Brigham and Women's Hospital
Founding Member, Mass General Brigham

HARVARD MEDICAL SCHOOL

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Submitted August 19, 2024

Re: **FR Doc. 2024–13373**
Request for Information on the National Institutes of Health Draft Public Access Policy

To whom it may concern:

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard ("MRCT Center") appreciates the opportunity to respond to the National Institutes of Health's (NIH's) draft "*Public Access Policy*" (the "Draft Policy"), published at 89 Fed. Reg. 51537 (June 18, 2024).

The MRCT Center is a research and policy center that seeks to improve the ethics, conduct, oversight, and regulatory environment of international, multi-site clinical trials. Founded in 2009, it functions as an independent convener to engage diverse stakeholders from industry, academia, patients and patient advocacy groups, non-profit organizations, and global regulatory agencies. The MRCT Center focuses on pre-competitive issues, to identify challenges and to deliver ethical, actionable, and practical solutions for the global clinical trial enterprise. The responsibility for the content of this document rests with the leadership of the MRCT Center, not with its collaborators nor with the institutions with which its authors are affiliated.[1]

The MRCT Center appreciates NIH's efforts to promote public access to publications stemming from the research it supports. Establishing clear expectations for researchers in providing public access to NIH-supported clinical research is an essential step in building public trust in research and delivering value on the use of taxpayer funds. We offer the recommendations below in full support of NIH's efforts.

Comments

General Comments

Prior to addressing specific comments, let us mention certain decisions that were made, and that we support:

- Clarity in definitions used is helpful and avoids misinterpretation.
- We agree with the broad scope that renders this policy applicable to all publications supported in whole or in part through NIH and the decision not to restrict applicability to research only. We also agree with a uniform effective date, and it will be easier to comply with the new Policy.

[1] Brigham and Women's Hospital, Mass General Brigham, Harvard Medical School, and Harvard University.

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- We further agree with the elimination of the Embargo period (and please see Comment #1 below)
- We agree with the absence of an end date for applicability to Manuscripts arising out of an award.
- We support the stated goal of rendering published work accessible and machine-readable as a high priority. We further suggest that NIH explore equipping PubMed Central with an accessibility tool to introduce the capacity for immediate translation and other modes of accessibility.

1. Additional comments on the Draft Public Access Policy

The changes NIH proposes to make to the current public access policy provide welcome clarity to certain ambiguous terms that had previously been open to interpretation and misinterpretation. The inclusion of the Definitions section in the Draft Policy is most helpful.

Given that the purpose of the Draft Policy is to provide open access to NIH-funded research to public stakeholders, we would like to recommend an additional bullet point to the Requirements section of the Draft Policy. In a time so rife with mis- and disinformation regarding biomedical research – see e.g., recently updated FDA guidance on combatting misinformation about drugs and devices (Docket #FDA-2014-D-0447) – we would recommend NIH consider requiring the inclusion of a "plain language abstract" to accompany each article submitted to PubMed under the Draft Policy. Such an abstract should be in language easily understood by non-technical audiences; it would help provide relevant context and promote meaningful comprehension of the discoveries discussed in the article. In the spirit of promoting public trust and delivering value, we cannot stress enough the importance of not only making NIH-funded research *available* to the public but ensuring it is *accessible* to them as well. By including peer-reviewed plain language abstracts alongside each manuscript submitted under the Draft Policy, NIH can ensure that stakeholders from broader, non-scientific communities have access to accurate information that can foster improved understanding of NIH's research goals and achievements and solidify public appreciation for the returns seen on NIH's investment of public funds across its funding portfolio.

Additionally, the MRCT Center has long supported the need for the results of clinical studies to be made available to the individuals who participated in those studies and to the public. The current public access policy has been a great help in removing financial barriers that would otherwise have prevented the achievement of that goal. Therefore, we fully support the Draft Policy's intention to remove the 12-month embargo period, thereby making the results of NIH-funded studies immediately available to any interested parties, including study participants. By removing both time constraints and financial barriers, we view this development in the Draft Policy as an important step toward achieving equity throughout the NIH-supported research ecosystem, and specifically in its clinical research portfolio.

2. Comments on the Draft Guidance on Government Use License and Rights

The inclusion of the draft guidance alongside and immediately available in the Draft Policy was especially helpful when reviewing the Draft Policy. As stated above, we support the Draft Policy's intent to remove the embargo period from NIH's current public access policy. However, we do wonder whether this development will affect the acceptance decisions of certain journals. The draft language that is included under "Guidance for Communicating Rights in Manuscripts" at 89 Fed. Reg. 51543 makes clear that the publishing journal will likely no longer receive any publishing fees for access to a given publication (e.g., charging a one-time fee to access a single article of interest rather than purchasing a full journal subscription). Because differential costs for publishing services for manuscripts subject to the Draft Policy are not permissible (see, "Other Unallowable Costs" at 89 Fed. Reg. 51543), does NIH intend to produce any guidance for peer-reviewed journals themselves for when the Draft Policy takes effect?

Additionally, the Draft Policy makes clear that the submitting author(s) must attest that they

> …hereby grant to NIH, a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use this work for Federal purposes, and to authorize others to do so.

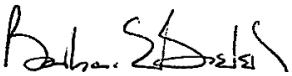
We respectfully request that the final Policy clarify the process by which NIH will authorize others to use the published work. Does the authorization require written permission, and are there restrictions upon the use? Does the grant of these rights, for instance, include the right to reproduce a figure in secondary publications with appropriate attribution, or must the journal grant that right – currently at a significant cost to the requestor?

3. Comments on the Draft Guidance on Publication Costs

Because implementation of the Draft Policy may result in less revenue for journals (e.g., no longer being able to charge a one-time fee to access a single article of interest rather than purchasing a full journal subscription) and because charging different publishing costs for manuscripts subject to the Draft Policy is expressly forbidden under NIH Grants Policy Statement § 7.9.1, we anticipate increased publication costs by journals across the board in response to removal of the embargo period. While we understand that NIH does not impose a firm threshold on its interpretation of "reasonable publication costs," we would encourage more comprehensive guidance on allowable publication costs, particularly with respect to producing an expanded list of "Points To Consider for Authors and Institutions in Assessing Reasonable Costs" (89 Fed. Reg. 51543). It would be a chilling unanticipated consequence if publishing fees currently paid by authors are increased even further than what they are today. Many academic and community researchers already have difficulty in finding funds to pay what often appear to be exorbitant charges.

As mentioned above, the MRCT Center supports NIH's efforts to promote public access to scientific research as critical to building public trust in the work we do. The MRCT Center appreciates the opportunity to contribute to this Draft Policy. We would welcome an opportunity to discuss. Please feel free to contact the MRCT Center or with me (bbierer@bwh.harvard.edu) if we can be helpful.

Respectfully submitted,



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