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NIH Office of Science Policy

Via online submission

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Authors Alliance is a 501(c)(3) nonprofit organization whose mission is to advance the interests of authors who want to serve the public good by sharing their creations broadly. We create resources to help authors understand and enjoy their rights and promote policies that make knowledge and culture available and discoverable.[1] This includes substantial efforts to support authors who seek to make their work available on an open access basis.

We applaud NIH's work on updating the 2008 Policy. Our thoughts on potential improvements to the the Draft Policy and the two supplemental draft guidance documents are as follows:

1. Comments on the Draft Public Access Policy:

We believe that the NIH Draft Public Access Policy serves an important role in furthering the interests of authors who want their work to achieve maximum reach and impact for the benefit of the public. Allowing immediate and free availability of Manuscripts on PubMed Central will increase research visibility and help authors reach a much larger audience. In turn, it will accelerate the pace of scientific innovation and expedite life-saving discoveries.

The removal of the embargo period will significantly improve transparency and accountability for NIH-funded research, helping combat low-quality research. Despite prestigious publishers' promise to provide rigorous peer reviews and editorial oversight, we continue to observe how commercial publishing is not the cure to fraudulent or defective publications.[2] We know from experience that public oversight and free critique, enabled by free public access to the latest publications, is the best method of identifying and addressing bad research quickly.

Any delay in removing the embargo period is therefore harmful both to authors' interests and the public's. Accordingly, we strongly support NIH's position of not changing the proposed effective date of the new Policy. Some publishers may request a delay in removing the embargo period, because the publishers' monopoly over research outputs helps them maximize profits. The Draft Policy will hamper such plans—but that is a business model conflict, not a legal one. We would like to emphasize that the removal of the embargo period does not conflict with the interests of grantees. In our experience, academic authors, universities, and federal agencies are largely in agreement that they would like to see the results of research reach the widest possible audiences and have the greatest possible impact.

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[1] For more information about Authors Alliance, see *About Us*, Authors All., http://www.authorsalliance.org/about.

[2] One example among many: https://www.springernature.com/gp/advancing-discovery/springboard/blog/blogposts-trust-integrity/tackling-paper-mills-and-bogus-research/20352610

Acting alone, most academic authors have very little power to negotiate favorable public access terms with their publisher, despite the authors' strong support for sharing and reuse. NIH's Draft Public Access Policy addresses this negotiating imbalance. It empowers authors to resist any pressure from publishers to assign exclusive rights to the publishers, ensuring that authors can share their work broadly and without delay.

We also recommend NIH to request source data resulting from NIH-funded research be made available publicly, and be dedicated to the public domain using a CC0 license. Currently, NIH grantees are able to fulfill their obligations under NIH DMS Policy by depositing data into certain repositories. Some of the repositories have embargo periods[3], and some are not easily accessible to the public[4]. Such segmented and opaque storage of data prevents potential meta-analysis as well as a more comprehensive public discourse on the latest research findings. By contrast, when research data is placed in the public domain and made transparent to all, other researchers and the general public are able to validate, replicate, and build on previous research more easily and smoothly.

2. Comments on the Draft Guidance on Government Use License and Rights:

NIH has the legal authority to make NIH-funded research publicly available based on Federal Purpose License[5] as codified in 45 CFR 75.322(b). Authors, universities, and research libraries have reached broad agreement that the Federal Purpose License is the appropriate mechanism and framework on which public access plans should be developed,[6] and we strongly encourage NIH to follow and make full use of the rights this license affords it.

Certain aspects of the NIH's planned implementation could be confusing to authors and institutions, and so we encourage NIH to clarify several things:

First, NIH should clarify that its rights to use and provide public access to Manuscripts remains valid irrespective of separate licensing arrangement, including any subsequent license granted to NIH when grantees accept funding or when grantees agree to the proposed submission statement of PubMed Central. Considering the Draft Policy is "to become effective for Manuscripts accepted for publication on or after October 1, 2025, …whether the award or contract is new or ongoing," it is crucial for stakeholders to understand that NIH does not need a separate license to exercise its right to use grantees' Manuscripts.

Second, NIH should clarify the effect of the proposed submission statement to PubMed Central ("I hereby grant to NIH, a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use

[3] E.g., https://exrna.org/resources/data/data-access-policy-summary/
[4] E.g., https://fitbir.nih.gov/content/access-data
[5] We are using "Federal Purpose License" to refer to the license described in 45 CFR 75.322(b) in accordance with the statutory language.
[6] *See* Statement in support of using the Federal Purpose License to implement the 2022 OSTP public access memo, The Right to Deposit, April 16, 2024, https://sites.google.com/ucop.edu/the-right-to-deposit/statement (statement jointly developed by the Authors Alliance and the University of California, with signatories representing over 300 institutions representing and well over 50% of all federal research funding).

this work for Federal purposes…"). While this submission statement conveys to grantees in easy-to-understand language NIH's right to provide public access to Manuscripts produced under NIH grants, it can be confusing to use language that ostensibly transfers a new right that in fact is already conferred under the Federal Purpose License.

We think the submission statement to PubMed Central should be straightforward in conveying the fact that NIH holds pre-existing rights to make NIH-funded research publicly available, and that the ostensibly-new copyright license granted to NIH will at best act as a fail-safe in some unlikely legal scenarios. Similarly, we encourage NIH to carefully craft the language in Notices of Award and other related contracts, to ensure grantees understand that NIH has always had a right to use NIH-funded research as soon as grantees accept funding.

Third, NIH should publish further guidance on what reuse rights NIH is granting to the public. The Federal Purpose License clearly allows for such reuses ("The HHS awarding agency 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."*** emphasis added), and the Nelson Memo specifically calls for clarity on this point ("plans should describe . . . any use and re-use rights, and which restrictions, including attribution, may apply.")[7]

To maximize the value and impact of NIH-funded research, NIH should facilitate and encourage lawful reuse of articles, especially reuse using techniques such as text and data mining and AI-enabled computational research. These methods enable subsequent researchers to uncover new insights that have been previously unattainable through traditional means. We believe that fair use already allows for many of these uses. But, an explicit grant to use NIH-funded research will provide clarity and lower barriers to this kind of reuse. This can especially encourage reuse among underprivileged and marginalized communities, when fair use, albeit a well-established and robust right, nevertheless is very complicated to understand and carries with it uncertainties that are too costly for those with fewer resources to shoulder.

The NIH can accomplish this with a modest change to its existing language. We agree with SPARC's comments that this change could be accomplished with text such as:

> *"NIH hereby exercises its right under this license to authorize members of the public to reuse the work for any purpose so long as the authors and the original publisher receive attribution in a reasonable manner."*

In general, we commend NIH for addressing potential areas of confusion with regard to rights and permissions. It is especially helpful to provide authors with sample language to include in their Manuscript when submitting to journals for publication, so that journals are fully informed that the Manuscripts will be made publicly available. In this way, grantees can avoid potential legal conflict with downstream transferees or licensees of rights.

3. Provide any comments on the Draft Guidance on Publication Costs below:

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[7] https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-access-Memo.pdf

We appreciate NIH's thoughtfulness in delineating allowable costs and unallowable costs. We agree that while grants should be allowed to cover reasonable publishing fees, no grant money should go toward paying "[j]ournal or publisher fees for submitting the Manuscript to PubMed Central…" or "[c]osts for publishing services that are charged differentially because an author's Manuscript is subject to the NIH Public Access Policy…"

At the same time, we would like NIH to make room for grantees utilizing NIH grant money to support other equitable solutions for publication, such as Diamond Open Access where no fees are levied against authors nor readers, or read-and-publish deals where institutions combine their subscription and publication deals for reduced costs.

We appreciate NIH's commitment to monitor publication costs and their potential effects on relevant communities beyond the implementation of the new Policy. It is important to remain vigilant that "publication costs" such as article processing charges (APCs) or other charges do not grossly exceed the true cost of distributing quality research. Grant money should be reserved for the production and dissemination of research rather than for generating extra profits for commercial publishers.

Sincerely,

Dave Hansen
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Yuanxiao Xu
Staff Attorney, Authors Alliance