Access Policy and that this means that NIH, as the funding agency, has the right to make the Manuscript publicly available in PubMed Central upon the Official Date of Publication. NIH provides standardized language in the Draft Guidance on Government Use License and Rights that authors may include in Manuscripts. Such a statement ensures transparency and awareness that NIH has the right to make the Manuscript available in PubMed Central without embargo upon the Official Date of Publication.

- Authors are not expected to provide rights to NIH to the Final Published

Article. However, as noted in “Compliance and Enforcement,” NIH will accept submission of the Final Published Article to PubMed Central from journals with formal agreements with NLM as compliant with the Policy when its release meets public access requirements outlined in this Policy.

Costs

Reasonable costs associated with publication that are allowable may be requested in the budget for the project as direct or indirect costs, as specified in the NIH Grants Policy Statement²² and as incorporated into Other Transactions and applicable contracts (see the Draft Guidance on Publication Costs for more information). Submission of Manuscripts to PubMed Central remains free for authors under the NIH Public Access Policy. If, during the course of the publication process, an author is asked to pay a fee for submission of the Manuscript to PubMed Central, such costs are not allowable.

Compliance and Enforcement

Regarding submission to PubMed Central, compliance with the Policy may be achieved through either:

- Submission of the electronic version of the final peer-reviewed manuscript (*i.e.*, Manuscript as defined above) to PubMed Central upon its acceptance for publication, for public availability without embargo upon the official date of publication or
- Submission of the Final Published Article to PubMed Central from a journal with a formal agreement with NLM, upon the Official Date of Publication, for public availability without embargo

Communicating and acknowledging federal funding enables a clear, public-facing indication of NIH funding in Manuscripts and Final Published Articles. Failure to include required acknowledgments may result in non-compliance with the NIH Public Access Policy, in addition to resulting in non-compliance with terms and conditions of funding regarding communicating and acknowledging federal funding.

Non-compliance with the NIH Public Access Policy may be considered by NIH regarding future funding decisions for the recipient institution (*e.g.*, as authorized in the NIH Grants Policy Statement, Section 8.5, Special Award Conditions and Remedies for Noncompliance (Special Award Conditions and Enforcement

Actions)).²³ Non-competing continuation grant awards are subject to a delay in award processing for non-compliance with the NIH Public Access Policy.

Draft Guidance on Government Use License and Rights

Purpose

Federal agencies have, by law, certain rights to products resulting from federal funding. For works (*e.g.*, manuscripts) under the Government Use License (45 CFR 75.322(b)), or its successor regulation, NIH “reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.” These rights also apply as incorporated into Other Transactions and applicable contracts (*e.g.*, the rights in data clause within the contract).

NIH proposes this Draft Guidance to assist authors in navigating compliance with the NIH Public Access Policy with minimal burden. NIH also encourages authors to be clear with the journals to which they submit their Articles, to ensure journals understand that NIH has a right to make Manuscripts publicly available upon the Official Date of Publication.

Public Access Policy Requirements Related to Rights

Upon accepting NIH funding, recipients grant to NIH the right to make Manuscripts arising from the funding publicly available in PubMed Central upon the Official Date of Publication, and this is affirmed via a statement in Notices of Award and applicable contracts.

Authors approving Manuscripts for inclusion in PubMed Central must agree to a submission statement²⁴ as part of the standard PubMed Central Manuscript submission process. Under the NIH Draft Public Access Policy, authors submitting a Manuscript to PubMed Central must provide NIH with a standard license that mirrors the Government Use License. This language will be included as part of this submission statement to PubMed Central and states:

I hereby grant to NIH, a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use this work for Federal purposes, and to authorize others to do so. This grant of rights includes the right to create derivative works and make

¹⁹ NIH Grants Policy Statement 4.2.1 Acknowledgment of Federal Funding (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.1_acknowledgement_of_federal_funding.htm) and 8.2.1 Rights in Data (Publication and Copyrighting) (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.1_rights_in_data_publication_and_copyrighting.htm).

²⁰ This happens typically through the NIH Manuscript Submission (NIHMS) System.

²¹ <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-75/subpart-D/subject-group-ECFR78b08d9c95aad03/section-75.322>.

²² https://grants.nih.gov/grants/policy/nihgps/html5/section_7/7.9_allowability_of_costs_activities.htm (See Publication and Printing Costs).

²³ https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.5_special_award_conditions_and_remedies_for_noncompliance_special_award_conditions_and_enforcement_actions_.htm.

²⁴ <https://support.nlm.nih.gov/knowledgebase/article/KA-05252/en-us>.

the final, peer-reviewed manuscript publicly available upon the Official Date of Publication.

The language in this statement may evolve as regulations change, but it includes a grant of rights to NIH such that NIH may make the Manuscript publicly available in PubMed Central without an embargo, upon the Official Date of Publication.

Guidance for Communicating Rights in Manuscripts

NIH highly encourages authors to be transparent when submitting Articles²⁵ for consideration for publication by indicating to the journal or publisher that the Article is subject to the NIH Public Access Policy, and that this means that NIH, as the funding agency, has the right to make the Manuscript publicly available in PubMed Central upon the Official Date of Publication. NIH does not require that authors demonstrate to NIH what was communicated to publishers.

NIH suggests that authors submit the points above as a statement in the Manuscript. Such a statement may accompany the required funding acknowledgment. NIH provides the following sample language that may be included in the Manuscript:

This manuscript is the result of funding in whole or in part by the National Institutes of Health. It is subject to the NIH Public Access Policy. Through acceptance of this federal funding, NIH has been given a right to make this manuscript publicly available in PubMed Central upon the Official Date of Publication, defined by NIH as “The date on which the article is first made available in final, edited form, whether in print or electronic (*i.e.*, online) format.

Draft Guidance on Publication Costs Purpose

NIH recognizes that authors publishing in peer-reviewed journals may incur associated costs, such as article processing charges (APCs) or other charges. Publication costs are allowable when they comport with the existing NIH cost principles.²⁶ Cost principles clarify when costs should be allocated as direct versus indirect costs, and they clarify charges and fees that are allowable under the conditions outlined.

This Draft Guidance clarifies publication costs that are not allowable

²⁵ Term used because they represent the pre-peer review stage.

²⁶ Grants Policy Statement Section 7.2. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7.2_the_cost_principles.htm) and Section 7.9 (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7.9_allowability_of_costs_activities.htm).

based on existing cost principles that provide a framework for allowable publication costs. It also provides points to consider to assist authors and institutions as they assess whether publishing costs are reasonable.

Public Access Policy Requirements Related to Costs

All costs must comport with 45 CFR 75, or its successor regulation, as implemented in NIH GPS Sections 7.2 and 7.9.1. These principles also apply as analogous requirements in Other Transactions and applicable contracts.

The NIH Draft Public Access Policy clarifies that reasonable costs that are allowable may be requested in the budget for the project as direct or indirect costs, as specified in the NIH GPS and as incorporated into Other Transactions and applicable contracts. Importantly, the NIH Draft Public Access Policy also states that submission of Manuscripts to PubMed Central remains free for authors. Journal or publisher fees for submitting the Manuscript to PubMed Central that may arise during the course of the publication process are not allowable costs.

Other Unallowable Costs

In addition to not allowing payment of fees to submit Manuscripts to PubMed Central, examples of other unallowable costs are listed below in the context of corresponding rules that can be found in the NIH GPS. This list may be updated as needed.

- Costs for services (*e.g.*, peer review) for which there is no resulting publication are unallowable because costs must be chargeable or assignable in accordance with the relative benefits received (GPS 7.2)
- Costs for which the institution already pays a fee that would cover publication costs (*e.g.*, an agreement the institution has with a publisher whereby authors from that institution publish for free in exchange for subscription services) are unallowable because costs may not be double charged or inconsistently charged as both direct and indirect costs (GPS 7.4)
- Costs for publishing services that are charged differentially because an author's Manuscript is subject to the NIH Public Access Policy are unallowable because charges must be levied impartially on all items published by the journal, whether or not under a federal award (GPS 7.9.1, Publication and Printing Costs)
- Costs for services incurred after closeout of the award, even for a publication subject to the NIH Public

Access Policy, are unallowable because the costs of publications must be incurred before closeout (GPS 7.9.1, Publication and Printing Costs)

Points To Consider for Authors and Institutions in Assessing Reasonable Costs

As stated in Section 7.2 of the NIH GPS, a cost may be considered reasonable if the nature of the goods or services acquired or applied and the associated dollar amount reflect the action that a prudent person would have taken under the circumstances prevailing when the decision to incur the cost was made. NIH promotes *reasonable* publication costs to ensure an equitable system for publishing opportunities. However, establishing a particular threshold for what is reasonable may lead to inequitable outcomes in specific circumstances. While NIH may modify this approach in the future, NIH encourages researchers and institutions to consider, when determining whether costs are reasonable:

- Size of publication cost in relation to NIH award
- Other publications researchers may wish to produce during an award period
- Professional and institutional priorities
- Sustainability in terms of the library budget, laboratory budget, etc., if such costs were to be consistently paid

In addition, NIH reiterates its Statement on Article Publication Resulting from NIH Funded Research,²⁷ a 2017 NIH Guide Notice that encourages authors to publish papers arising from NIH-funded research in reputable journals. Fees paid to journals that have characteristics described in this Statement may be considered unreasonable.

NIH seeks public comments on any aspect of the NIH Draft Public Access Policy and supplemental Draft Guidance.

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²⁷ <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-011.html>.