



April 24, 2023

Response to Request for Information (RFI): *NIH Plan to Enhance Public Access to the Results of NIH-Supported Research* (NIH Public Access Plan); NOT-OD-23-091

The American Medical Informatics Association (AMIA) appreciates the opportunity to comment on the *NIH Plan to Enhance Public Access to the Results of NIH-Supported Research* (NIH Public Access Plan); NOT-OD-23-091. AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, and public health experts who bring meaning to data, manage information, and generate new knowledge across the health and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

AMIA offers the following comments for NIH's consideration.

Embargo Period

The goal of offering faster access to NIH-funded research publications is laudable, however, it is unclear what the impact of the policy proposed by NIH would be on both researchers and journals.

Specifically:

1. That NIH-funded researchers might be forced to limit publication to journals willing to accept NIH's proposed policy of not allowing any period during which the publisher had exclusive rights to the publication. It is unclear how big a problem this may be, however:
 - a. This could preclude publication in more desired outlets in terms of subject matter and intended audience.
 - b. This could cause publishing delays if researchers need to submit to journals that are not their first choice in terms of intended audience, possibly reducing their

chance of acceptance, which – paradoxically – could cause even longer delays until the results are publicly available.

- c. If researchers make new discoveries based on data generated under NIH-funding, but after such funding has ended, does this still apply to them?
2. That some journals may be adversely affected financially if they cannot recoup their costs based on subscription/membership fees. In the case of niche or highly specialized journals the impact of this loss of income could be particularly acute. While not all research is NIH-funded, a great deal of academic research is.

Authors' Freedom to Choose

NIH states:

As noted previously in this Plan, the NIH Public Access Policy does not affect authors' freedom to choose the vehicle or venue for publishing their results. NIH does not propose requiring authors to publish in any particular type of journal or journal with any specific type of business model (e.g., subscription model, open access model). NIH expects that NIH-supported investigators will continue to publish the results of their research consistent with their professional autonomy and judgment to advance science as efficiently and comprehensively as possible. As previously stated through this [Guide Notice](#), NIH encourages authors to publish in reputable journals that follow accepted standards of publishing practices and ethics.

AMIA believes the above statement is only accurate if the chosen journal allows immediate public access. Authors may be forced into suboptimal choices when the ideal journal(s) enforce a strict embargo."

Supplemental Materials

The NIH proposal needs to be clearer about the relationship between supplemental materials and manuscripts.

Investigator Rights

AMIA is concerned about the aggressive timeline for this proposal. NIH states it will 'develop language that NIH-supported investigators may use for submission with their peer-reviewed manuscripts to journals to retain rights to make the peer-reviewed manuscript available post-publication in PMC as soon as processing is complete, without an embargo period.'

Given that all federal agencies must implement the OSTP open access proposal no later than December 31, 2025, is there a timeline for NIH to develop this language for investigators?

NIH RFI Questions

- 1. How to best ensure equity in publication opportunities for NIH-supported investigators.** The NIH Public Access Plan aims to maintain the existing broad discretion for researchers and authors to choose how and where to publish their results. Consistent with current practice, the NIH Public Access Plan allows the submission of final published articles to PMC (in cases where a formal agreement is in place) to minimize the compliance burden on NIH-supported researchers and also maintains the flexibility of NIH-supported researchers to submit the final peer-reviewed manuscript. These submission routes are allowed regardless of whether or not the journal uses an open access model, a subscription model of publishing, or other publication model. This flexibility aims to protect against concerns that have been raised about certain publishing models potentially disadvantaging early career researchers and researchers from limited-resourced institutions or under-represented groups. NIH policy already allows supported researchers to charge reasonable publishing costs against their awards. 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.

AMIA Response: Overall, it would be beneficial to have more of a cost-benefit analysis to justify changes that could have a negative impact on authors and on the speed with which new research might actually reach the optimal audience.

- 2. Steps for improving equity in access and accessibility of publications.** Removal of the currently allowable 12-month embargo period for NIH-supported publications will improve access to these research products for all. As noted in the NIH Public Access Plan, NIH also plans to continue making articles available in human and machine-readable forms to support automated text processing. NIH will also seek ways to improve the accessibility of publications via assistive devices. 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.

AMIA Response: AMIA disagrees with NIH's assumption that "Removal of the currently allowable 12-month embargo period for NIH-supported publications will improve access to these research products for all." NIH defines public access as "free availability of federally funded scholarly materials to the public (including publications, data, and other research outputs). The removal of the embargo period is simply that; there is nothing to suggest this will uniformly and consistently 'improve access to these research products for all.'

3. **Methods for monitoring evolving costs and impacts on affected communities.** NIH proposes to actively monitor trends in publication fees and policies to ensure that they remain reasonable and equitable. NIH seeks information on effective approaches for monitoring trends in publication fees and equity in publication opportunities.

AMIA Response: Monitoring does not ensure that fees and policies “remain reasonable,” only that it will be more quickly detected if they do not. Given the potential revenue loss journals may anticipate or experience, this policy could directly incentivize journals to increase publication fees. What is the proposed NIH redress if fees escalate unreasonably, and who would determine what is unreasonable?

4. **Early input on considerations to increase findability and transparency of research.** Section IV of the NIH Public Access Plan is a first step in developing the NIH’s updated plan for PIDs and metadata, which will be submitted to OSTP by December 31, 2024. NIH seeks suggestions on any specific issues that should 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.

AMIA Response: More clarity is needed to understand what NIH seeks with regard to “transparency of research.” We look forward to more detailed information from NIH and opportunities to comment on future NIH plans for PIDs and metadata.

Thank you for your time and consideration of these comments. If you have questions or require additional information, please contact Tayler Williams, AMIA Public Policy Manager, at twilliams@amia.org

Sincerely,



Gretchen Purcell Jackson, MD, PhD, FACS, FACMI, FAMIA
President and Board Chair, AMIA
Vice President & Scientific Medical Officer, Intuitive Surgical
Associate Professor of Surgery, Pediatrics, and Biomedical Informatics, Vanderbilt University
Medical Center