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## RE: Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research

On behalf of the members of the American Society for Pharmacology and Experimental Therapeutics (ASPET), we appreciate the opportunity to submit comments on the National Institutes of Health (NIH) *Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research (NOT-OD-23-091)*.

ASPET is 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. We are in constant pursuit of our Mission through research, education, innovation, and advocacy.

ASPET owns and self-publishes four journals covering a wide range of pharmacological topics. They are *The Journal of Pharmacology and Experimental Therapeutics (JPET)*, *Pharmacological Reviews (Pharm Rev)*, *Molecular Pharmacology (Mol Pharm)*, and *Drug Metabolism and Disposition (DMD)*. ASPET co-publishes a fifth journal, *Pharmacology Research & Perspectives (PR&P)*, with the British Pharmacological Society and Wiley. All four of ASPET's wholly-owned journals continuously accept articles and have published continuously accepted articles and posted fully formatted versions as soon as they were ready. Formatted articles are freely available during a rolling five-year window, where articles are freely accessible for five years, starting 12 months after publication. After those five years are up, the articles go back to being under access control. NIH-funded articles are deposited in PubMed Central on behalf of authors by ASPET. All ASPET journals are Plan S compliant and meet NIH Data Availability requirements. Journal authors range from undergraduates, and postdoctoral students, to PhD scientists at universities, government agencies, and in industry.

NIH's proposal is commendable in its goal to allow for instantaneous access to NIH supported research publications. ASPET agrees with NIH that all involved in the scientific research enterprise are trustees of the public's funds and thus the public should have access to the research results. ASPET is concerned, though, that the NIH's goal does not account for the reality of the level of administrative burden that will occur, and the cost borne to the entire research enterprise, to achieve this goal.

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Scholarly scientific societies were founded to convene researchers in a field and advance a particular branch of science. ASPET has long accomplished this goal through various means, including establishing best practices and standards, policy feedback, workforce and career development, awards and recognition, advocacy, education, and communicating advances in science through publications, conferences, and other means. We are led by and represent many of the same scientists who conduct research funded by NIH. As a nonprofit, revenues we collect are reinvested in advancing science and supporting the research community.

Before addressing NIH's interest in Section III of the NIH Plan to Enhance Public Access, ASPET would like to provide the following comments on Section II.

## **II. Scientific Data**

**II.C. NIH will rely on the approaches and timelines for data sharing specified in the NIH DMS Policy. The NIH DMS Policy indicates that scientific data that are *not* associated with peer-reviewed scholarly publications should be made accessible as soon as possible, and no later than the end of the performance period for the research award.**

The peer reviewed scholarly publication is the hallmark of NIH funded research. The publication has a structure that with known production values, processes, and locations. Including additional scientific data that is not associated with the peer reviewed scholarly publication for the sake of inclusion creates more administrative burden. There may be value in scientific data underlying null and negative findings, or other data that was tangential that is included in preprints, conference proceedings, or book chapters, but those decisions should be left to the professional judgment of the author as to whether they rise to the level of scientific data sufficient to be included in a peer reviewed scholarly publication. There is a high bar to meet with data that is included in the peer reviewed publication. NIH should keep its focus on peer reviewed publications and not the inclusion of all data that may exist.

The other issue that arises with the inclusion of the entire universe of data is that it becomes administratively burdensome. The current process for disseminating scholarly research is through journals with their own set of criteria for reviewing and validating data. If NIH expects that conference proceedings, book chapters, and preprints are to be included in its Public Access Plan, by which method would it like to see the material submitted? Does NIH expect its partner scientific associations, such as ASPET, to record all conference sessions and digitize all related documents and submit to NIH in a Dropbox file or is there more that needs to be done administratively to meet NIH's plan? NIH has not shown there is a need to have these additional proceedings included in the public record and thus this takes away from its intended goal of allowing public access to scholarly peer reviewed publications.

**How to best ensure equity in publication opportunities for NIH-supported investigators. NIH policy already allows supported researchers to charge reasonable publishing costs - NIH seeks information on additional steps it might consider taking to ensure that proposed changes to implementation of the NIH Public Access Policy do not create new inequities in publishing opportunities or reinforce existing ones.**

Item III.D.1 notes *"NIH intends to develop supplemental information that elaborates on and clarifies allowable costs for publication, consistent with these conditions."* ASPET encourages NIH to include that such supplemental information covers *all* allowable paths for charging publishing costs, including from indirect costs and other university general or restricted funds. ASPET also encourages NIH to include in this guidance coverage for all costs, such as open access fees, page charges, and submission fees among other costs.

Inequities in the publishing world already exist, with those researchers at larger universities having the benefit of administrative support and scale in terms of libraries, while those in

underserved areas and populations do not have the level of support at institutes to assist them with publishing. NIH should allow all avenues to be available for publication and should not limit how a grant is to be used for publications. Whether this will require an increase in the grant amount, or NIH including publication costs within the grant, is a matter for future study by NIH. However, if NIH has the goal to increase publications from these communities, NIH needs to make all efforts available and provide maximum flexibility.

NIH should also allow for flexibility and choice for both the authors and publishers in publishing research so that the appropriate reuse of articles can be determined by the author and publisher. ASPET encourages NIH to permit CC BY-NC license options that allow for the free reuse of content by the public (in line with the goals of NIH) but not for commercial purposes.

**Steps for improving equity in access and accessibility of publications. NIH welcomes input on other steps that could be taken to improve equity in access to publications by diverse communities of users, including researchers, clinicians and public health officials, students and educators, and other members of the public.**

Scholarly societies, such as ASPET, are a unique partner in this area of improving equity in access and accessibility of publications. Operating simultaneously in the scientific enterprise, in education, and in business, societies can pull best practices and implement them across multiple sectors at once. However, financial support for equity efforts is lacking. With proper funding, scholarly societies would be ideal partners to improve equity in access and accessibility. Examples of practical steps that could be taken more broadly include plain language summaries, alt text for images, creating more videos, working with media on news stories, and engaging through social media. Societies are also well-situated to develop educational materials and facilitate training to support researchers and the broader diverse community on improving communication around the scientific process and a specific field of science. To facilitate this, resources from NIH could be specifically allocated to address the financial need for domain-specific experts, including scholarly societies.

**Methods for monitoring evolving costs and impacts on affected communities. NIH seeks information on effective approaches for monitoring trends in publication fees and equity in publication opportunities.**

ASPET recommends that NIH not monitor publication fees, which could lead to a system that favors quantity over quality. Any “one-size fits all” pricing structure which is the logical result of this type of monitoring does not enhance the publication’s quality; it just streamlines the bookkeeping.

While there might be an interest in monitoring whether funded researchers are requesting more total resources in the direct versus indirect portion of the grant and resultant changes in awarded amounts over time, this would be challenging to monitor without an effective baseline. The determination of the baseline will shift as this Policy is implemented as there should be more articles published and discoveries occurring with more public access. While there are also the dangers, such as AI produced manuscripts and paper mills, that will need to be guarded against, that will also shift future baselines. Ultimately, NIH should allow the marketplace and competition between publishers to determine the reasonable publication costs.

If NIH feels there needs to be more publication avenues, there could be further discussion. However, if NIH’s goal is to increase those affected communities’ publication rates, NIH should work with its scientific societies to improve resources and education to allow those impacted to publish in existing journals.

Monitoring equity in funded grants will be important, as is understanding where and how the system is developing and evolving. To obtain a snapshot of the current environment and assess impact of policy changes, NIH could compare the total, median, and mean number of publication fees in the direct portion of grants for different stakeholder groups over time and as a percentage of total published articles funded by the agency.

**Early input on considerations to increase findability and transparency of research. NIH seeks suggestions on any specific issues that be considered in efforts to improve use of PIDs and metadata, including information about experiences institutions and researchers have had with adoption of different identifiers.**

ASPET supports NIH's commitment to engage with existing identifier infrastructure and standards already in use across many scholarly societies. Requiring ORCID (Open Researcher and Contributor ID) for the corresponding and/or submitting author has been seamless for integration into societies' manuscript submission, peer review, and publication systems; requiring ORCID for *all* co-authors has posed more challenging but is improving with time. ASPET supports NIH adoption of a DOI (Digital Object Identifier) overlay on existing grants; this activity could foster a more connected ecosystem of grants, publications, and data.

## **Conclusion**

ASPET commends NIH for engaging to improve the plan for public access and to develop a policy that allows researchers to comply more readily. We hope to continue the discussion and offer to work with NIH as it moves forward with its plan.