UW-Madison Public Access Service

Review: Request for Information (RFI) on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research

On February 21, 2023, the NIH issued an updated public access policy overview for public comment. The RFI asked for input on the elements of this potential revision, which were based on the White House Office of Science and Technology Policy's 2022 memorandum, "Ensuring Free, Immediate, and Equitable Access to Federally Funded Research."

Like other public comment requests, the NIH's public access RFI provides a preview of the issues the agency has identified as central to their initiative. Reviewing the content of the request provides a preview of future policy or, at minimum, a road map of where the policy might go over time.

Policy Elements – Scientific Data

The data policy proposed in the RFI is based on the NIH's position that data generated by research supported by NIH awards should be made freely available to the public as soon as possible, with qualifications. The NIH scientific data policy explored in the RFI includes:

- Defining scientific data "as the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications." According to the NIH, this definition does not include secondary resources such as lab notebooks or drafts of scientific papers.
- Continuing to support established Data Management Plan (DMP) and sharing policies. Investigators must explain in their DMP's what data is being shared, how it will be shared and why specific data will not be shared. Investigators are expected to share data as soon as possible or by the time the scholarly work derived from the data is published.
- Encouraging investigators to make data related to the unpublished, underlying findings or conclusions of research publicly accessible as soon as possible, or by the end of the funding period.
- Recommending that investigators use established repositories that typify the traits found in the National Science and Technology Council's "<u>Desirable Characteristics of Data</u> <u>Repositories for Federally Funded Research</u>."

- Emphasizing that the management and sharing of human participant data should always adhere to federal, state, local, tribal, and institutional rules, statutes, and policies.
- Urging researchers to maximize the sharing of scientific data in light of legal, ethical, or technical requirements that may limit sharing.
- Stipulating that data management and sharing costs may be included in project proposal budgets.

Policy Elements – Scholarly Publications

In much the same way that the NIH's data proposals focus more on clarification then generating new policy, the agency's publication policy update attempts to streamline the accessibility process through fine-tuning. The exception to this is the NIH's elimination of the embargo period, or what many observers considered the previous policy memorandum's ill-considered public access paywall. The revised policy areas include:

- The removal of the 2013 OSTP memorandum's 0-12 months embargo period, which allowed journals and publishers to restrict public access to the full text of a publication added PubMed Central (PMC) for up to 12 months past the paper's official publication date. Publications added to PMC will be fully accessible immediately following their official date of publication.
- A paper's official publication date will be redefined as the date on which the journal or publisher first makes it available, either online or in print. Doing so eliminates the previous definition of "official," which for hybrid journals meant the print publication date.
- Other than noted changes, the NIH will continue to utilize all previous public access to publications policies and processes outline in the 2013 OSTP memorandum and Division F, Section 217 of PL111-8 of the 2009 Omnibus Appropriations Act. These include the continued use of PMC for article public access as well as the requirement that PI's ensure the submission of publications to PMC upon acceptance.
- Manuscripts submitted to the NIH Manuscript Submission system (NIHMS) will be made fully accessible in PMC at the end of their process period if the publication date has passed or immediately following their official publication date.
- Investigators must ensure that manuscripts are submitted to the NIHMS upon acceptance in cases where journals have a formal agreement to submit directly to PMC but with an embargo period that extends beyond the date of publication. Otherwise, the PI's must work with the journal to submit the published article directly to PubMed Central without an embargo period.

What the RFI Means

There are few surprises to be found in the RFI as far as where it suggests NIH public access policy is heading. As expected, it closely follows the changes made in the OSTP's 2022 memorandum, filling in the details of the policy initiatives fashioned through that document. And while the policy changes the NIH is looking for comment on do not declare a future direction, there are some underlying themes found in both data and publications access that imply a new emphasis.

- Immediacy is central to both future access of publications and data. Much of the 2022 OSTP memorandum's justification for removing the embargo period from the publication process was based on how effective immediate access had been during the COVID crisis. The RFI does not spell this out in quite the same terms, but the deletion of the embargo period, changing the definition of official publication dates, and the support of scientific data being made accessible by a work's publication date, continues the focus on fast.
- Expanding the extent of scientific data made accessible is found throughout the RFI. Whether it is the reiterative support of the maximum amount of data be made accessible or advocating the accessibility of data indirectly related to publications, the RFI appears to point toward an expansion of the data universe that researchers should be prepared to make publicly accessible.

Finally, while the NIH's public access RFI makes it clear that the changes made in the OSTP's memorandum are the limit of policy updates for now, the basic changes in approach to faster delivery and more data suggests that future refinements may demand greater transparency in exchange for financial support.

If you are interested in providing input on the NIH's updated public access policy, you can do so <u>here</u>. Comments from interested individuals, parties and organizations must be submitted by April 24, 2023.