August 19, 2024

STM response to Request for Information on the National Institutes of Health Draft Public Access Policy (89 FR 51537)

Thank you for the opportunity to comment on the "**the National Institutes of Health Draft Public Access Policy**" ("draft policy"), as issued in the Request for Information **89 FR 51537**. STM is pleased a number of our comments on the Public Access Plan were considered in the development of the draft policy. In particular, we appreciate that the draft policy provides flexibility for implementation in several respects, recognizing, as we noted in our response to the RFI on the NIH Public Access Plan, that there is not one best route to providing access. That said, below we provide recommendations for improvement of the plan to ensure it fully achieves NIH's goals for public access, whilst minimizing research burdens, respecting academic freedom, and ensuring a vibrant and well-functioning ecosystem for trusted scholarly communication.

STM stands for advancing open and trusted research, where researchers and the rest of society can rely on information that is trusted, accessible, linked, and searchable in perpetuity. Our members therefore are committed to continuing to make needed advancements in systems and infrastructure and investments in people to ensure the quality, integrity, and persistence of the scholarly record to support research.

Publishers have led and responded to the interest in open science by investing heavily in open science over the last 25 years, broadening and expanding the public's ability to understand and access the work of scientists and scholars. Many of the products necessary for open science were created and maintained by publishers, including online infrastructure, as well as pre-printing, archiving, linking, and data management, and we continue to support and grow those efforts today. Our members have also invested in new models and approaches to providing access, including experimentation with a variety of business models to support quality, sustainability, and equity.

STM and our members remain fully committed to our responsibility to protect and improve research integrity. As the volume of research has increased, and there has been a rise in mis-/dis-information, with emerging tools including generative artificial intelligence creating new challenges, publishers and our partners have continued to invest in systems, people, and processes to preserve trust and validation of the scholarly record, such as STM Solutions.

We offer the following recommendations consistent with our desire to work with NIH, its funded researchers and institutions, and all stakeholders, to support the sharing of high-quality, vetted information. STM supports an environment where publishers can continue to drive quality, integrity, and innovation in scholarly communication, in collaboration with NIH, and the broad stakeholder communities that are funded and engaged in research related to NIH-funded

projects.

We therefore hope that STM and its members will have the opportunity to work with NIH to support researchers to advance biomedical research and public health, as well as promote quality, trust in science, equity, and the sustainability of the scholarly communications ecosystem.

1. Recommendations for the Draft Public Access Policy

In responding to the RFI questions below, STM would like to highlight the following overarching considerations:
- NIH should carefully consider how to reduce burdens on researchers and their institutions, including the challenges the policy may present for co-funded work for which different policies apply
- NIH must ensure that the policy respects author rights and copyright law
  NIH should ensure that the policy sufficiently acknowledges sustainable models for researcher compliance.

Reducing burdens on researchers and institutions

As has been true since the NIH first introduced a public access policy two decades ago, STM and its members stand ready to work with NIH and funded researchers to provide the broadest possible access to articles reporting on NIH-funded research. However, a successful partnership towards this end needs to be an equal one, where collaboration on efficient and effective solutions can be sought, and where publishers and NIH work together on education of the research community on potential approaches to "publishing models and/or discipline-specific requirements."

A key goal of such a partnership should be to reduce administrative burdens for funded researchers and institutions. There are several places in the Policy where a collaborative approach could yield better outcomes for all stakeholders than the outlined approach. Compliance and enforcement could be better addressed through utilising sustainable publication models for access, and collaboration with efforts like CHORUS (www.chorusaccess.org),[1] SeamlessAccess,[2] and GetFTR;[3] multi-stakeholder initiatives that are already providing easier access to articles and metadata. Implementation could best minimize burdens by ensuring flexibility in all aspects: business models, licensing, and implementation

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[1] CHORUS partners with funders and publishers to share knowledge, develop solutions, advance innovation, and support collective efforts. https://www.chorusaccess.org/
[2] SeamlessAccess is a service designed to help foster a more streamlined online access experience when using scholarly tools and shared research infrastructure. https://seamlessaccess.org/
[3] GetFTR (Get Full Text Research) works to ensure researchers can easily discover and access the content they are entitled to read https://www.getfulltextresearch.com/

processes. Specific recommendations related to each of these aspects is addressed respectively in the Policy and Guidance recommendations sections below.

Similarly, efforts are underway by publishing organizations to improve accessibility and understandability of articles in the manner envisioned in NIH's Public Access Plan that could be leveraged to minimize burdens both on researchers/institutions and on NLM itself. Rather than duplicate efforts already underway by the scholarly community, STM suggests that NLM focus on leveraging and seeking partnerships with publishers and others who are already providing access, accessibility, and utility for the scholarly record. In addition to these ideas raised in the introduction to the Policy, discoverability and curation should be understood as a key feature of accessibility and understandability. Support for such services, and for an effective and sustainable system that provides them, should therefore be a key feature of the Policy and its implementation.

A mixed ecosystem will persist for some time, as publishers adopt different models to serve the unique segments of the global research community on whose behalf they publish. One way NIH can minimize burdens for a large segment of researchers while supporting the needed features of the scholarly ecosystem is by more clearly and consistently supporting a fully-funded gold open access route for publication, where the Version of Record (VoR) can be made available to the public and publishers can be recompensed for the valuable investments they make to the integrity of the scholarly record. The VoR is the authoritative version for researchers and the public, and it is more cited, used, and garners more attention than other versions of an article.[4] The VoR is also the version that will be updated post-publication should there be any issues of research integrity. Supporting fully funded gold open access is the simplest route to minimize burdens and support research integrity, accessibility, and utility.[5]

Ultimately, the NLM needs to consider how it can ensure that the Policy avoids creating an unreasonable burden on researchers, their institutions, and publishers and negatively impacting the availability, quality, and integrity of the scholarly record. This is especially true as the Policy, as drafted, applies to any works reporting on NIH-funded research in perpetuity but does not provide support and funding for compliance in perpetuity.

Respecting author rights and copyright law

As a fundamental principle, STM notes that both the statute establishing NIH's Public Access Policy and the 2022 OSTP Memorandum clearly state that implementation must be consistent with copyright law, which grants authors exclusive rights to determine the dissemination of the

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[4] Researchers prefer the Version of Record according to multiple surveys. See, for example, a 2021 Springer Nature survey "Exploring researcher preference for the version of record:" https://www.springernature.com/gp/open-research/version-of-record.

[5] For example, the VoR can link bi-directionally to research objects like data and code, has the latest updates on corrections, and sits on the publisher's platform where it can be integrated with other relevant content, allowing the public to better put this information into context.

works they create. Authors can assign these rights to works that they have created, or contract to create works that will become the property of others (e.g., in the case of "works made for hire") by function of law, license, or assignment (for more details, see https://www.stm-assoc.org/wp-content/uploads/Authors-Rights-in-Scholarly-Publishing-Narrative-May29_2024.pdf.).[6] To be consistent with Copyright Law and academic freedom, researchers should be able to exercise their exclusive rights, including through licensing, under copyright law without undue constraint. Whilst HHS and OMB guidance (including 45 CFR 75.322(b) referred to in the policy) stipulate a (regulatory, but not statutory) Government Use License, the Policy may be seen to go further than this license repository.

More specifically, the application of requirements, and any license, should be understood in the context of author rights and contract law. The Policy requests submission only of Manuscripts that are accepted for publication, and therefore the production of such Manuscripts and their availability must be consistent with the desires of the author for such a manuscript and the requirements of the journal that has accepted the Manuscript. Where NIH "clarifies that compliance with the Policy is free," this should be contextualized with an acknowledgement that compliance is only possible through the work of publishers like our members, whose resources and expertise ensure that high quality, trustworthy content comprise the scientific record, and that compliance with the Policy must therefore be consistent with agreements made with such publishers. The Policy could otherwise be understood to suggest that authors might ignore publication costs or license restrictions that are part of the conditions of acceptance of an article, which would be inconsistent with copyright law, contract law, and vital tenets of academic freedom.

Similarly, requirements that would impact works already created or that do not provide appropriate notice to researchers, institutions, and third parties (i.e., publishers) should be avoided to prevent misunderstanding or conflict with the law.

Finally, allowing the government free rein to create derivative works has no basis in the Government Use License, the governing regulations or any of the prior agency publication, and undermines right holders' authority to determine how their research is represented in works attributed to them. A broad license to create derivative works without any oversight or review by the author could also enable political influence in the representation of such works or introduce errors or other misrepresentations, with significant impact on the integrity and reliability of the scholarly record. We recommend that in place of this broad license, NIH state exactly what is needed to ensure accessibility.

Specific Recommendations

Definitions

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[6] See STM's white paper on Author Rights in Scholarly Publications for more details https://www.stm-assoc.org/wp-content/uploads/Authors-Rights-in-Scholarly-Publishing-Narrative-May29_2024.pdf.

The definition of article should refer to the NISO Journal Article Versions (JAV) Recommended Practice,[7] which has recently been updated after a multi-year, broad stakeholder consensus process. Nomenclature should be consistent throughout the Policy and the Draft Guidance.

The definition of Manuscript appropriately recognizes the importance of the peer-review process, which is managed and enabled by journal communities and their publishers.

Policy Effective Date
The effective date of the Policy should be with respect to new grants, rather than with respect to the acceptance date of a publication. As written, the Policy is retroactive to works already created, which may have already been submitted, without assigned publishing costs and close to acceptance before the Policy goes into effect. This could create conflict with author rights and publisher agreements or understandings. The Policy appropriately calls for author education and notice to third parties who might review or publish such manuscripts; this will not be possible for manuscripts already under review when the Policy is finalized.

The section on Government Use License and Rights limits claims to those in 45 CFR 75.322(b) and 2 CFR 200.315(b). It is critical to note that these provisions do not have a statutory basis and may be subject to challenge, especially in the face of recent Supreme Court decisions. Regardless of the basis in law, the regulatory framework should provide the outer limit of the license claims in the Policy and related guidance.

Rights in Manuscripts
STM appreciates that the Government Use License and Rights section acknowledges that rights in the Final Published Article may be different from the permissions and responsibilities in the Accepted Manuscript. Where the Final Published Article's license provides rights for it to be linked to or submitted to PubMed Central, compliance should be possible regardless of whether a journal has a formal agreement with NLM. The Compliance and Enforcement section should reflect this.

2. **Recommendations for Draft Guidance on Government Use License and Rights**

In addition to noting the rights that Federal agencies have, this guidance should also note NIH's respect for intellectual property rights and copyright, as well as academic freedom. Such a commitment to authors' rights should be included in the Purpose section.

The second paragraph of the Draft Guidance appropriately encourages authors to communicate expectations to publishers to support and enable dialogue on rights and options regarding the licensing of articles. Publishers support such clarity and would welcome a dialogue with NIH to support author education regarding NIH's public access policy and licensing.

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[7] NISO RP-8-2008, Journal Article Versions (JAV): Recommendations of the NISO/ALPSP JAV Technical Working Group | NISO website

The submission statement proposed in the Draft Guidance is not consistent with the language in the policy or with 45 CFR 75.322(b) and 2 CFR 200.315(b), nor with the Public Access Policy Requirements Related to Rights as articulated in the previous paragraphs. STM strongly recommends that the clause claiming that the license "includes the right to create derivative works" be deleted; this has no basis in the Government Use License, the governing regulations or any of the prior agency publications.

In particular, as noted in the comments and recommendations on the Draft Policy, STM and its members are concerned about the potential of NIH to provide third-parties with the right to distribute works in competition with publishers without a clear Federal purpose, and in a manner that is inconsistent with a sustainable scholarly communications ecosystem. Similarly, government creation of derivative works in place of the author has the potential to conflict with academic freedom, research integrity, and the sustainability of peer-reviewed scholarly communications.

In the section "Guidance for Communicating Rights in Manuscripts" the footnoted use of the term "Articles" is inconsistent with the definition in the Policy. To improve clarity, STM recommends the use of the phrase "works reporting on NIH-funded research" in place of "Article" here. Similarly, the term Manuscript is used to mean different versions in different places in this section. STM recommends that NIH utilize the NISO Journal Article Versions (JAV) Recommended Practice (see footnote above) to be clear when "submitted manuscript," "accepted manuscript," or another version is meant.

3. Recommendations for Draft Guidance on Publication Costs

In general, STM appreciates that this section acknowledges the costs of the publication process and emphasizes that these costs should be an allowable budget expense.

As noted in our comments on the NIH Public Access Plan (https://www.stm-assoc.org/document/stm-response-to-request-for-information-on-the-nih-plan-to-enhance-public-access-to-the-results-of-nih-supported-research-not-od-23-091/), guidance on publication costs should emphasize author choice for whatever journals they choose to advance their research and impact, regardless of whether this incurs a direct cost. In order to ensure equity for all researchers, NIH should clarify that funding will be provided on an equal basis so that researchers who choose to publish in journals that are supported by APCs are not disadvantaged in the resources available for their research, student support, and other critical needs.

The Draft Guidance should emphasize that costs not only "may be requested," but "should be requested." STM also recommends that the Draft Guidance provide that budgets will be reviewed to ensure that there is adequate funding for intended and potential publications, similar to the manner in which the NIH Data Sharing and Management guidance indicates that

budgets will be reviewed to ensure that there is adequate funding for data sharing and management.

Under "Other Unallowable Costs," STM notes that costs incurred after closeout are unallowable. STM would like to reiterate our concern about compliance with an open-ended policy and encourages NIH to add policy language and guidance regarding how researchers can address the costs of publications subject to the Policy that are published (or even written) after closeout. NIH could consider automatic grant extensions and/or supplemental grant opportunities for publication costs, amongst other options.

In the section on "Points to Consider […] in Assessing Reasonable Costs," STM urges NIH to provide guidance that reflects the full value of the publishing ecosystem. The last bullet regarding library budgets is particularly concerning as an issue that can be read as bias against support for publishing costs, and STM recommends its removal. In addition, NIH could consider the impact of not supporting publishing costs as a key consideration for authors and institutions. As some illustrative examples (not meant to be exhaustive), the draft guidance could suggest consideration of:

- Impact on biblio-diversity and research integrity, if such costs were to not be consistently paid;
- Sustainability of the publishing ecosystem

The reference to the 2017 Guide Notice to avoid disreputable publishers is a welcome one. STM also encourages NIH to direct Authors and Institutions to consider publishers who ascribe to the COPE[8] guidelines, as well as consultation of "Think. Check. Submit.,"[9] and scholarly communications initiative to support publication in reputable journals.

Finally, the Draft Guidance should note that publication practices and business models are actively evolving. NIH should ensure that reliable and sustained funding is available for any and all business models that support immediate access to articles reporting on NIH-funded research. STM would welcome the opportunity for additional dialogue to ensure that all publication costs, regardless of business model, including but not limited to APCs, are allowable costs and supported to promote public access and research integrity.

About STM

At STM we support our members in their mission to advance trusted research worldwide. Our more than 140 members collectively publish 66% of all journal articles and tens of thousands of

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[8] COPE: The Committee on Publication Ethics, promotes integrity in research and its publication https://publicationethics.org/
[9] Think. Check. Submit. helps researchers identify trusted journals and publishers for their research. https://thinkchecksubmit.org/

monographs and reference works. As academic and professional publishers, learned societies, university presses, start-ups and established players, we work together to serve society by developing standards and technology to ensure research is of high quality, trustworthy and easy to access. We promote the contribution that publishers make to innovation, openness and the sharing of knowledge and embrace change to support the growth and sustainability of the research ecosystem. As a common good, we provide data and analysis for all involved in the global activity of research.

The majority of our members are small businesses and not-for-profit organizations, who represent tens of thousands of publishing employees, editors, reviewers, researchers, authors, readers, and other professionals across the United States and world who regularly contribute to the advancement of science, learning, culture and innovation throughout the nation. They comprise the bulk of a $25 billion publishing industry that contributes significantly to the U.S. economy and enhances the U.S. balance of trade.