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August 14, 2024

Monica Bertagnolli, M.D.

Director

National Institutes of Health

9000 Rockville Pike

Bethesda, MD 20892

RE: Request for Information on the National Institutes of Health Draft Public Access Policy

Dear Dr. Bertagnolli,

The American Academy of Neurology (AAN) is a global association of more than 40,000 neurologists and neuroscience professionals. The AAN's mission is to enhance member career fulfillment and promote brain health for all. A neurologist is a doctor who specializes in the diagnosis, care, and treatment of brain, spinal cord, and nervous system disease. These neurological conditions affect over one in three people worldwide and include Alzheimer's disease, stroke, concussion, epilepsy, Parkinson's disease, multiple sclerosis, headache, migraine, and more.

The AAN appreciates the opportunity to provide feedback in response to the National Institutes of Health (NIH) draft public access policy and draft supplemental guidance request for information. While the AAN is supportive of the goal of enhancing public access to the results to NIH-supported research, the AAN is deeply concerned that the draft NIH Public Access Policy has failed to adequately account for stakeholder feedback in response to the "Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research" [NOT-OD-23-091] and will be highly disruptive to journal operations and the dissemination of key findings stemming from NIH-supported research. The AAN is a long-standing partner in ensuring the rapid dissemination of critical discoveries and improvements stemming from NIH-supported research and is eager to collaborate with the NIH in support of policies that enhance public access, while ensuring that policy changes do not detrimentally impact the research pipeline and the ability of the AAN's journals to continue to provide critical value to researchers and the broader community impacted by neurologic disease.

The AAN currently operates two publications that are likely to be impacted by the updated NIH Public Access Policy, *Neurology®* and *Neurology Clinical Practice®*. Information describing the journals and the value they add to the body of scientific research is described below.

As the leading clinical neurology journal worldwide, *Neurology*® is directed to physicians concerned with diseases and conditions of the nervous system. The journal's purpose is to advance the field by presenting new basic and clinical research with emphasis on knowledge that will influence the way neurology is practiced. The journal is at the forefront in disseminating cutting-edge, peer-reviewed information to the neurology community worldwide. Editorial content includes Research, Clinical/Scientific Notes, Views & Reviews (including Medical Hypothesis papers), Issues of Neurological Practice, Historical Neurology, NeuroImages, Humanities, Disputes & Debates: Editors' Choice, and position papers from the American Academy of Neurology. Contents appearing solely online include the Patient Page, CME Quizzes, Podcasts, and play-in-place video.

Neurology Clinical Practice® focuses mainly on two aspects of neurologic care: 1) Clinical research on patient-reported outcomes and quality, including original research articles and meta-analyses/systematic reviews; and 2) Commentaries, reviews, and research articles on general practice, billing and coding, wellness and burnout, diversity and inclusion in the workplace, telehealth, health care policy, and financial management.

Purpose

In justifying the draft Public Access Policy NIH states that “[t]he ability for patients, families, and members of the public to access published findings resulting from NIH funding enables them to better understand and address the most critical public health concerns facing their communities. It also allows researchers, students, and health care providers in all communities to have equitable access to such content.”¹ The AAN believes that the NIH Public Access Policy will result in numerous unintended consequences, resulting from the need for journals like *Neurology*® and *Neurology Clinical Practice*® to substantially modify their revenue models.

The AAN believes that changes to the underlying business model stemming from implementation of the draft policy will likely necessitate a shift of financial responsibility from paid subscribers to the researchers seeking to have their research published, creating substantial additional barriers for those seeking publication. The rapid implementation of the draft Public Access Policy, specifically the elimination of the 12-month embargo, is extremely disruptive and may negatively impact the financial underpinnings of scholarly publishing and dissemination. The AAN is alarmed by the potential to create substantial inequity in those able to contribute to the body of peer-reviewed published scientific research.

Definitions

The AAN appreciates that the NIH has defined several key terms that are critical to understanding this proposal. Notably, NIH states that “The NIH Public Access Policy applies to any Manuscript accepted for publication in a journal, on or after October 1, 2025, that is the result of funding by NIH in whole or in part through:

- A grant or cooperative agreement, including training grants,

¹ 89 Fed. Reg. at 51537

- A contract,
- An Other Transaction,
- NIH intramural research, or
- The official work of an NIH employee.

For the purposes of the NIH Public Access Policy, NIH is proposing to define “manuscript” as “[t]he author’s final version that has been accepted for journal publication and includes all revisions resulting from the peer review process, including all associated tables, graphics, and supplemental material.”² The AAN is concerned that this proposed definition will prove infeasible for journal operations. The AAN’s current subscription-based publishing model provides equal opportunity for all authors to submit for review and publication by the journal, and to benefit from the peer review process, as well as the journal’s editorial oversight, production, and dissemination without charge. The AAN’s peer review and publication process adds substantial value to authors as they refine their submission throughout the peer-review process and to the broader neurology and neuroscience community through the development of supplemental content aimed at enhancing reader understanding of published articles. These substantial additions in value are reflected in the subscription price for AAN journals and the AAN fears that the significant costs borne by the journal to engage in these activities may not be able to be recouped under the Draft Public Access Policy.

The AAN takes its role in preserving the scientific integrity of research published in our journals very seriously. The AAN is committed to expedient but thorough review and publication of research that affects patient care. Maintaining this trusted role in society, at a time when disinformation is rampant, requires a significant amount of investment. Vigilance in publication research integrity and conflict of interest management not only aligns with the AAN’s mission but, more importantly, gives confidence to clinicians and researchers that the information we publish has been verified and is reliable.

Given the substantial investment the AAN makes in the peer review process, as well as the development of supplemental materials, and our desire to continue to maintain the highest standards of scientific integrity for research published in our journals, the AAN recommends that NIH modify the proposed definition of manuscript to mean the “article originally submitted by the author along with any supplemental materials generated by the author, as originally received by the journal.” Further, the AAN believes it would be beneficial for PubMed Central to only include metadata for papers that report on NIH funded research, with the accepted content, either the peer reviewed accepted manuscript or the version of record, being accessible only on the publisher site. Absent these modifications, the AAN is concerned that we will no longer be able to equitably provide equal opportunity for all authors to receive the requisite services involved in developing a peer-reviewed, published piece in our journals without charge.

Scope and Effective Date

The AAN appreciates that NIH has clarified the scope of the public access policy and clearly stated that NIH will take action “to clarify in FAQs that using NIH resources, such as

² 89 Fed. Reg. at 51541

datasets available through NIH repositories and physical resources and infrastructure supported by the NIH, when no NIH funds were used for the work upon which the Manuscript is based, does not subject a resulting Manuscript to the NIH Public Access Policy.”³ The AAN believes additional clarification and guidance will be necessary so that both authors and journals fully understand which manuscripts fall under the proposed policy and which do not. Such scenarios may include but are not limited to:

- Cases in which NIH-supported researchers submit for publication after grant funding has elapsed and they no longer have funding to cover article processing charges (APCs) or other fees.
- Instances in which an author is receiving NIH-funding for a subject other than the topic of the work that is seeking publication.
- Commentaries on, state-of-the-art reviews of, and educational content relating to NIH-supported research or drafted by NIH-supported researchers.

In clarifying the scope of this proposed change, the AAN asks that this policy be restricted to articles detailing the results of original research for which the corresponding author has access to funding through the NIH to support publication of the specific work.

The AAN recognizes that in adhering to the 2022 Office of Science and Technology Policy, NIH plans to update the Public Access Policy with “an effective date no later than December 31, 2025.”⁴ However, NIH is proposing to make the Public Access Policy “effective for Manuscripts accepted for publication on or after October 1, 2025.”⁵ NIH does not include any rationale for this accelerated timeline and the AAN is concerned that the proposed timeline will be overly burdensome, given the need for many journals to completely overhaul their subscription and advertising revenue models in support of the new policy.

Further, many journal publishers have agreements pertaining to the deposit of manuscripts that mentioned NIH funding to PubMed Central, as prior to the implementation of publisher bulk deposit agreements, compliance with NIH requirements was extremely low. These agreements were made under current policy which allowed for a 12-month embargo and limitations on reuse rights and derivative works. The AAN is concerned that publishers may not have enough time under the currently proposed deadline to secure new agreements and implement new processes for journals that choose to continue to make bulk deposits of accepted manuscripts under the newly proposed policy. The AAN urges NIH to, at a minimum, delay implementation of the policy until December 31, 2025, and to consider whether additional delay is necessary to allow all involved stakeholders to make the necessary adjustments to promote the sustainability of their journals and to allow for the adequate time that is needed for stakeholder education to promote compliance.

Government Use License and Rights

³ 89 Fed. Reg. at 51539

⁴ Nelson, Alondra. “Ensuring Free, Immediate, and Equitable Access to Federally Funded Research.” *White House*, 25 Aug. 2022, www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf.

⁵ 89 Fed. Reg. at 51539

The AAN appreciates that NIH is clarifying its policy surrounding government use rights for NIH funding research. Specifically, the AAN appreciates NIH's commitment that a "statement granting NIH rights to make Manuscripts publicly available in PubMed Central upon the Official Date of Publication is proposed to be incorporated into Notices of Award and applicable contracts. This ensures it is understood that NIH's rights are automatically established at the acceptance of funding, without requiring funded recipients to take additional steps." Further the AAN appreciates that NIH is encouraging "authors to clearly communicate NIH's rights through a statement in the Manuscript itself" and that NIH has "has proposed standardized language authors may choose to place in their Manuscripts." The AAN believes that these steps are critical to ensuring that authors fully understand the implications associated with accepting NIH funding to support their manuscript in whole or in part and so that journals can have a mechanism to understand which papers are covered under the Public Access Policy.

Further, NIH states that "[a]uthors are not expected to provide rights to NIH to the Final Published Article. However, as noted in 'Compliance and Enforcement,' NIH will accept submission of the Final Published Article to PubMed Central from journals with formal agreements with NLM as compliant with the Policy when its release meets public access requirements outlined in this Policy."⁶ The AAN is concerned that this policy may be confusing to authors and that associated compliance burden will be significant. Further, this draft policy gives the NIH the right to reproduce papers and create derivative works "for federal purposes." The ambiguity of this term is highly problematic and the AAN's detailed concerns with this proposal are detailed in response to the "Draft Guidance on Government Use License and Rights."

Publication Costs

The AAN appreciates NIH's clarification that "[r]easonable costs associated with publication that are allowable may be requested in the budget for the project as direct or indirect costs."⁷ Detailed comments regarding NIH's approach to APCs and other associated fees are included in response to the "Draft Guidance on Publication Costs."

Compliance and Enforcement

NIH states that compliance may be achieved through either:

- Submission of the electronic version of the final peer-reviewed manuscript (i.e., Manuscript as defined above) to PubMed Central upon its acceptance for publication, for public availability without embargo upon the official date of publication or
- Submission of the Final Published Article to PubMed Central from a journal with a formal agreement with NLM, upon the Official Date of Publication, for public availability without embargo

Further, NIH states that "[n]on-compliance with the NIH Public Access Policy may be considered by NIH regarding future funding decisions for the recipient institution."

⁶ 89 Fed. Reg. at 51542

⁷ Id.

The AAN appreciates the clarification regarding author self-deposit of the accepted manuscript. The AAN notes that many publishers have historically facilitated this submission to ensure that the version published by the journal is the same as the one deposited. While the AAN recognizes that fees associated with deposit in PubMed Central are impermissible under the draft Public Access policy, if NIH does not modify the proposed definition of manuscript in alignment with our feedback, the AAN is concerned that this proposal may result in significant non-compliance and inconsistency between what is published in the journal and what is submitted by authors. The AAN notes that many authors are unfamiliar with the process of depositing a manuscript in PubMed Central and the burdens of compliance and associated penalties for non-compliance are substantial. The AAN believes a dedicated education campaign will be necessary to promote compliance in advance of the proposed deadline.

Draft Guidance on Government Use License and Rights

The draft guidance states that “Authors approving Manuscripts for inclusion in PubMed Central must agree to a submission statement as part of the standard PubMed Central Manuscript submission process.”⁸ The statement is as follows:

I 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. This grant of rights includes the right to create derivative works and make the final, peer-reviewed manuscript publicly available upon the Official Date of Publication.

In implementing this provision, in order to make the peer-reviewed content accessible without an embargo, and in recognition of the AAN’s continued support in aiding researcher compliance with NIH requirements, the AAN asks that the NIH interpret this statement so that it will refrain from restricting our ability to establish copyright and preserve the downstream revenue associated with the final version of record. The value we provide to our research community is at risk when content is under licenses that allow broad re-use of content, particularly for commercial purposes.

The AAN requests clarification regarding what would constitute “Federal purposes” under this definition and is concerned that absent clarification that this could be misinterpreted to allow the Federal government to authorize reuse of journal content in accordance with any purpose, so long as it is supported by the Federal government. This is especially concerning as the proposed policy allows for the reproduction of papers and the production of derivative works. Absent much needed clarification, the AAN believes ambiguity surrounding “Federal purposes” could potentially allow the federal government or a third party designated by the federal government to recreate journal content or produce derivative content, in the absence of rigorous research integrity controls, and with no attribution to the author or the publisher. The AAN believes that this poses a significant risk of perpetuating harmful misinformation and is a threat to copyrights held by authors and publishers. As a general principle, the AAN believes that researchers should not be forced to disseminate their research in a manner that could harm its integrity without their express consent. Further, absent clear attribution of reproductions and derivative works, there is no clear mechanism to ensure that updates,

⁸ Id.

corrections, and retractions of content are incorporated in reproductions and derivative works developed for “federal purposes,” harming public trust in the content contained therein, while allowing for inaccurate information to spread unchecked.

The AAN appreciates the inclusion of suggested language that authors may submit regarding communication of rights during the process of manuscript submission. The AAN recommends that inclusion of this language be made a requirement, rather than a mere suggestion when an author submits a manuscript based in whole or in part on NIH funding. The AAN does note that compliance with this mandate may be quite burdensome for authors and urges NIH to work with both authors and journals to ensure that appropriate education is disseminated to researchers in advance of implementation of this policy.

Draft Guidance on Publication Costs

The NIH Draft Public Access Policy states that “reasonable costs that are allowable may be requested in the budget for the project as direct or indirect costs, as specified in the NIH GPS and as incorporated into Other Transactions and applicable contracts.”⁹ Of note, “[j]ournal or publisher fees for submitting the Manuscript to PubMed Central that may arise during the course of the publication process are not allowable costs.”¹⁰

Although the AAN appreciates that NIH clarified the intent of this policy, the AAN is deeply concerned that doing so will likely result in changes to the underlying publication business model resulting in AAN journals at least partially needing to be funded through APCs and other fees borne by authors. While this policy may result in greater immediate access to published literature for individuals who do not subscribe to the AAN’s journals, the AAN believes that this policy significantly disadvantages researchers who are either unfunded or have limited funding to allocate towards the APCs and other fees that are necessitated by the draft Public Access Policy.

The NIH has specifically enumerated several additional unallowable costs. They are as follows:

- Costs for services (*e.g.*, peer review) for which there is no resulting publication are unallowable because costs must be chargeable or assignable in accordance with the relative benefits received.
- Costs for which the institution already pays a fee that would cover publication costs (*e.g.*, an agreement the institution has with a publisher whereby authors from that institution publish for free in exchange for subscription services) are unallowable because costs may not be double charged or inconsistently charged as both direct and indirect costs.
- Costs for publishing services that are charged differentially because an author’s Manuscript is subject to the NIH Public Access Policy are unallowable because charges must be levied impartially on all items published by the journal, whether or not under a federal award.

⁹ 89 Fed. Reg. at 51543

¹⁰ *Id.*

- Costs for services incurred after closeout of the award, even for a publication subject to the NIH Public Access Policy, are unallowable because the costs of publications must be incurred before closeout.

The AAN is concerned that the proposed set of unallowable costs fails to account for the substantial differential in submission volume to higher impact and higher prestige journals as opposed to lower impact and lower prestige journals. Journals incur costs, on a per submission basis, associated with reviewing all papers that are submitted for publication, regardless of whether the submission actually results in publication. Disallowing costs for services for which there is no resulting publication would necessitate that the most prestigious and highly selective journals either bear the costs associated with reviewing all NIH-supported papers which are submitted but ultimately not published, or alternatively create a fee structure in which published papers effectively cover the costs incurred by papers that do not result in publication. In either scenario, highly selective journals, which receive a relatively higher volume of submissions, and adhere to the most rigorous standards for review and publication are systematically disadvantaged. The AAN is concerned that this would lead to an environment in which highly selective journals can no longer operate under the same degree of rigor. The AAN is disturbed by the prospect that this will incentivize a “race to the bottom” wherein many journals may choose to reject a far lower proportion of submitted papers, so that they can support their operations through allowable fees, leading to a degradation of both journal quality and trust in the validity of peer-reviewed, published research.

Prior to implementing this draft policy, the AAN urges the NIH to provide an economic impact statement to provide greater insight into the projected financial impact on publishers and relevant specialty societies including the AAN. We strongly believe that devaluing subscriptions in the manner detailed by this proposal is likely to have a substantial detrimental impact on journal operations, revenue models, and sustainability.

Conclusion

As the world’s largest neurology specialty society, the AAN is deeply committed to ensuring that equitable access to the most current and impactful clinical neurology research is widely available. The AAN welcomes the opportunity to continue our longstanding collaborative relationship with the NIH to ensure that any plan that may disrupt the existing business model for the AAN family of journals is implemented in a way that minimizes adverse consequences and achieves the administration’s aim of promoting broad access to NIH-funded research.

The AAN is deeply concerned that the Public Access Policy as currently drafted serves to harm the scientific integrity of the body of peer-reviewed scientific literature, harms journals’ economic stability with a disproportionate impact on the most highly selective journals and infringes upon journals’ rights to reproduce and create derivative works from published content. Further, as NIH-funded researchers compose a significant portion of our membership, the AAN is deeply concerned with policy proposals that restrict the abilities of our members to choose where, how, and under what licenses they publish their research.

The AAN urges the NIH to heed our recommendations in response to this RFI to ensure continued equitable access to clinical neurology research. Please contact Patty Baskin, the Senior Director of Publications at the AAN at pbaskin@aan.com or Matt Kerschner, the AAN's Director, Regulatory Affairs and Policy at mkerschner@aan.com with any questions or requests for additional information.

Sincerely,

A handwritten signature in black ink that reads "Carlyne E. Jackson". The signature is written in a cursive, flowing style.

Carlyne E. Jackson, MD, FAAN
President, American Academy of Neurology