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**Response to Request for Information (RFI) on the National Institutes of Health (NIH) Draft Public Access Policy; NOT-OD-24-144**

Deputy Director Tabak,

The American Medical Informatics Association (AMIA) appreciates the opportunity to comment on the *National Institutes of Health Draft Public Access Policy; NOT-OD-24-144*. 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 and Publication Costs**

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.
  3. 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.’
  4. Under the Publication Costs section, NIH states:  
“NIH proposed to continue monitoring trends in publication fees and policies to ensure that they remain reasonable and do not disproportionately burden one or more segments of the NIH-supported community, and that opportunities to publish are equitable and consistent with NIH's strategic priorities.” <https://www.federalregister.gov/d/2024-13373/p-59>

“NIH will continue to consider appropriate methods to monitor costs for potential impacts on relevant communities once the final Public Access Policy has been implemented and any downstream effects are more readily apparent.”  
<https://www.federalregister.gov/d/2024-13373/p-68>

Monitoring does not ensure that fees and policies remain reasonable, only that it will be more quickly detected if they do not. What is the proposed NIH redress if fees escalate unreasonably, and who would determine what is unreasonable?

### **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?

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](mailto:twilliams@amia.org)

Sincerely,

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