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Submitted online via RFI website on August 19, 2024.

RE: Request for Information: National Institutes of Health Draft Public Access Policy

On behalf of the members of the American Society for Pharmacology and Experimental Therapeutics (ASPET), we appreciate the opportunity to provide comments on the Request for Information (RFI) regarding the National Institutes of Health (NIH) Draft Public Access Policy (NOT-OD-24-144) and supplemental guidance related to government use license and rights and publication costs.

ASPET is a 4,000-member scientific society whose members conduct basic and clinical pharmacological research and work in academia, government, industry, and non-profit organizations. ASPET members conduct research leading to the development of new medicines and therapeutic agents to fight existing and emerging diseases. ASPET is a global pharmacology community that advances the science of drugs and therapeutics to accelerate the discovery of cures for disease.

ASPET commends NIH's continual efforts to engage with stakeholders throughout the policy development process, including its first Public Access Plan issued in February 2023. ASPET's comments continue in line with its earlier [comments](#) submitted to the first Public Access Plan. We offer the following comments on the Policy Draft:

ASPET appreciates the proposed policy's emphasis on peer-reviewed publications, as peer review and scientific integrity are the hallmark of NIH funded research and how it is shared with the greater community. ASPET shares its comments to help provide areas that need clarification to strengthen the Draft Public Access Policy.

Definitions

ASPET strongly recommends simplifying definitions in the draft policy. In the current proposed draft, three definitions are used to describe a single piece of written material: "manuscript," "final published article," and "article." NIH included "article" as a response to a clarification question concerning the scope of the draft plan. Instead of clarifying, NIH created a definition that encompasses both that of "manuscript" and "final published article," thus creating unnecessary confusion for the research community.

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Moreover, in the draft policy’s definition of “manuscript.” it states:

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**. (Emphasis added).

Although ASPET appreciates that NIH recognizes that the manuscript is the result of the peer review process, we are concerned that NIH is expanding the sphere of peer review to encompass preprints, conference proceedings, book chapters, editorials through the inclusion of “supplemental material.” This expansion would add administrative burdens on scientists. As [previously stated](#), ASPET recommends explicitly specifying what “supplemental material” entails. If it entails more than the traditional understanding of materials present in a journal publication, NIH needs to explicitly state this as well as what it expects for reporting and allow the community to comment. ASPET strongly encourages NIH to remove “article” and “final published article” as the definitions do not accomplish the clarification of what is covered by the NIH Public Access Policy. The Policy applies to “any Manuscript accepted for publication in a journal.” NIH has defined “manuscript.” Additional clarifications within the definition are appreciated, however no additional definitions need to be created.

Scope and Effective Date

ASPET finds the effective date of October 1, 2025, to be arbitrary, and shortens the time that NIH can effectively aid the research community for implementation date. Should NIH revise its effective date to December 31, 2025, this would allow NIH an added three months of preparation time to create a policy that aligns with the intent of the OSTP Memorandum. As it stands, there would be little under a year for NIH to communicate its final Policy to the research community and aid in the transition. The research community has already had enough shifting caused by the OSTP Memorandum and the impact on its publishing capabilities.

Compliance and Enforcement

ASPET asks that NIH publish a plan that details its implementation plan and allows for public comments. With so many different moving parts within the publishing world, time is not on the side of publishers and scientific societies to implement the Policy. Clear, concise, and detailed policies and plans are necessary to not only remove the burden, but also allow for clarity on what is expected by all parties.

Government Use License and Rights:

ASPET appreciates the need for publicly sponsored research to be accessed within the public arena and supports authors ability to have academic freedom to choose how their findings will be delivered, including a journal of their choice as well as license for reuse. Several times throughout the Plan the terms “derivatives” and “reuse rights” appear without clear definitions which lead to concerns about misrepresentation of findings that could be used to impeach the investigator, funding agencies, and scientific integrity.

The use of “derivatives” could potentially allow irresponsible AI owners and even responsible AI owners to use content without providing credit to authors or allowing the misrepresentation to exist without anyone knowing. The policy goal of the Plan is to open research to the public, not allow it to be manipulated for other purposes. We strongly ask that any derivative rights be removed in the final policy. We also strongly recommend that there be included stronger intellectual property protections against intrusive AI and nefarious agents repurposing or misrepresenting findings within the given findings.

Comments on the Draft Guidance on Publication Costs:

ASPET appreciates the strides that NIH has taken to allow “allowable costs” to be considered. We also commend the “Other Unallowable Costs” section and “Points to Consider” additions to aid authors and institutions. Yet ASPET is still concerned that NIH is not watching the expansive growth in new publishing models and open access infrastructure. NIH’s push to open access has created disparities impacting communities and researchers from historically excluded backgrounds, early-stage investigators and lower-resource institutions. Without a step to open access, business models have been disruptive, and that disruption has been passed on to those authors. NIH should include sections that outline how it will support these groups. NIH has a role and responsibility to make open access equitable to all. The worst outcome is not that research is behind a paywall for a year, it is that research is never published due to high costs, or an author is forced to publish some place where the discovery will languish away from sight.

Conclusion

ASPET is very appreciative of NIH’s continued efforts to engage stakeholders throughout this process. ASPET calls upon NIH to work expeditiously through the submitted comments and share a revised draft policy before continuing into a final policy. ASPET looks forward to an improved play for public access and a policy that allows researchers to comply more readily without administrative burdens or misrepresentation of their work.