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RE: Request for Information on the National Institutes of Health Draft Public Access Policy. Submitted online at: *https://osp.od.nih.gov/comment-form-national-institutes-of-health-draft-public-access-policy/*.

The Association of American Medical Colleges (AAMC), Association of American Universities (AAU), Association of Public & Land Grant Universities (APLU), and Council on Governmental Relations (COGR) appreciate the opportunity to provide feedback in response to the National Institutes of Health (NIH) Draft Public Access Policy ("the Policy"). Our organizations are strongly supportive of the goal of providing public access to scholarly publications resulting from NIH-funded research. We are pleased to provide comments below on the draft Policy as well as the draft guidance on government use license and rights and publication costs.

Draft Public Access Policy

We appreciate the agency's overview of public comments and the additional clarity provided in the draft regarding the scope of the Policy and definition of key terms. We also appreciate the clear distinction between the 'Manuscript' and the 'Final Published Article' in the submission requirements, and the ability for researchers to meet the Policy requirements by submitting the Manuscript to Pubmed Central.

Scope and effective date

We have significant concerns about the timeline for implementation, specifically the proposal to implement the updated Policy on October 1, 2025, for current awards or awards made prior to October 1, 2025. For these awards, researchers secured funding under the current policy, and the budgets were submitted to the agency at the start of the grant period, often with predetermined publication plans. Specifically, we are concerned that researchers and institutions will not have budgeted publishing costs for a zero-day embargo. A more gradual and phased-in transition period would allow the research community to adapt to the new requirements with less disruption to research dissemination plans and budgets.

To address our concerns, we recommend that the current 12-month embargo remain in effect for awards made before October 1, 2025, to allow researchers to fulfill the commitments made under the policy at the time of the original terms and condition of the award and included in budgets accordingly.

As the research community transitions to comply with the new policy, we also urge NIH to consider providing supplemental funding to cover publishing costs for immediate public access for awards made prior to October 1, 2025.

Researchers will need clear guidance and the appropriate resources and support to successfully navigate this change. We appreciate NIH's commitment to working with the research community to prepare for the implementation of the new Policy.

Accessibility and understandability

We commend NIH's commitment to ensuring that PubMed Central content is available in machine-readable formats. This approach improves accessibility for users of assistive technologies, enables text mining of NIH-funded research, and facilitates analysis of the entire corpus of NIH-funded work without being limited by individual publisher platforms.

To achieve this goal, we seek clarification on how NIH plans to implement these accessibility and machine-readable measures to ensure they don't create additional burdens for researchers during the submission process. We recommend that NIH explicitly state in the policy that PubMed Central -- not individual researchers or their institutions -- is responsible for creating accessible, machine-readable formats. This clarification of the responsible entity would ease concerns about potential increases in researchers' workloads and avoid new technical hurdles in the submission process. It would also facilitate the adoption of and compliance with the policy across the research community.

Government Use License and Rights

While we understand that NIH is working to implement the August 2022 OSTP Memo "Ensuring Free, Immediate, and Equitable Access to Federally Funded Research," we have significant concerns about the Policy language that mandates that an additional license be granted to NIH that "mirrors that of the Government Use License at 45 CFR 75.322(b)." We urge NIH to revisit the legal basis of such a provision.

Unlike other federal agencies, NIH already possesses statutory authorization from Congress on the topic of open access, embodied in Section 218 of the Consolidated Appropriations Act of 2008 (Pub. L. 110-161) that states:

> SEC. 218. The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than *12 months after the official date of publication*: Provided, *That the NIH shall implement the public access policy in a manner consistent with copyright law.* (emphasis added)

This statutory authority provides the metes and bounds of NIH's Open Access policies. However, the Policy proposes that:

> When a Manuscript is submitted to NIH, providing NIH with a standard license that mirrors that of the Government Use License at 45 CFR 75.322(b), 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.

We are concerned that mandating an additional compulsory license under the auspices of government use is potentially an expansion beyond NIH's current existing legal authority to disseminate copyrighted works and is not consistent with copyright law. This license would ostensibly give NIH the unfettered ability to post and disseminate copyrighted works under the auspices of "government use" completely negating any rights reserved to the copyright holder. The draft policy does not provide the legal authority under which such an expansion is authorized.

We recommend the removal of reference to the Government Use License as well as a specific change to the language in the Policy:

- [Original Text] When a Manuscript is submitted to NIH, providing NIH with a standard license that mirrors that of the Government Use License at 45 CFR 75.322(b), 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.

- [Proposed Text] When a Manuscript is submitted to NIH, providing NIH with a license that explicitly grants NIH the right to make the Manuscript publicly available through PubMed Central upon the Official Date of Publication.

Publication Costs

We appreciate NIH's allowance for reasonable publication costs, including article processing charges. We suggest that the NIH facilitate the inclusion of these costs as direct costs in the grant budget and provide clear guidelines on what constitutes "reasonable publication costs." Prioritizing publication costs as direct costs will promote greater transparency in budgeting and expenditure.

Costs for manuscript preparation and publication following conclusion of the funding period

NIH's current grant policy, which does not allow for publication costs after an award's closeout creates an additional financial burden on institutions. Research often culminates in publications after the grant period has ended; the current requirement to make these publications publicly accessible without providing funding support for publication costs creates a funding gap. We recommend the creation of a separate supplemental funding mechanism to support post-award publication costs, which will allow institutions to meet this obligation should it remain in the final policy.

The draft Policy requires submission of the "Manuscript," defined as "the author's final version that has been accepted for journal publication and includes all revisions resulting from the peer review process." This definition acknowledges the crucial role of peer review in ensuring the quality and reliability of scientific publications. However, the policy also states that "costs for services (e.g., peer review) for which there is no resulting publication are unallowable..." The approach in the draft Policy does not adequately account for the prolonged timeline of publication, in which pre-publication costs may occur before the close out of the award, but the publication does not occur within the funding period. We recommend that supplemental funding should allow for the cost of peer review, as well as other valuable pre-publication services such as copyediting for preprints or a review of statistical methods, even when there is not a publication before the closeout of the award.

Additionally, the current language in the draft guidance may inadvertently hinder institutions' transition to diamond open-access models, where peer review is included within the cost of ensuring publication quality. We suggest allowing reasonable costs for peer review services, either within the original grant budget or as part of supplemental costs. Finally, we recommend that NIH work with the research community to develop clear and specific guidance on allowable costs which cover peer review and other pre-publication costs.

Aligning NIH policy with evolving publishing models and agreements

We appreciate NIH's effort to prevent double charging of publication costs. However, the current language regarding institutional agreements with publishers raises concerns due to potential conflicts with current and future transformative agreements. We suggest modifying the language to read as follows (bold text indicates modifications):

> "Costs for which the institution already pays a fee that would cover **all** publication costs (e.g., an agreement the institution has with a publisher whereby authors from that institution publish **all** articles 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)."

The proposed modification acknowledges that some agreements may have caps on the number of articles published per year by the institution and ensures that the policy does not unintentionally discourage transformative agreements. Additionally, we urge NIH to consider how this policy might impact institutions' flexibility in managing their publication resources. Institutions should retain the ability to allocate their publication funds among their researchers, including those whose work is supported by the NIH, without being constrained by restrictive policies. We note the California Digital Library's multi-payer workflow as a model in which there is a collective funding model with some ownership from researchers and some obligation from the funder and institution to enable open access.

On behalf of our associations, we appreciate NIH's engagement with stakeholders during the development of the NIH Public Access Policy and look forward to continued engagement on this issue as the final policy and other guidance are developed. We greatly appreciate our ongoing partnerships with NIH in ensuring federally funded research is publicly accessible and would be glad to provide further information or answer any questions about these comments.