Compiled Public Comments on the Request for Information on the National Institutes of Health Draft Public Access Policy

June 18, 2024 – August 30, 2024

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140. American Society of Transplant Surgeons & American Society of Transplantation
141. New England Journal of Medicine
142. ASME
143. Society for Industrial and Applied Mathematics
144. Public Library of Science (PLOS)

Submit date: 6/18/2024

I am responding to this RFI: On behalf of myself

Name: T L Herbert

Name of Organization: MUSC

Type of Organization: University

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   The problem and danger of Predatory publishers is not at all addressed in this plan. Just because a journal is listed in the NLM Catalog does not make it a good peer-reviewed journal. Predatory publishers are dumping 'pay for publication' articles onto the public under the guise of being peer-reviewed. Diagnoses, treatments, discoveries Not Peer-Reviewed are harming legitimate scientists all over the world. NIH needs to address this problem, removing these non-peer-reviewed journals from Medline and PubMed.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Submit date: 6/20/2024

I am responding to this RFI: On behalf of myself

Name: Naomi Ohashi

Name of Organization: Frederick Naitonal Laboratory for Cancer Research

Type of Organization: Other

Type of Organization-Other: FFRDC

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   It is important to ensure the policy provides transparency, inclusiveness, and accessibility to legitimate users. At the same time, users should be responsible for access privileges. I propose a few thoughts about public access. All users should be required to watch training videos as a mandatory requirement to ensure ethical use. This would discourage unethical intentions to get access. Needless to say, public access should have standard account control, such as a strong password and two-factor authentication.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Submit date: 6/25/2024

I am responding to this RFI: On behalf of myself

Name:

Name of Organization: N/A

Type of Organization:

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   If I understand this correctly, the NIH proposes to yield authority to investigators/institutions to negotiate on its behalf with publishers to maintain Government Use License and Rights. Is this even legal? Can a federal entity ask non-federal associates to negotiate on behalf of the federal entity to ensure its rights?

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   While I fully support equitable and timely public access to publicly funded research results, it seems the NIH stance that "submission to PUBMED CENTRAL is free" is an insensitive response to the concerns raised by investigators, institutions and publishers over the costs and consequences of compliance with this policy. This policy invites publishers to inflate prices for immediate release of articles (a practice that is already pervasive) and shackles investigators/institutions that are obligated to comply with the NIH policy. Investigators from institutions that are less well-endowed will be forced to choose lower impact journals based on cost considerations, which creates inequities in access to audiences, assignment of research impact and other measures important to investigator exposure and reputation, which in turn impacts academic promotion and ability to attract extramural funding. The Federal Government is able to negotiate Medicare/Medicaid reimbursement costs for prescription drugs with pharmaceutical companies. Why cannot the NIH negotiate the terms of publication costs for NIH supported research directly with publishers via contractual agreements? This would make budgeting for publications much simpler in grant applications and ensure more equitable access to top tier journals for NIH-supported investigators. It would also have the effect of normalizing and stabilizing publication costs and procure Government Use License and Rights agreements with the publishers, while unburdening investigators/institutions from this responsibility.

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Submit date: 6/28/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   Please clarify whether the journal automatically sends the manuscript to PubMed or whether the author needs to contact PubMED directly to send the manuscript.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 6/28/2024

I am responding to this RFI: On behalf of myself

Name: Jo Lynne Rokita

Name of Organization: Children's Hospital of Philadelphia

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   I am fully in favor of this policy and agree any NIH-funded work should be public. I submit any manuscripts under my control to preprint servers now and not having to pay open access fees to journals will be extremely helpful in redirecting money to research. I do not think a preprint should count as "Open Access" under this policy because many publishers do not allow updates to the preprints and the preprints can change drastically by the end of the revision process. It is important that the final manuscript is publicly available.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   If researchers stop paying for open access fees since manuscripts will "freely" become open, what will prevent journals from increasing their regular publication fees, and how will NIH help keep this price low this for researchers? The lower the cost of publication and the wider spread the publications are, the better.

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Description:

Submit date: 6/28/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Submit date: 7/2/2024

I am responding to this RFI: On behalf of myself

Name: Peggy Jo Murphy Lentz

Name of Organization: Henry Ford Health System

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   Open Access has exorbitant costs to participate; All Journals should comply with Method A and deposit the finally accepted version of manuscript into the depository. It is cumbersome for the PI to find what Method A, B, C, or D a Journal participates in the Policy. The Embargo period is too long to withhold vital information for folks who do not have a subscription to have access i.e. "Public" Access.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description: Open Access has exorbitant costs to participate; All Journals should comply with Method A and deposit the finally accepted version of manuscript into the depository. It is cumbersome for the PI to find what Method A, B, C, or D a Journal participates in the Policy. The Embargo period is too long to withhold vital information for folks who do not have a subscription to have access i.e. "Public" Access.

Submit date: 7/3/2024

I am responding to this RFI: On behalf of myself

Name: Patríck murundu Andieli

Name of Organization: Kibera COMMUNITY RESOURCE GROUP CBO

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   We support you and your program for good work done by you working tomorrow for change

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   Making changes and law enforcement and relation between law enforcement and funds grand for all .we requested that you keep on

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   Us very interested in all law

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Submit date: 7/5/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization: University of California, Davis

Type of Organization: University

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   As a senior NIH funded researcher, this change from the 2008 embargo policy will dramatically shift the publication strategy for my research group. My group normally publishes approximately 6-9 journal papers per year. The 12 month embargo method allowed me to do this, and it allowed a reasonable time for the results to get into the public domain. With the updated plan, I would need to pay as much as $3,000 - $5,000 (or more) per paper that is published. That means an annual publication $45,000 (or more) budget for my lab. This will either require: hiring one less researcher to do the actual scientific work, or publishing less frequently. Both are bad outcomes, and reduces the quality and impact of the work that NIH supports. This will reduce our impact on important societal issues, and ultimately reduce quality information available to the public.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   Having to budget $45,000 (or more) for publications each year will reduce the number of papers that my lab produces. We will now pick and choose how to combine our data into the fewest papers possible, due to the excessive journal fees for immediate open access. It will also negatively impact both graduate student and postdoc trainees, for whom I will have to select which papers are worth the money to publish immediate open access. This will reduce the effective training environment for my laboratory, and I will ultimately train fewer scientists as a result. If this occurs across the USA, it will be incredibly damaging for our country.

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Submit date: 7/9/2024

I am responding to this RFI: On behalf of an organization

Name: Leanne B. Scott, PhD

Name of Organization: Baylor College of Medicine

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   Changing the due date to the date of publication and eliminating the embargo period would increase the administrative burden on researchers. Currently most publications are posted by the journals themselves and are the high quality, professional text with inset figures and graphs. The researchers do not have to do any extra work. The people who view it later have the actual published version to read. In general, these are all posted within 3 months of the publication date. In the big picture that is excellent for any researcher wanting to find info related to their own research. By changing the date, the researchers will have to submit the original, unformatted manuscript to the NIH Manuscript portal to go through all the steps to deposit it in PMC. The lead author has to submit, NIH has to approve - ARE YOU GOING TO TRIPLE YOUR STAFF?? and then the author has to approve the PMC formatted version again. Currently this process is very slow and requires administrative support to track and make sure that these steps are completed. Co-authors have absolutely no control over this process. A very busy lead author might not reply or touch it for weeks. This is an unfunded mandate already and changing the date when it must be in PMC creates unnecessary administrative burden on all the parties including NIH.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Submit date: 7/10/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   Currently many journals have a hybrid publishing model where you can pay an APC for immediate open access publishing vs subscription. I assume that APC fees for hybrid journals will not be allowable costs because authors could just be depositing into PMC under the new policy. Can this be clarified in allowable costs?

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Submit date: 7/15/2024

I am responding to this RFI: On behalf of myself

Name: Jose J Sanchez

Name of Organization: The university of California

Type of Organization: University

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   Without Access and the help of other's we're does that get us.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   First you draft then you draft some More know you're getting somewhere.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   Without a draft you have a blank Page but know fill in the blanks and things come together don't be bothered like what you do.

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Description:

Submit date: 7/30/2024

I am responding to this RFI: On behalf of an organization

Name: Jamie Bay Nishi

Name of Organization: American Society of Tropical Medicine and Hygiene

Type of Organization: Professional org association

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   As misinformation and disinformation continue to be disseminated around the world, the American Society of Tropical Medicine and Hygiene (ASTMH) and its journal, the American Journal of Tropical Medicine and Hygiene (AJTMH), hope the National Institutes of Health (NIH) continues to value the importance of rigorous peer review prior to publishing the final version of record to ensure the highest quality science is shared. We support PubMed Central and look forward to continuing to work with NIH-funded authors to publish their findings.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/2/2024

I am responding to this RFI: On behalf of an organization

Name: Erin O'Shea

Name of Organization: Howard Hughes Medical Institute

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   We commend the NIH for eliminating the embargo period on publications resulting from NIH-funded research. We also support the proposed language in the draft Public Access Policy that clearly states that submission of manuscripts to PubMed Central (PMC) remains free for authors. This provides a critical option to ensure that publication costs do not impede any NIH-funded researcher's ability to comply with the policy.
   Re-use rights for the public: To unlock their full value, we encourage the NIH to ensure that the public is explicitly authorized to fully reuse publications resulting from NIH research. To this end, we recommend that the NIH add language to its Public Access Policy making this clear.
   We suggest that NIH add the following language (or similar) to its Policy text: "NIH hereby exercises its right under this license to authorize members of the public to reuse all or any part of the work for any purpose so long as the original authors receive attribution in a reasonable manner."
   This language has the added advantage that it brings the NIH policy in closer alignment with immediate open access policies from funders and philanthropies, including HHMI, who have opted for a CC BY license requirement to support as broad a public reuse right as possible. Without the added language, the NIH policy may inadvertently cause a retrenchment from CC BY as the preferred license for open access.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   In addition to including the recommended language above to the Policy itself, explicit authorization for the public to reuse publications should also be incorporated in two additional places in the Guidance:
   1) In the statement NIH requires of authors submitting manuscripts to PMC; and
   2) In the sample language NIH recommends that authors attach to manuscripts.
   Incorporating language that explicitly authorizes public reuse in these two places will ensure that authors and users of the publications clearly understand that the public can make broad reuse of the work.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

As fees that some publishers charge for open access continue to increase, this Guidance will be important to reduce the inequities resulting from article fee-based business models that require authors to pay to publish. This Guidance should not impede and perhaps can help to encourage the development of alternative models for research communication (including preprints; Publish, Review, Curate models; Diamond Open Access models; etc).

Unallowable costs: The draft policy states that '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.' We advise against limiting the term 'publication' to the peer reviewed article and suggest a minor edit to clarify that published peer review reports can serve as a publication for purposes of assessing the relative benefits received: 'Costs for services (e.g., peer review) for which there is no resulting publication (e.g., peer reviewed article or peer review reports) are unallowable because costs must be chargeable or assignable in accordance with the relative benefits received.'

We and others have suggested that a preprint-based publishing system would improve the rigor and efficiency of publishing services (Stern B and O'Shea E, 2019; Avissar-Whiting M et al, 2023; Sever R, 2023). Researchers would publish preprints that are improved and validated through open post-publication peer review and subsequent curation efforts (Publish, Review, Curate). An open peer review process enables better accountability and credit for authors, peer reviewers, and journals and provides useful context for readers. We understand that the NIH public access policy applies to the final peer reviewed article and does not take a position on preprints and open post-publication peer review. But these publishing practices can still contribute to the trustworthiness of the final peer reviewed article and should thus not be excluded from financial support. Without the suggested clarification, the NIH public access policy may inadvertently undermine a path towards sustainable business models for innovative publishing approaches that use preprints and open post-publication peer review.

Assessing 'reasonable' publishing costs: We support NIH's positions that 'reasonable publication costs ensure an equitable system for publishing opportunities' and that reasonable costs can be defined based on factors that include the size of grant awards, library budgets and institutional priorities. But we are concerned that NIH plans to encourage 'authors to publish papers arising from NIH-funded research in reputable journals.' We suggest a revised sentence to expect scientists (not journals) to act reputably, or with integrity, throughout the publishing process, for example: 'we expect scientists to act with integrity in the publishing process, by adhering to high standards of research and publishing ethics and by contributing to a rigorous peer review process'. While journal standards are important, these standards are eroding not just because of bad journal actors but also because even so-called reputable journals suffer from system-level challenges that undermine their quality control mechanisms. These challenges arise in part because even so-called reputable journals do little to prevent another (reputable) journal from publishing an article that their expert peer reviewers deemed flawed. This rejection "" resubmission 'loophole' has turned publishing into a game of getting articles into the right journals, wastes time in the form of redundant peer review, increases publishing costs, and undermines quality control at the systems level and at the level of individual journals, including so-called reputable ones. For example, many journals need to spend more resources than in the past on screening submissions and finding suitable reviewers which elevates the risk that their quality control mechanisms will be overwhelmed. We worry that without revising the

recommendation to make clear that scientific authors are expected to do more than simply publish in reputable journals, this Guidance could stymie the important goals of reasonable publishing costs and rigorous evaluation of research findings.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/240729-final-HHMI-letter-for-NIH-public-access-policy-draft.pdf

Description: HHMI response to NIH draft public access policy

Submit date: 8/5/2024

I am responding to this RFI: On behalf of myself

Name: Anthony James Biernot

Name of Organization: Self

Type of Organization: Other

Type of Organization-Other: Civilian

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   The NIH Draft Public Access Policy and two supplemental draft guidance documents regarding government use license and rights and costs for publications, seem so professional, well put together, informative, & covers a broad range of legalities that is also legible for someone to read & understand properly. I just wanted to say I approve with unwavering support. As an American, I thank you for the time you have invested in making these guidelines which simplify the legalities efficiently in order to make the process's of the data & it's wide variety of application & usage properly handled & addressed so the knowledge can be shared amongst colleagues, researchers, developers, professionals, professors, etc., by all varieties of individuals & institutions whom have some form of involvement with The NIH's Public Access Policy & all it encompasses (seamlessly so). Thank you!

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   I believe this draft already understands how to address & provide proper Guidance on Government Use Licensing and Rights.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   My only recommendation or request would be for an option to provide open source material free of charge for particular institutions &/or individuals whose current field(s) of research, or any broader spectrum of the knowledge's use being accessed for any legitimate reasoning be allowed. Only offer a free of charge allowance when approved by the NIH.

Uploaded File:

Description: Thank you.

Submit date: 8/6/2024

I am responding to this RFI: On behalf of an organization

Name: Katie Steen-James

Name of Organization: SPARC

Type of Organization: Other

Type of Organization-Other: Library Advocacy Organization

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
We applaud NIH for removing the previously allowed 12-month embargo on publications resulting from federally funded research. Communities and individuals across the country face urgent health challenges every day and cannot wait up to a year to access critical research. With this change to NIH's draft policy, patients, doctors, and researchers will now have the latest information at their fingertips to more quickly turn discoveries into cures and treatments. One immediate example of what can happen when the public is given immediate and free access to research is what happened during the COVID-19 pandemic, when paywalls on research were voluntarily lifted to accelerate knowledge of an emerging virus. Now, families across the U.S who deal with health concerns ranging from diabetes to cancer will benefit from the same rapid knowledge sharing that led the research community to develop vaccines and treatments for COVID-19 in record time.
We also offer our strong support for the proposed language in the draft policy that clearly states that submission of manuscripts to PubMed Central (PMC) remains free for authors and that any fee requested during the publication process for submission to PMC (e.g., "article development charges" or similar) is not an allowable cost. Ensuring authors do not face financial barriers like publication costs to comply with the agency's new requirements will support equity among NIH's grantees and make compliance easier for all researchers.
To further strengthen this aspect of NIH's draft policy, we encourage the agency to clearly communicate to grantees that there is a no-cost compliance option available to all researchers and institutions. We consistently hear from our member institutions that many on their campuses mistakenly assume that compliance with the new policy requires the payment of a publishing fee to a journal. It is incumbent upon the agency, with support from the research community, to educate grantees about the free option available to authors so that they do not end up paying unnecessary publication fees.
We strongly support the OSTP Memorandum's explicitly-stated requirement that agencies should make articles immediately available in formats that enable machine-readability. This ensures that these articles are broadly accessible via assistive devices, and also that they are readily available for state of the art computational uses. We appreciate the NIH's consistent use of standards that promote this, including the NISO 39.96-2015 JATS XML standard.
The Memorandum also asks agencies to clarify what use and reuse rights accompany these articles, and we recommend that NIH make adjustments to its draft policy to explicitly authorize the public to fully reuse publications resulting from its research. To this end, we specifically

recommend that NIH add the following language to the "Government Use License and Rights" section of its draft policy:

"NIH hereby exercises its right under this license to authorize members of the public to reuse the work for any purpose so long as the authors and the original publisher receive attribution in a reasonable manner."

Adding this language will enable NIH to make all research articles available under terms that allow for full reuse and secondary analysis—just as it did when it made more than 350,000 coronavirus-related articles immediately available in PMC to respond to the COVID-19 health crisis. NIH's swift action during the pandemic was critical to the creation of the CORD-19 dataset, a machine-readable corpus of articles that allowed researchers to deploy novel machine-learning techniques to answer key questions about the virus.

Without the accompanying rights to fully reuse the articles, the CORD-19 dataset would not have been nearly as useful to researchers. The ability to fully reuse publications should not be limited to a public health emergency, but should apply to advancing progress in all areas where NIH conducts research from curing cancer to addressing economic disparities in healthcare.

As the transformative potential use of AI in research comes into focus, it further highlights the need to ensure that the public has full reuse rights to the articles reporting on federally funded research. By doing so, NIH will avoid making researchers reliant on proprietary platforms in order to use the most innovative AI-enabled analysis techniques on the wealth of knowledge produced with NIH funding. If NIH does not enable productive reuse, the agency risks limiting the impact of its investment in research.

SPARC and our member libraries have long supported the development of institutional repositories as a critical component of our shared national research infrastructure. Institutional repositories can (and do) serve as a convenient locus for faculty to deposit articles. They also provide institutions with an important mechanism to ensure that scientists and scholars—and their institutions—retain control of their intellectual output. Institutional repositories can also play an important role in easing policy compliance burdens on authors, improving discoverability of research outputs, and providing long-term preservation support for publications.

Over the past few years, the U.S. Repository Network (USRN) has been working to increase the technical readiness of repositories, improve their ease of use, and increase interoperability, and facilitate the critical link between research articles and the data underlying their conclusions. To help educate the community, the USRN recently released a document outlining "Desirable Characteristics of Digital Publication Repositories."

We recommend that NIH's draft policy include language that would allow for the deposit of the author's manuscript into local, institutional repositories—not just PMC. We recognize that technical developments to fully support this option are ongoing, and also suggest that NIH engage with the USRN to develop a pathway for identifying additional repositories for authors to deposit their manuscripts into.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
In our feedback on the draft policy, we recommended that NIH add specific language that states that the agency authorizes the public to fully reuse the research articles resulting from its funded research.

In addition to adding the recommended language to the policy itself, we recommend adding language in two additional places in the guidance to explicitly authorize the public to reuse publications:
1) In the statement NIH requires of authors submitting manuscripts to PMC, add to the end:
"I acknowledge that this includes the right of NIH to authorize members of the public to reuse the work for any purpose so long as the authors and the original publisher receive attribution in a reasonable manner."
2) In the sample language NIH recommends that authors attach to manuscripts, add to the end:

"Members of the public are authorized to reuse this work for any purpose so long as the authors and the original publisher receive attribution in a reasonable manner."
Incorporating language that explicitly authorizes public reuse in these two places is an important implementation aspect of the policy and will ensure that authors and users of the publications understand the public can make broad reuse of the work.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
In its draft policy, NIH ensures there is always a free path to compliance and this additional guidance equips grantees to better assess when—and when not—to pay fees required by some publishers. We appreciate the clarity that the updated guidance provides on the types of publisher fees that will not be considered allowable costs (e.g., "article development charges'') along with the helpful guidance for assessing whether any costs levied are "reasonable." We particularly appreciate the call for funding recipients to consider the potential impact of these fees on library and institutional budgets.
As the cost of fee-based Open Access options continues to increase (specifically those for "article processing charges (APCs)"), this guidance will play an increasingly important role in helping funding recipients make informed choices that avoid the inequities resulting from article fee-based business models that require authors to pay to publish.

It is also important that NIH's policy and guidance do not inadvertently undermine new and innovative models for research communication that are emerging. Models like preprints, the "Publish, Review, Curate" model, and Diamond Open Access provide important opportunities for the research community to incentivize and reward a much wider variety of research outputs and not limit the ability for researchers to be credited only for publication of an article in a "reputable" journal.
To encourage a robust, diverse, and equitable research ecosystem, we recommend that the NIH consider adding additional language to clarify that publication costs may be allowed for models that produce other outputs of value—not just a journal article. We are concerned that, as written, the current language limits allowable costs to only those associated with APC-based models.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/NIH-Policy-RFI-SPARC-Response.pdf

Description: SPARC's RFI response in letter format including hyperlinks and a description of SPARC

Submit date: 8/6/2024

I am responding to this RFI: On behalf of an organization

Name: Naomi Charalambakis

Name of Organization: Federation of American Societies for Experimental Biology (FASEB)

Type of Organization: Professional org association

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide comments to the Request for Information (RFI) regarding the National Institutes of Health (NIH) Draft Public Access Policy (NOT-OD-24-144) and supplemental guidance related to government use license and rights and publication costs. As a coalition of 22 scientific societies collectively representing over 110,000 biological and biomedical researchers, we recognize the pivotal role of public access in fostering a more equitable, efficient, and collaborative research ecosystem.
FASEB commends NIH's efforts to engage with stakeholders throughout the policy development process, including its initial Public Access Plan issued in February 2023. FASEB's comments build upon our previous feedback on this plan, offering suggestions for improved clarity to facilitate effective implementation. Recognizing the time constraints outlined in the Office of Science and Technology Policy (OSTP) 2022 memorandum, we encourage NIH to share an implementation plan upon finalizing the policy and provide an opportunity for public comment. This approach aligns with the goals of the public access policy to foster trust and transparency and could enhance policy compliance by providing stakeholders with sufficient time to review and prepare for the proposed October 1, 2025 effective date.
FASEB applauds the proposed policy's emphasis on peer-reviewed publications, as peer review and scientific integrity are inextricably linked and remain a central part of the science communication process. As the scholarly landscape continues to evolve, the following recommendations aim to ensure that the final policy acknowledges the complexities of various publishing models, minimizes administrative burden for investigators, and prioritizes the needs of underserved researchers and institutions.
Definitions
The draft policy's definition of "manuscript" remains unclear and could lead to confusion for the research community. As stated in our previous comments, FASEB recommends specifying whether review articles, perspectives, commentaries, and/or editorials fall under the scope of the policy. Many of these
manuscripts are developed outside of research grants but are still subject to a journal's peer review process, creating a contradiction between two major aspects of the policy as written (emphasis ours): "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…" and the proposed definition of manuscripts: "The author's final version that has

been accepted for journal publication and includes all revisions resulting from the peer review process…". To avoid inadvertent publisher policy changes and potentially higher costs for authors, it would be beneficial to clarify the manuscript types in the policy definition.

Requirements

While FASEB appreciates the policy's clear listing of requirements, we believe additional requirements related to persistent identifiers will advance the agency's goal of improving the discoverability and transparency of research. Echoing our previous comments, FASEB recommends requiring grantees to have an Open Researcher and Contributor ID (ORCiD) to enable greater interoperability between investigators and their work. Considering NIH's current use of this identification system via SciENcv and eRA has been effective thus far, expanding the requirement will foster an even more connected ecosystem of data, grants, publications, and institutions. More importantly, requiring ORCiD could facilitate the agency's ongoing efforts to track grant funding and research outputs in a streamlined manner, alleviating administrative burden for both NIH and researchers. FASEB recommends evaluating the impacts of the 2019 policy (NOT-OD-19-109), which required individuals supported by research training, fellowship, research education, and career development awards to have an ORCiD, to inform the broader policy for all grantees.

As another cost-effective approach, FASEB also encourages NIH to assign a digital object identifier (DOI) for all grants to strengthen interconnectivity between funding sources, data, publications, and other research outputs. Multiple federal agencies (Department of Energy, National Institute of Standards and Technology, etc.) already have this infrastructure in place and are using it with great success, which can facilitate a seamless transition for NIH. FASEB encourages the final policy to reflect this new requirement that will have positive ramifications for all research stakeholders.

Compliance and Enforcement

To ensure adequate compliance and enforcement of the public access policy, FASEB strongly recommends publishing a detailed implementation plan with a public comment period. This is particularly important given OSTP's ambitious timeline. Stakeholders need sufficient lead time to develop and negotiate potential new licensing agreements for manuscript deposition, among other plans before the effective date. In many cases, this will require significant coordination with the National Library of Medicine (NLM), which holds agreements with various publishers that are also depositing accepted manuscripts or final published articles into PubMed Central. Issuing an implementation plan acknowledges the challenges institutions, publishers, and NLM are facing to comply with the policy while providing the time and information they need to allocate resources and staff accordingly.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**

Ensuring research is properly attributed while encouraging broader reuse opportunities is an essential balance necessary for scientific integrity and research transparency. FASEB reaffirms its support for researchers having the academic freedom to choose where they communicate and share their findings, including their preferred choice of journal or license for reuse. Without researcher input on derivatives produced from their work or the parties that create those

derivatives, scientific findings could be misrepresented, potentially undermining the investigator, funding agencies, and scientific integrity.

While we appreciate the draft policy not requiring researchers to apply a specific license to their final published articles, the terms “derivatives” and “reuse rights” could be further specified to ensure works are appropriately used and scientific integrity is protected. Similar to the current draft’s delineation of “manuscript” and “article,” FASEB recommends adding definitions for “derivatives” and “reuse rights” with language that underscores researchers’ rights and ensures derivatives do not adversely affect scientific integrity.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

FASEB commends NIH for stating that “allowable” costs associated with publications in budget requests can derive from direct or indirect funds, a key position highlighted in our previous comments. Given the rapid growth of new publishing models and open science infrastructure, FASEB appreciates the guidance’s inclusion of examples of unallowable costs and “points to consider” for authors and institutions. However, considering the disparities faced by underserved populations—such as researchers from historically excluded backgrounds, early-stage investigators, and lower-resource institutions—FASEB suggests enhancing this guidance by making commitments to support these groups during policy implementation. Specific details could be further outlined in the implementation plan, including education plans for program officers that focus on promoting equity in publication opportunities, outreach strategies to improve awareness of the policy, and resources for investigators and institutions that may lack the administrative capacity to support publication efforts.

Conclusion

FASEB appreciates NIH’s efforts to engage with stakeholders on this important topic and looks forward to future updates. To ensure compliance with the final policy is feasible for researchers and institutions of all backgrounds and capacities, we strongly encourage developing an implementation plan informed by stakeholder feedback. Clear guidelines and stakeholder participation are crucial to advance the community’s shared goal of promoting scientific integrity and research equity.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/FASEB-Response-NIH-Draft-Public-Access-Policy_August2024.pdf

Description: PDF Copy of FASEB's Response to NIH Draft Public Access Policy

Submit date: 8/7/2024

I am responding to this RFI: On behalf of an organization

Name: Joseph G. Rogers, MD

Name of Organization: International Society for Heart and Lung Transplantation

Type of Organization: Professional org association

Type of Organization-Other:

Role: Medical provider

1) **Provide any comments on the Draft Public Access Policy below:**
   Please see uploaded letter.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   Please see uploaded letter.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   Please see uploaded letter.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/ISHLT-NIH-Draft-Public-Access-Policy-Letter.pdf

Description: Please see uploaded letter regarding National Institutes of Health's Draft Public Access Policy (June 2024).

Submit date: 8/9/2024

I am responding to this RFI: On behalf of an organization

Name: O'Brian Henriquez

Name of Organization: Institute for Clinical and Translational Science at UC Irvine

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   Regarding the removal of the embargo period, there is some ambiguity around how much time will be allowed for investigators to make their publications compliant.
   Manuscript submissions usually require significant processing time, sometimes taking weeks. We would like to propose a grace period of two-three months to ensure adequate time for processing and submission of manuscripts to PMC, especially considering any potential delays for corrections and approvals via the NIHMS system.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/12/2024

I am responding to this RFI: On behalf of an organization

Name: Geeta Swamy, MD - Associate Vice President for Research, Duke University Office of Research and Innovation

Name of Organization: Duke University

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   One of Duke University's key strategic goals is using knowledge in the service of society. We encourage our researchers to make the results of their research (publications, data, and code) as broadly available as possible, and to translate their research into modes that can be effectively consumed by the public and be used to generate economic and social value. As an institution, we have put in place a number of initiatives to support this, including open access policies for faculty and graduate student publications, multiple open repositories with services to integrate them into researcher workflows and staff to provide support in using them, and funding to support open access journals, monographs, and publishers. Duke University leadership is deeply engaged with the HELIOS initiative, and provides support for a variety of programs and training opportunities that encourage our researchers to make open scholarship practices a key part of their research workflows and culture. We are pleased that the NIH is working to expand timely public and equitable access and benefit for more federally funded research, and offer these comments in response to the recent RFI.
   We support the intent of the NIH Draft Public Access Policy, and the explanations given of refinements made in response to previous public comments, including ours.
   Our remaining concerns are largely around how principal investigators, researchers, and authors will interpret or misinterpret the new policy and methods for its implementation. In our experience, PIs often are not fully informed of the public access obligations under grants they have accepted, and often only become aware of them at the point of publication (when their publishers have a heavy influence on their actions) or when compliance deadlines are rapidly approaching (when research administration staff in their institutions must remind them to complete their obligations). This puts the publishers in a position of power, able to communicate misinformation that may benefit the publisher (such as the requirement to pay an article processing for "gold" open access) and institutional research administration at a disadvantage (as researchers get annoyed with staff "nagging" them to comply).
   We strongly encourage NIH to provide clearer and bolder communications to PIs earlier in the process. This should include in the policy's Frequently Asked Questions information that more clearly and explicitly addresses their obligations, options, and potential misinformation or misunderstandings. It should be made abundantly clear to PIs and authors that they are not required to pay any open access charges to publishers or service providers, and that the preferred method of meeting their funder obligations is through PubMed Central deposit.

Specific potential misinformation and misunderstandings should be addressed, and PIs and authors should be given language and support to push back against any incorrect information about the policy and how to comply with it.
The FAQ should explain in clear and concise language many of the issues addressed in the overview of public comments, which were points of confusion to readers of earlier policy drafts. We support the conclusions that the new draft includes, but believe that some of the policy language may leave space for ongoing misunderstanding and potential exploitation by organizations that seek to use the policy to their advantage.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
We support application of the Government Use License to research outputs from federally funded research, and agree that this is a clean and effective way to retain rights for public access regardless of what later contracts authors may be asked or pushed to agree to by their publishers.
As noted above, our main concerns are with how this will be received and understood (or misunderstood) by researchers and authors. We expect authors will hear from their publishers that this license is incompatible with their journal, that it represents an unfair taking of their rights, and that they are required to pay a fee to compensate the publisher for it. NIH should provide clear and bold language to PIs, authors, institutional research administration staff, and publishers to push back against this misinformation, and to provide support for researchers and authors who will feel they are trapped between conflicting information and requirements.
PIs and authors are also likely to be confused by what might appear to be retroactive application of this license, for publications resulting from grants that were funded prior to the implementation of this new policy. We agree with and support the approach outlined in the draft policy, and again strongly encourage NIH to provide clear language about its application, including addressing potential misunderstandings or misinformation. We expect that there will be confusion about this, and some of that confusion may be exploited by publishers telling authors they need to come up with funding to compensate the publisher for use of this license. Authors may come to believe that there was a “bait and switch” and that since they were unaware they should have asked for funding for APCs in their proposal, they should not have to comply now. NIH should make abundantly clear that APCs are not required to meet this obligation, with redirection to the PubMed Central process and language authors can send to their journals to counter any misinformation about this.
We encourage NIH to also make clear to PIs and authors that the Government Use License being granted as a condition of funding may also be used to make the resulting outputs available in institutional or disciplinary repositories or through other appropriate venues. The policy language already states that NIH may “authorize others to do so” – we encourage NIH to provide language (in an FAQ, if not in the policy itself) that gives examples of other uses that NIH authorizes, to make clear up front that authors may deposit in other repositories in addition to depositing in PubMed Central. Authors who have publications that are able to be made openly available because of their NIH funding may wish to also deposit those publications to their institutional repositories, for display in their university profiles or lab web sites, or other places where they wish to feature their research. NIH should provide language explicitly authorizing

this, and guidance on how to ensure proper attribution and links back to canonical copies (DOI and/or PMID) are included in any secondary copies.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
We support NIH's emphasis of the free PubMed Central pathway for compliance with this policy, for all the reasons outlined in the draft policy. However, as noted above, we expect that researchers may mistakenly be led to believe that article processing charges are required for compliance, and may feel that NIH is putting them in a difficult position with their publisher or institution. We encourage NIH to be very clear that PubMed Central deposit is the primary and preferred method of meeting researcher funding obligations, and to provide strong language that PIs and institutions can use to counter any information to the contrary.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/Duke-University-response-to-NIH-Public-Access-RFI-August-2024.pdf

Description: PDF of comments submitted on behalf of Duke University, including names and titles of Duke University administrators who approved and support these comments

Submit date: 8/12/2024

I am responding to this RFI: On behalf of myself

Name: Alexia Thompson-Young

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/12/2024

I am responding to this RFI: On behalf of myself

Name: Molly Rainard

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I'm writing to express support of the NIH draft plan to make grant-funded research freely & immediately available to the public.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   Particularly, I'd like to express my enthusiastic support to the use of the Federal Purpose License / Government Use License to govern the use of such publicly funded research. Exorbitant pricing is only one part of the issue with publishing of publicly funded research; equally important to consider are the restrictive terms that publishers regularly impose on the use of this research through their contracts with libraries. As a licensing librarian who negotiates complicated vendor licenses for a living, I urge you to not overlook this important part of the puzzle. It is absolutely vital to not let publishers dictate the terms by which publicly funded research is accessible. A standardized license laying out the terms of use in uncomplicated language is ideal for this purpose, and should be adopted.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Nancy E. Adams

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Colleen Lyon

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost. As a librarian at a research intensive university, I see first hand how difficult it is for faculty to widely share their work when the default is for publishers to require a transfer of copyright as a condition of publishing. Using the Federal Purpose License allows faculty to widely share their work (which almost all of them want to do) and since the license is non-exclusive, faculty can still reuse the work however they want. It's a great combination of sharing plus faculty control.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Cindy Gurwell

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I/We believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Teresa L. Knott

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   As an academic health sciences librarian, I strongly support the NIH draft plan to make grant-funded research immediately available to the public for free.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost. It is morally challenging that publishers benefit from the investment of federally-funded research to turn around and extract extraordinary profits from research and academic enterprises based on a relatively small investment on their part.

Uploaded File:

Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Joanna Thielen

Name of Organization: University of Michigan Library

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Ariel Andrea

Name of Organization: University of Wisconsin - Madison

Type of Organization: University

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
Per: "The NIH Draft Public Access Policy minimizes burden by proposing to adopt the same pathways to compliance under the current Public Access Policy." To ensure a smoother transition, please harmonize language as to pathways from current policy to the new policy. The current NIH Public Access policy has been in effect since 2008 and investigators and administrators are familiar with the compliance pathways, i.e., Submission Methods (A, B, C, and D). Use of the same language as to pathways is highly encouraged to minimize the burden on investigators and administrators. If not able to do so, create a map or graphic to display the new compliance pathways. https://www.federalregister.gov/d/2024-13373/p-72.
Clarify if an acknowledgment in the Manuscript regarding Communicating Rights in Manuscripts required or encouraged. https://www.federalregister.gov/d/2024-13373/p-124.
How will implementation of public availability without embargo will take into account processing time that may be needed before public availability in PubMed Central, in particular, how can investigators demonstrate documentation of compliance during processing? https://www.federalregister.gov/d/2024-13373/p-29?
   - For journals that follow the current Submission Methods A and B, will "PMC Journal - in Process" still be allowed for compliance purposes?
   - For journals that follow current Submission Methods C and D, will the NIHMSID still be allowed for compliance purposes?

How will the final, edited form of an article be identified, and by whom? https://www.federalregister.gov/d/2024-13373/p-29.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
Clarify if the Government Use License and Rights statement is required or encouraged for the final, peer-reviewed manuscript version. https://www.federalregister.gov/d/2024-13373/p-124.
Clarify if the Government Use License and Rights statement will need to be added to the manuscript by the authors or will the statement be included in the manuscript by NIHMS during the submission process? https://www.federalregister.gov/d/2024-13373/p-118.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Please require the National Library of Medicine to collect article processing charge (APC) data from all MEDLINE-indexed journals.

Uploaded File:

Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost."

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of an organization

Name: Paul Sharpe

Name of Organization: University of Texas Rio Grande Valley

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   "We support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. We believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost."

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Kathrin Plath

Name of Organization: UCLA

Type of Organization: University

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of an organization

Name: Robert L Stakes

Name of Organization: University Library, University of Texas at El Paso

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   We support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. We believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Lorelei Tanji

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License (aka Government Use License) in support of authors' right to deposit their works is the right approach, since it will avoid overburdening researchers and universities with legal complexity or additional cost. Making grant-funded research available to the public for free will have a beneficial impact to society and will be in the interests of the common good.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Kelly Gonzalez

Name of Organization: UT Southwestern Medical Center Library

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

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Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Leila Sterman

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support NIH draft plan to use the federal Purpose License. The time and effort lost to accessing work, figuring out the policies of journals, or making sense of each new money making scheme from publishers is orthogonal scientific improvement. Streamlining the process while increasing access to information is the most responsible public health decision the NIH can make.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Michele Gibney

Name of Organization: University of the Pacific

Type of Organization: University

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I endorse the NIH draft plan to ensure that grant-funded research is made freely accessible to the public immediately upon publication. The NIH's application of the Federal Purpose License to uphold authors' rights to deposit their works for this purpose is particularly commendable. I believe that the NIH is proposing an effective, consistent, and straightforward approach that will prevent researchers and universities from being encumbered by legal complexities or additional costs.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description: Support for NIH Plan

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Mike Jung

Name of Organization: California Institute of Integral Studies - San Francisco, CA

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of an organization

Name: Rachel Paprocki

Name of Organization: Notre Dame de Namur University

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Deborah Farber

Name of Organization: California University of Science and Medicine

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Jamie Hazlitt

Name of Organization: Loyola Marymount University

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost."

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Kristin Laughtin-Dunker

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Jeanette Duffels

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Daniel Fitzroy

Name of Organization: The Claremont Colleges Library

Type of Organization: University

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost."

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization: University

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional costs.

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Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Brian Aby

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Jenny Pierce

Name of Organization: Temple University Health Sciences Libraries

Type of Organization: University

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   As a librarian supporting an academic health institution, I support the NIH draft plan to make grant-funded research immediately available to the public for free.
   I agree with the NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose.
   The NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Amy Heberling

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost."

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Samantha S.

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Tony Diaz

Name of Organization: California Institute of Technology

Type of Organization: University

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost."

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Submit date: 8/14/2024

I am responding to this RFI: On behalf of an organization

Name: Nicole Zimmerman

Name of Organization: American Society for Microbiology

Type of Organization: Professional org association

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/ASM-response-NIH-Open-Access-RFI.pdf

Description: Please see the following response submitted on behalf of the American Society for Microbiology.

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Dianne Johnson

Name of Organization: Wake Forest University School of Medicine

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I/We believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   As a librarian who helps researchers find appropriate journals, the publication costs are prohibitive especially to new/young researchers. By lowering them and holding publishers accountable, it really is providing health for ALL.

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Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Rachel Scott

Name of Organization:

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research available to the public with no embargo.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   I was pleased by the NIH's use of the Federal Purpose License in support of authors' right to deposit their works. I believe that it will simplify processes, reduce costs, and minimize legal complexity for authors and institutions.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   I agree with respondents that it would be helpful to define reasonable publication costs, even though these will necessarily evolve. As a librarian who supports institutional open access publishing agreements with several publishers, I also have concerns about the high costs of article processing charges. I would encourage the NIH to considering capping per-article publication-related costs.

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Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of an organization

Name: Robyn Ward

Name of Organization: Westminster University

Type of Organization: University

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost."

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Sanjeet Mann

Name of Organization: California State University, San Bernardino

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   I'm an educator and academic librarian working at a public university with R2 standing. I'm writing to share my support for the NIH draft plan to make grant-funded research immediately available to the public for free. One of the strengths of the plan is using the Federal Purpose License to support authors' right to deposit their works in open repositories. This is the most time and cost effective way to secure open access to federally funded research.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Patient advocate

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Michael Kares

Name of Organization: William Jessup University

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost."

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Norma D.

Name of Organization:

Type of Organization: University

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Eric Phetteplace

Name of Organization: California College of the Arts

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Paige Mann

Name of Organization: University of Redlands

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. Health research should benefit the public making public access to the research a no-brainer. As an academic librarian I also value free, public access to enable lifelong learning and to equip the public to be informed advocates for their own health.The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. There is no need to devote unnecessary time and resources to reinvent the wheel. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Sara Samuel

Name of Organization:

Type of Organization: University

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   As a librarian that works with health sciences and medical researchers, I support the NIH draft plan to make grant-funded research immediately available to the public for free.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   The NIH's use of the Federal Purpose License (or Government Use License) in support of authors' right to deposit their works for this purpose is particularly welcome. I believe the NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of an organization

Name: Matt Kerschner

Name of Organization: American Academy of Neurology

Type of Organization: Professional org association

Type of Organization-Other:

Role: Medical provider

1) **Provide any comments on the Draft Public Access Policy below:**
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." 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,
- 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." 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 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." 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." However, NIH is proposing to make the Public Access Policy "effective for Manuscripts

accepted for publication on or after October 1, 2025." 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

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." 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." 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."

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.

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.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**

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." 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, 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.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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." 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."

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.
- 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.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/Final-AAN-Comments-NIH-Public-Access-Policy.pdf

Description: Please see the attached for comments from the American Academy of Neurology in response to the Draft Public Access Policy, the Draft Guidance on Government Use License and Rights, and the Draft Guidance on Publication Costs.

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Lise I. Bretton

Name of Organization: Sharp Healthcare

Type of Organization: Health care delivery organization

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost."

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   I support this plan to make grant-funded research immediately available to the public for free. NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I appreciate that this plan avoids overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Patient advocate

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Ruth Hanlon

Name of Organization: Hawaii Pacific University

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of an organization

Name: John P. Ochs

Name of Organization: American Chemical Society

Type of Organization: Professional org association

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/2024-8-14-ACS-response-to-NIH-RFI-89-FR-51537.pdf

Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Sion Romaine

Name of Organization: University of Washington Libraries

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   Please do not bend to publisher pushback; please move forward with the NIH draft plan to make grant-funded research immediately available to the public for free. An effective and straightforward approach, such as the one proposed by the NIH, will ensure that reporting out on research remains affordable for universities and libraries in the years to come.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Chuck Koontz

Name of Organization: Biola University LIbrary

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Michele Nielsen

Name of Organization: University of Redlands Armacost Library Archives

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. Health research should benefit the public making public access to the research a no-brainer. As an academic librarian I also value free, public access to enable lifelong learning and to equip the public to be informed advocates for their own health. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. There is no need to devote unnecessary time and resources to reinvent the wheel. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I strongly support the NIH draft plan to make grant-funded research immediately and freely available to the public.
   The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/15/2024

I am responding to this RFI: On behalf of myself

Name: Shawn Nicholson

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public with no use cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   The Federal Purpose License will reduced complexity and supports authors' right to deposit their works.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/15/2024

I am responding to this RFI: On behalf of myself

Name: Patrick Newell

Name of Organization:

Type of Organization: University

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   Isupport the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost."

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/15/2024

I am responding to this RFI: On behalf of an organization

Name: J. Carl Maxwell

Name of Organization: Association of American Publishers

Type of Organization: Other

Type of Organization-Other: Trade Association

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   Please find attached an electronic copy of the comments on the proposed Draft Public Access Policy by the Association of American Publishers.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/AAP_NIHRFI_89-FR-51537_Final08152024.pdf

Description: Response to Request For Information on the National Institutes of Health Draft Public Access Policy by the Association of American Publishers

Submit date: 8/15/2024

I am responding to this RFI: On behalf of myself

Name: Amy Sharpe

Name of Organization: Sharp Healthcare

Type of Organization: Health care delivery organization

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   Publicly funded research should be available to all US IP addresses to improve public health and patient outcomes. Rural medicine would especially benefit from this. Reducing or eliminating embargos would be extremely beneficial to providers and patients. Text mining of publicly available content will be vital to expedite progress.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   Open access publishing supports scholarship and innovation. Also, leveraging text mining and natural language processing will facilitate innovations.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/16/2024

I am responding to this RFI: On behalf of an organization

Name: Caroline Sutton

Name of Organization: STM

Type of Organization: Professional org association

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
Thank you for the opportunity to comment on the "the National Institutes of Health Draft Public Access Policy" ("draft policy"), as issued in the Request for Information 89 FR 51537. STM is pleased a number of our comments on the Public Access Plan were considered in the development of the draft policy. In particular, we appreciate that the draft policy provides flexibility for implementation in several respects, recognizing, as we noted in our response to the RFI on the NIH Public Access Plan, that there is not one best route to providing access. That said, below we provide recommendations for improvement of the plan to ensure it fully achieves NIH's goals for public access, whilst minimizing research burdens, respecting academic freedom, and ensuring a vibrant and well-functioning ecosystem for trusted scholarly communication.
STM stands for advancing open and trusted research, where researchers and the rest of society can rely on information that is trusted, accessible, linked, and searchable in perpetuity. Our members therefore are committed to continuing to make needed advancements in systems and infrastructure and investments in people to ensure the quality, integrity, and persistence of the scholarly record to support research.
Publishers have led and responded to the interest in open science by investing heavily in open science over the last 25 years, broadening and expanding the public's ability to understand and access the work of scientists and scholars. Many of the products necessary for open science were created and maintained by publishers, including online infrastructure, as well as pre-printing, archiving, linking, and data management, and we continue to support and grow those efforts today. Our members have also invested in new models and approaches to providing access, including experimentation with a variety of business models to support quality, sustainability, and equity.
STM and our members remain fully committed to our responsibility to protect and improve research integrity. As the volume of research has increased, and there has been a rise in mis-/dis-information, with emerging tools including generative artificial intelligence creating new challenges, publishers and our partners have continued to invest in systems, people, and processes to preserve trust and validation of the scholarly record, such as STM Solutions.
We offer the following recommendations consistent with our desire to work with NIH, its funded researchers and institutions, and all stakeholders, to support the sharing of high-quality, vetted information. STM supports an environment where publishers can continue to drive quality, integrity, and innovation in scholarly communication, in collaboration with NIH, and the

broad stakeholder communities that are funded and engaged in research related to NIH-funded projects.

We therefore hope that STM and its members will have the opportunity to work with NIH to support researchers to advance biomedical research and public health, as well as promote quality, trust in science, equity, and the sustainability of the scholarly communications ecosystem.

Recommendations for the Draft Public Access Policy

In responding to the RFI questions below, STM would like to highlight the following overarching considerations:

NIH should carefully consider how to reduce burdens on researchers and their institutions, including the challenges the policy may present for co-funded work for which different policies apply NIH must ensure that the policy respects author rights and copyright law NIH should ensure that the policy sufficiently acknowledges sustainable models for researcher compliance.

Reducing burdens on researchers and institutions

As has been true since the NIH first introduced a public access policy two decades ago, STM and its members stand ready to work with NIH and funded researchers to provide the broadest possible access to articles reporting on NIH-funded research. However, a successful partnership towards this end needs to be an equal one, where collaboration on efficient and effective solutions can be sought, and where publishers and NIH work together on education of the research community on potential approaches to "publishing models and/or discipline-specific requirements."

A key goal of such a partnership should be to reduce administrative burdens for funded researchers and institutions. There are several places in the Policy where a collaborative approach could yield better outcomes for all stakeholders than the outlined approach. Compliance and enforcement could be better addressed through utilising sustainable publication models for access, and collaboration with efforts like CHORUS (www.chorusaccess.org), SeamlessAccess, and GetFTR; multi-stakeholder initiatives that are already providing easier access to articles and metadata. Implementation could best minimize burdens by ensuring flexibility in all aspects: business models, licensing, and implementation processes. Specific recommendations related to each of these aspects is addressed respectively in the Policy and Guidance recommendations sections below.

Similarly, efforts are underway by publishing organizations to improve accessibility and understandability of articles in the manner envisioned in NIH's Public Access Plan that could be leveraged to minimize burdens both on researchers/institutions and on NLM itself. Rather than duplicate efforts already underway by the scholarly community, STM suggests that NLM focus on leveraging and seeking partnerships with publishers and others who are already providing access, accessibility, and utility for the scholarly record. In addition to these ideas raised in the introduction to the Policy, discoverability and curation should be understood as a key feature of accessibility and understandability. Support for such services, and for an effective and sustainable system that provides them, should therefore be a key feature of the Policy and its implementation.

A mixed ecosystem will persist for some time, as publishers adopt different models to serve the unique segments of the global research community on whose behalf they publish. One way NIH

can minimize burdens for a large segment of researchers while supporting the needed features of the scholarly ecosystem is by more clearly and consistently supporting a fully-funded gold open access route for publication, where the Version of Record (VoR) can be made available to the public and publishers can be recompensed for the valuable investments they make to the integrity of the scholarly record. The VoR is the authoritative version for researchers and the public, and it is more cited, used, and garners more attention than other versions of an article. The VoR is also the version that will be updated post-publication should there be any issues of research integrity. Supporting fully funded gold open access is the simplest route to minimize burdens and support research integrity, accessibility, and utility.

Ultimately, the NLM needs to consider how it can ensure that the Policy avoids creating an unreasonable burden on researchers, their institutions, and publishers and negatively impacting the availability, quality, and integrity of the scholarly record. This is especially true as the Policy, as drafted, applies to any works reporting on NIH-funded research in perpetuity but does not provide support and funding for compliance in perpetuity.

Respecting author rights and copyright law

As a fundamental principle, STM notes that both the statute establishing NIH's Public Access Policy and the 2022 OSTP Memorandum clearly state that implementation must be consistent with copyright law, which grants authors exclusive rights to determine the dissemination of the works they create. Authors can assign these rights to works that they have created, or contract to create works that will become the property of others (e.g., in the case of "works made for hire") by function of law, license, or assignment (for more details, see https://www.stm-assoc.org/wp-content/uploads/Authors-Rights-in-Scholarly-Publishing-Narrative-May29_2024.pdf.). To be consistent with Copyright Law and academic freedom, researchers should be able to exercise their exclusive rights, including through licensing, under copyright law without undue constraint. Whilst HHS and OMB guidance (including 45 CFR 75.322(b) referred to in the policy) stipulate a (regulatory, but not statutory) Government Use License, the Policy may be seen to go further than this license repository.

More specifically, the application of requirements, and any license, should be understood in the context of author rights and contract law. The Policy requests submission only of Manuscripts that are accepted for publication, and therefore the production of such Manuscripts and their availability must be consistent with the desires of the author for such a manuscript and the requirements of the journal that has accepted the Manuscript. Where NIH "clarifies that compliance with the Policy is free," this should be contextualized with an acknowledgement that compliance is only possible through the work of publishers like our members, whose resources and expertise ensure that high quality, trustworthy content comprise the scientific record, and that compliance with the Policy must therefore be consistent with agreements made with such publishers. The Policy could otherwise be understood to suggest that authors might ignore publication costs or license restrictions that are part of the conditions of acceptance of an article, which would be inconsistent with copyright law, contract law, and vital tenets of academic freedom.

Similarly, requirements that would impact works already created or that do not provide appropriate notice to researchers, institutions, and third parties (i.e., publishers) should be avoided to prevent misunderstanding or conflict with the law.

Finally, allowing the government free rein to create derivative works has no basis in the Government Use License, the governing regulations or any of the prior agency publication, and undermines right holders' authority to determine how their research is represented in works attributed to them. A broad license to create derivative works without any oversight or review by the author could also enable political influence in the representation of such works or introduce errors or other misrepresentations, with significant impact on the integrity and reliability of the scholarly record. We recommend that in place of this broad license, NIH state exactly what is needed to ensure accessibility.

Specific Recommendations

Definitions

The definition of article should refer to the NISO Journal Article Versions (JAV) Recommended Practice (NISO RP-8-2008, Journal Article Versions (JAV): Recommendations of the NISO/ALPSP JAV Technical Working Group | NISO website), which has recently been updated after a multi-year, broad stakeholder consensus process. Nomenclature should be consistent throughout the Policy and the Draft Guidance.

The definition of Manuscript appropriately recognizes the importance of the peer-review process, which is managed and enabled by journal communities and their publishers.

Policy Effective Date

The effective date of the Policy should be with respect to new grants, rather than with respect to the acceptance date of a publication. As written, the Policy is retroactive to works already created, which may have already been submitted, without assigned publishing costs and close to acceptance before the Policy goes into effect. This could create conflict with author rights and publisher agreements or understandings. The Policy appropriately calls for author education and notice to third parties who might review or publish such manuscripts; this will not be possible for manuscripts already under review when the Policy is finalized.

The section on Government Use License and Rights limits claims to those in 45 CFR 75.322(b) and 2 CFR 200.315(b). It is critical to note that these provisions do not have a statutory basis and may be subject to challenge, especially in the face of recent Supreme Court decisions. Regardless of the basis in law, the regulatory framework should provide the outer limit of the license claims in the Policy and related guidance.

Rights in Manuscripts

STM appreciates that the Government Use License and Rights section acknowledges that rights in the Final Published Article may be different from the permissions and responsibilities in the Accepted Manuscript. Where the Final Published Article's license provides rights for it to be linked to or submitted to PubMed Central, compliance should be possible regardless of whether a journal has a formal agreement with NLM. The Compliance and Enforcement section should reflect this.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**

In addition to noting the rights that Federal agencies have, this guidance should also note NIH's respect for intellectual property rights and copyright, as well as academic freedom. Such a commitment to authors' rights should be included in the Purpose section. The second paragraph of the Draft Guidance appropriately encourages authors to communicate expectations to

publishers to support and enable dialogue on rights and options regarding the licensing of articles. Publishers support such clarity and would welcome a dialogue with NIH to support author education regarding NIH's public access policy and licensing.

The submission statement proposed in the Draft Guidance is not consistent with the language in the policy or with 45 CFR 75.322(b) and 2 CFR 200.315(b), nor with the Public Access Policy Requirements Related to Rights as articulated in the previous paragraphs. STM strongly recommends that the clause claiming that the license "includes the right to create derivative works" be deleted; this has no basis in the Government Use License, the governing regulations or any of the prior agency publications.

In particular, as noted in the comments and recommendations on the Draft Policy, STM and its members are concerned about the potential of NIH to provide third-parties with the right to distribute works in competition with publishers without a clear Federal purpose, and in a manner that is inconsistent with a sustainable scholarly communications ecosystem. Similarly, government creation of derivative works in place of the author has the potential to conflict with academic freedom, research integrity, and the sustainability of peer-reviewed scholarly communications.

In the section "Guidance for Communicating Rights in Manuscripts" the footnoted use of the term "Articles" is inconsistent with the definition in the Policy. To improve clarity, STM recommends the use of the phrase "works reporting on NIH-funded research" in place of "Article" here. Similarly, the term Manuscript is used to mean different versions in different places in this section. STM recommends that NIH utilize the NISO Journal Article Versions (JAV) Recommended Practice (see footnote above) to be clear when "submitted manuscript," "accepted manuscript," or another version is meant.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

In general, STM appreciates that this section acknowledges the costs of the publication process and emphasizes that these costs should be an allowable budget expense.

As noted in our comments on the NIH Public Access Plan (https://www.stm-assoc.org/document/stm-response-to-request-for-information-on-the-nih-plan-to-enhance-public-access-to-the-results-of-nih-supported-research-not-od-23-091/), guidance on publication costs should emphasize author choice for whatever journals they choose to advance their research and impact, regardless of whether this incurs a direct cost. In order to ensure equity for all researchers, NIH should clarify that funding will be provided on an equal basis so that researchers who choose to publish in journals that are supported by APCs are not disadvantaged in the resources available for their research, student support, and other critical needs.

The Draft Guidance should emphasize that costs not only "may be requested," but "should be requested." STM also recommends that the Draft Guidance provide that budgets will be reviewed to ensure that there is adequate funding for intended and potential publications, similar to the manner in which the NIH Data Sharing and Management guidance indicates that budgets will be reviewed to ensure that there is adequate funding for data sharing and management.

Under “Other Unallowable Costs,” STM notes that costs incurred after closeout are unallowable. STM would like to reiterate our concern about compliance with an open-ended policy and encourages NIH to add policy language and guidance regarding how researchers can address the costs of publications subject to the Policy that are published (or even written) after closeout. NIH could consider automatic grant extensions and/or supplemental grant opportunities for publication costs, amongst other options.

In the section on “Points to Consider […] in Assessing Reasonable Costs,” STM urges NIH to provide guidance that reflects the full value of the publishing ecosystem. The last bullet regarding library budgets is particularly concerning as an issue that can be read as bias against support for publishing costs, and STM recommends its removal. In addition, NIH could consider the impact of not supporting publishing costs as a key consideration for authors and institutions. As some illustrative examples (not meant to be exhaustive), the draft guidance could suggest consideration of:

- Impact on biblio-diversity and research integrity, if such costs were to not be consistently paid;
- Sustainability of the publishing ecosystem

The reference to the 2017 Guide Notice to avoid disreputable publishers is a welcome one. STM also encourages NIH to direct Authors and Institutions to consider publishers who ascribe to the COPE guidelines, as well as consultation of “Think. Check. Submit.,” and scholarly communications initiative to support publication in reputable journals.

Finally, the Draft Guidance should note that publication practices and business models are actively evolving. NIH should ensure that reliable and sustained funding is available for any and all business models that support immediate access to articles reporting on NIH-funded research. STM would welcome the opportunity for additional dialogue to ensure that all publication costs, regardless of business model, including but not limited to APCs, are allowable costs and supported to promote public access and research integrity.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/STM-submission-to-NIH-draft-public-access-policy-RFI-FINAL-DRAFT-Aug-14.pdf

Description: Full STM submissison

Submit date: 8/16/2024

I am responding to this RFI: On behalf of an organization

Name: Corbin Evans

Name of Organization: American Psychological Association

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/Letter-in-Response-to-NIH-RFI-on-Enhancing-Access.08.19.24.pdf

Description: See comment attached.

Submit date: 8/16/2024

I am responding to this RFI: On behalf of myself

Name: Julie Bill

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/16/2024

I am responding to this RFI: On behalf of an organization

Name: Sharon Smith Terry

Name of Organization: Orthopaedic Research Society

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Lyric Jorgenson, PhD
Acting Associate Director for Science Policy
NIH Office of Science Policy
6705 Rockledge Drive
Bethesda, MD 20892

Dear Dr. Jorgenson,

For 70 years, the Orthopaedic Research Society has been the leading international research society supporting engineers, orthopaedic surgeons, biologists, veterinarians, and clinicians in pursuit of a world without musculoskeletal limitations. Our members represent academic, industry/private sector, government, and private practice at all career levels from around the world. As part of our efforts to serve our membership and disseminate cutting-edge orthopaedic research to the community, we have founded two society journals: the Journal of Orthopaedic Research (JOR) and the Journal of Orthopaedic Research – Spine (JORS). While JORS was founded as an open-access journal, it remains subscription-based (with no publication fee). Articles are only open-access after a 12-month embargo, consistent with current NIH guidelines. As a society of researchers, we are deeply appreciative of NIH's commitment to disseminating research to the public and improving accessibility to NIH-funded work. We believe that access to research findings fuels scientific innovation, collaboration, and translation. In considering the new proposed guidelines, we hope the NIH will consider some of the discussion points that were raised by members of the ORS Publications Committee and the JOR Editor-in-Chief.

1. There are some concerns that the subscription-based model will no longer be viable under the new policy and publishers will shift journals to open-access only. As open-access journals typically charge large publication fees (up to $10K for some journals), how this will impact investigators (especially new investigators) is unclear. While we appreciate that NIH grants will continue to allow budgeting for publication, a larger proportion of research budgets will now be needed for publications rather than research. Certain NIH institutes already apply broad budget cuts to NIH grants, thus further reducing funding for actual research. Fundamentally, we are asking: What should a peer-reviewed publication in a long-standing society journal cost, and who should pay for this?

2. Related to point 1, will there be a cap on the amount that publishers can implement for publication fees? The open-access model has already created a slew of for-profit, predatory journals. The dramatic increase in journals and the consequent increase in the demands on scientists to serve as volunteer reviewers has already placed a significant burden on our community and compromised the peer review process as a result. Will the new model alleviate this burden or add to it?

We thank the NIH for providing this opportunity for our feedback and look forward to continuing discussions on the topic.

Uploaded File:

Description: Open Access Journal - A Challenge in the Current State

Submit date: 8/16/2024

I am responding to this RFI: On behalf of an organization

Name: Karen Caputo

Name of Organization: Kelvin Smith Library, Case Western Reserve University

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
CWRU Libraries strongly supports NIH's elimination of the embargo period on publications resulting from NIH-funded research. Many of our researchers receive NIH funding and immediate access to their publications will help increase the visibility and impact of our researchers and the institution.
Furthermore, we were encouraged by the addition of language clarifying that deposit of the manuscript in PMC is a free option for compliance with the policy. In our previous comments, this was of particular importance to us. This clarified language will be especially useful for our researchers and librarians who are already hearing incorrect information from some publishers who claim public access policies require federally funded researchers to publish open access and pay an APC.
Finally, we would like to see pathways to deposit in repositories like PMC that also allow for deposit in institutional repositories or allow us to help our researchers with deposit into PMC. A common complaint by researchers is the added effort to deposit both in funder repositories and institutional repositories.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
As our library signed on to a Statement (https://sites.google.com/ucop.edu/the-right-to-deposit/statement) in support of using the Federal purpose license to implement the 2022 OSTP public access memo, we were encouraged to see the use of the Government Use License in this draft. We are also in favor of the agency providing language for researchers to share with their publishers to help create consistent messaging and transparency.
We would recommend the agency also include more explicit language allowing for public reuse of publications which accelerates the progress of science and increases innovation and collaboration. Our researchers benefit from being able to reuse NIH-funded research as well as benefit from reuse of their own research by others.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
As publication costs are sometimes covered through our transformative agreements with publishers, publication costs are of particular interest to us and the wider library community. Already our library has heard some publishers use 2022 OSTP Memo publication sharing requirements as talking points for why we should enter into transformative agreements with them and claim the 2022 OSTP Memo requires OA publishing. The clarification that the policy

does not require OA publishing and APC payment helps both our researchers and librarians in responding to these talking points and reassures our researchers that they still have the freedom to decide where to publish their work.
Our library supports NIH's decision not to pay fees for submission of manuscripts to PMC or other publishing costs that only apply to manuscripts subject to NIH or other agency's Public Access Policies. We agree that these are not legitimate publication costs. We would recommend that NIH continue to monitor publications costs and fees to help the community better understand publication costs and determine which are reasonable.

Uploaded File:

Description:

Submit date: 8/16/2024

I am responding to this RFI: On behalf of an organization

Name: Kacy Redd

Name of Organization: APLU, AAU, AAMC, and COGR

Type of Organization: Professional org association

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/2024-NIH-Public-Access-RFI-COGR-AAMC-APLU-AAU-final2.pdf

Description: The Association of American Medical Colleges (AAMC), Association of American Universities (AAU), Association of Public & Land Grant Universities (APLU), and Council on Governmental Relations (COGR) have provided comments on the draft Policy and the draft guidance on government use license and rights and publication costs.

Submit date: 8/16/2024

I am responding to this RFI: On behalf of an organization

Name: Samuel H. Selesnick MD FACS

Name of Organization: The Laryngoscope

Type of Organization: Professional org association

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   please see attached document

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   please see attached document

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   please see attached document

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/The-Laryngoscope-response-to-NIH-draft-public-access-policy-8-16-24.pdf

Description: The response of the medical journal, The Laryngoscope

Submit date: 8/16/2024

I am responding to this RFI: On behalf of an organization

Name: Yuanxiao Xu

Name of Organization: Authors Alliance

Type of Organization: Professional org association

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
We believe that the NIH Draft Public Access Policy serves an important role in furthering the interests of authors who want their work to achieve maximum reach and impact for the benefit of the public. Allowing immediate and free availability of Manuscripts on PubMed Central will increase research visibility and help authors reach a much larger audience. In turn, it will accelerate the pace of scientific innovation and expedite life-saving discoveries.

The removal of the embargo period will significantly improve transparency and accountability for NIH-funded research, helping combat low-quality research. Despite prestigious publishers' promise to provide rigorous peer reviews and editorial oversight, we continue to observe how commercial publishing is not the cure to fraudulent or defective publications. We know from experience that public oversight and free critique, enabled by free public access to the latest publications, is the best method of identifying and addressing bad research quickly.
Any delay in removing the embargo period is therefore harmful both to authors' interests and the public's. Accordingly, we strongly support NIH's position of not changing the proposed effective date of the new Policy. Some publishers may request a delay in removing the embargo period, because the publishers' monopoly over research outputs helps them maximize profits. The Draft Policy will hamper such plans—but that is a business model conflict, not a legal one.
We would like to emphasize that the removal of the embargo period does not conflict with the interests of grantees. In our experience, academic authors, universities, and federal agencies are largely in agreement that they would like to see the results of research reach the widest possible audiences and have the greatest possible impact.
Acting alone, most academic authors have very little power to negotiate favorable public access terms with their publisher, despite the authors' strong support for sharing and reuse. NIH's Draft Public Access Policy addresses this negotiating imbalance. It empowers authors to resist any pressure from publishers to assign exclusive rights to the publishers, ensuring that authors can share their work broadly and without delay.
We also recommend NIH to request source data resulting from NIH-funded research be made available publicly, and be dedicated to the public domain using a CC0 license. Currently, NIH grantees are able to fulfill their obligations under NIH DMS Policy by depositing data into certain repositories. Some of the repositories have embargo periods, and some are not easily accessible to the public. Such segmented and opaque storage of data prevents potential meta-analysis as well as a more comprehensive public discourse on the latest research findings. By contrast,

when research data is placed in the public domain and made transparent to all, other researchers and the general public are able to validate, replicate, and build on previous research more easily and smoothly.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
NIH has the legal authority to make NIH-funded research publicly available based on Federal Purpose License as codified in 45 CFR 75.322(b). Authors, universities, and research libraries have reached broad agreement that the Federal Purpose License is the appropriate mechanism and framework on which public access plans should be developed, and we strongly encourage NIH to follow and make full use of the rights this license affords it.
Certain aspects of the NIH's planned implementation could be confusing to authors and institutions, and so we encourage NIH to clarify several things:
First, NIH should clarify that its rights to use and provide public access to Manuscripts remains valid irrespective of separate licensing arrangement, including any subsequent license granted to NIH when grantees accept funding or when grantees agree to the proposed submission statement of PubMed Central. Considering the Draft Policy is "to become effective for Manuscripts accepted for publication on or after October 1, 2025, …whether the award or contract is new or ongoing," it is crucial for stakeholders to understand that NIH does not need a separate license to exercise its right to use grantees' Manuscripts.
Second, NIH should clarify the effect of the proposed submission statement to PubMed Central ("I hereby grant to NIH, a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use this work for Federal purposes…"). While this submission statement conveys to grantees in easy-to-understand language NIH's right to provide public access to Manuscripts produced under NIH grants, it can be confusing to use language that ostensibly transfers a new right that in fact is already conferred under the Federal Purpose License.
We think the submission statement to PubMed Central should be straightforward in conveying the fact that NIH holds pre-existing rights to make NIH-funded research publicly available, and that the ostensibly-new copyright license granted to NIH will at best act as a fail-safe in some unlikely legal scenarios. Similarly, we encourage NIH to carefully craft the language in Notices of Award and other related contracts, to ensure grantees understand that NIH has always had a right to use NIH-funded research as soon as grantees accept funding.
Third, NIH should publish further guidance on what reuse rights NIH is granting to the public. The Federal Purpose License clearly allows for such reuses ("The HHS awarding agency reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so." emphasis added), and the Nelson Memo specifically calls for clarity on this point ("plans should describe . . . any use and re-use rights, and which restrictions, including attribution, may apply.")
To maximize the value and impact of NIH-funded research, NIH should facilitate and encourage lawful reuse of articles, especially reuse using techniques such as text and data mining and AI-enabled computational research. These methods enable subsequent researchers to uncover new insights that have been previously unattainable through traditional means. We believe that fair use already allows for many of these uses. But, an explicit grant to use NIH-funded research will provide clarity and lower barriers to this kind of reuse. This can especially encourage reuse

among underprivileged and marginalized communities, when fair use, albeit a well-established and robust right, nevertheless is very complicated to understand and carries with it uncertainties that are too costly for those with fewer resources to shoulder.
The NIH can accomplish this with a modest change to its existing language. We agree with SPARC's comments that this change could be accomplished with text such as:
"NIH hereby exercises its right under this license to authorize members of the public to reuse the work for any purpose so long as the authors and the original publisher receive attribution in a reasonable manner."
In general, we commend NIH for addressing potential areas of confusion with regard to rights and permissions. It is especially helpful to provide authors with sample language to include in their Manuscript when submitting to journals for publication, so that journals are fully informed that the Manuscripts will be made publicly available. In this way, grantees can avoid potential legal conflict with downstream transferees or licensees of rights.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
We appreciate NIH's thoughtfulness in delineating allowable costs and unallowable costs. We agree that while grants should be allowed to cover reasonable publishing fees, no grant money should go toward paying "[j]ournal or publisher fees for submitting the Manuscript to PubMed Central…" or "[c]osts for publishing services that are charged differentially because an author's Manuscript is subject to the NIH Public Access Policy…"
At the same time, we would like NIH to make room for grantees utilizing NIH grant money to support other equitable solutions for publication, such as Diamond Open Access where no fees are levied against authors nor readers, or read-and-publish deals where institutions combine their subscription and publication deals for reduced costs.
We appreciate NIH's commitment to monitor publication costs and their potential effects on relevant communities beyond the implementation of the new Policy. It is important to remain vigilant that "publication costs" such as article processing charges (APCs) or other charges do not grossly exceed the true cost of distributing quality research. Grant money should be reserved for the production and dissemination of research rather than for generating extra profits for commercial publishers.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/Authors-Alliance-comment-for-NIH-draft-public-access-policy-.pdf

Description: The pdf file include footnotes

Submit date: 8/16/2024

I am responding to this RFI: On behalf of an organization

Name: Liz Borkowski

Name of Organization: Women's Health Issues

Type of Organization: University

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   We applaud NIH for taking steps to make agency-funded research findings immediately available to the public but are concerned about the potential impacts on journals such as ours that rely on subscription revenue — and the resulting impacts on authors who have the fewest resources. We suggest ways to modify the policy to mitigate the potential harms and enhance equity in academic publishing. Please see the attached comment for details.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/WHI-Comment-on-89-FR-51537.pdf

Description: Comments from the editor-in-chief and managing editor of the peer-reviewed journal Women’s Health Issues

Submit date: 8/16/2024

I am responding to this RFI: On behalf of myself

Name: Gabriel J. Gardner

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. Use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is a brilliant strategy that should apply to all research supported (even in part) by federal dollars. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional costs.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/16/2024

I am responding to this RFI: On behalf of an organization

Name: Sarah Ohlhorst, MS, RD

Name of Organization: American Society for Nutrition

Type of Organization: Professional org association

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   The American Society for Nutrition (ASN) appreciates the NIH's consideration of how its public access policy will impact the research ecosystem. Continual engagement and collaboration with the research community, including professional, scientific societies, is also central to the success of the public access policy. ASN encourages partnering with scientific societies like ASN to maximize networking capabilities and ensure future guidance and resources address author and other stakeholder concerns. These partnerships would favorably complement NIH's draft policy.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   ASN appreciates that authors are not expected to provide rights to NIH to the Final Published Article while understanding that NIH has a right to make Manuscripts arising from the funding publicly available in PubMed Central upon the Official Date of Publication. It is important for NIH to ensure that attribution to authors is maintained, as well as broad adoption of digital persistent identifiers (DPIs or PIDs) including DOIs and ORCIDs for funding sources, data descriptions, authors, data, and associated research products.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   ASN applauds the NIH for confirming that publications costs for electronic and print media, including distribution, promotion, and general handling are allowable expenses in research budgets, including page charges for professional journal publications. ASN is particularly pleased that the NIH's Grants Policy Statement allows the non-Federal entity to charge these costs to the Federal award before closeout, even if the publication expenses are incurred after the period of performance. This flexibility is vital, as publication acceptances and associated fees often arise after the closeout of awards.
   ASN also appreciates NIH's encouragement for authors to publish papers arising from NIH-funded research in reputable journals to maintain scientific rigor of publications. The concern remains that to save money, researchers may look for the cheapest publication option available, thereby hindering access to the scientific information resulting from federally funded research. While there may be greater overall access to the article, this could restrict access to the best scientific journal options in a researcher's field and therefore restrict visibility and dissemination to the intended audience. To help monitor this, the NIH could develop range distribution graphs of publication and data fees over time, showing points by quartile, along with relevant

demographic data, including the reach of an article within its field. This approach prioritizes quality over quantity, thereby preserving the integrity of scientific research and publications. Finally, ASN would like to highlight the positive experiences of authors who have published in our journals. These authors have consistently reported high satisfaction with ASN's rigorous peer review process, which they believe substantially improved their articles. The peer review process is crucial for enhancing scientific rigor and ensuring that readers access the highest quality content. Therefore, it is essential that researchers retain the ability to choose where they publish their work, ensuring the continued advancement of science.

Uploaded File:

Description:

Submit date: 8/16/2024

I am responding to this RFI: On behalf of an organization

Name: Emily Kansler

Name of Organization: The American Association of Immunologists

Type of Organization: Professional org association

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
AAI understands and appreciates NIH's goal of increasing public access to the results of federally funded research and is intensely aware of the importance of sharing accurate scientific and medical information with the public. AAI remains concerned, however, about the impact that this policy will have on not-for-profit scientific societies that publish scholarly journals, many of which rely heavily on subscription revenue from their journals to support their operations. Scholarly scientific society publishers play an essential role in the publication of high-quality scientific research by conducting peer review (including identifying appropriate reviewers), and by editing, disseminating, monitoring (including corrections and retractions), and archiving manuscripts/articles.
Furthermore, AAI appreciates NIH's acknowledgement that in order to make scientific discoveries accessible to the public, the information should be presented in digestible and meaningful ways. AAI has a long history of establishing programs and developing materials to assist the public in understanding complex scientific information, including during the COVID-19 pandemic and most recently with AAI's Immunology Explained campaign. As NIH moves forward, it should bear in mind the unique role and position of not-for-profit scientific societies and consider how to prevent harm as a result of this new policy.
The draft policy applies to manuscripts, defined as "the 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" that are "the result of funding by NIH in whole or in part." AAI urges NIH to explicitly define what constitutes a "manuscript," in particular by specifying whether review articles, editorials, commentaries, and/or perspectives are included under the term.
AAI thanks NIH for stressing the continued importance of peer review by requiring submission of the final, peer-reviewed author accepted manuscript (AAM) to PubMed Central (PMC). However, AAI would like to emphasize that the journal version of record (VOR) (defined in the policy as "Final Published Article") is the most scientifically robust version, as this version is typically copyedited, proofread, and screened carefully for errors and fraud (e.g., image manipulation) to ensure accuracy and scientific integrity.
In addition, AAI reiterates that NIH should consider ways to reduce the administrative burden associated with the policy. Many not-for-profit scholarly publishers, including AAI, currently deposit manuscripts into PMC on behalf of authors. As a result of the elimination of the 12-month embargo, revenue from subscriptions is likely to decrease, giving not-for-profit

publishers less ability to provide services like article deposition and potentially forcing them to shift this responsibility to authors. This in turn could make these journals less attractive to authors, making not-for-profit scholarly publishers less competitive in the marketplace and dealing a further blow to their efforts to not only publish high-quality journals but also provide educational and programmatic services to their members. AAI urges NIH to consider and implement ways to minimize the administrative burden resulting from the policy, including by widely communicating clear instructions and available resources for author-driven submission into PMC (Method C of the NIH Manuscript Submission System).

Given that the policy is set to become effective in just over a year, AAI urges NIH to create and disseminate a clear implementation plan, formulated with stakeholder input, to facilitate a smooth transition for publishers and authors.

Finally, AAI cautions NIH to be aware of, and prepared to address, the potential for an increase in misinformation and disinformation as a result of immediate and free dissemination of full-length scientific articles, which are tailored to highly trained experts in a specific discipline.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
AAI thanks NIH for the clarity provided on government use license and rights, and for providing standardized language which authors can easily insert into their final manuscripts. AAI appreciates that NIH does not require authors to use a particular copyright license to retain their rights to their final published articles. AAI encourages NIH to establish specific definitions of the terms “derivatives” and “reuse rights” in the context of this public access policy to ensure that authors understand their rights.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
AAI is pleased to see that the draft policy clarifies that direct or indirect costs may be used to cover reasonable, allowable publication costs. However, AAI is troubled that neither journal nor publisher fees for submitting a manuscript to PMC are allowable under the policy, especially given the financial constraints that this new policy will place on many not-for-profit scholarly publishers.

Further, NIH should clarify and more carefully define the “free pathway” of compliance described in the policy, to avoid misinterpretation that publishers should deposit manuscripts into PMC on behalf of authors without charging a fee. NIH should clearly communicate that the onus for deposition into PMC is on authors, and that the policy does not require publishers to deposit manuscripts on their behalf.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/AAI-Response-to-NIH-Public-Access-Policy-RFI_8.16.24.pdf

Description:

Submit date: 8/16/2024

I am responding to this RFI: On behalf of an organization

Name: Sarah L. Shreeves

Name of Organization: University of Utah

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   Please see attached letter.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/Coments-for-the-NIH-letter.pdf

Description: Full comments from the University of Utah

Submit date: 8/17/2024

I am responding to this RFI: On behalf of myself

Name: Andrea Wirth

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. Specifically, I appreciate the inclusion of the use of the Federal Purpose License. Additionally, I believe the NIH could be clearer about which rights usage rights the public has and agree with SPARC's suggestion to add the following:
   "NIH hereby exercises its right under this license to authorize members of the public to reuse the work for any purpose so long as the authors and the original publisher receive attribution in a reasonable manner." Public access should mean more than simply readability and including clarity in this part of the policy will ensure members of the public understand their rights and obligations in using the works.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   I appreciate the clarity around free paths to compliance and also about which fees are allowed (reasonable APCs) and which are not (paying to deposit).

Uploaded File:

Description:

Submit date: 8/18/2024

I am responding to this RFI: On behalf of an organization

Name: Adrian Ho

Name of Organization: University of Chicago Library

Type of Organization: Other

Type of Organization-Other: Research library

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
The University of Chicago (UChicago) Library (https://www.lib.uchicago.edu/) supports free inquiry and expression and strives to transform the global knowledge environment to be open, accessible, and equitable. We wholeheartedly endorse the National Institutes of Health's (NIH) draft policy that enables free public access to publications stemming from NIH-funded research with no embargo. This way, biomedical researchers everywhere will be able to build on the published findings more quickly to advance their disciplines. Similarly, clinicians can translate grantees' insights into practices without delay while providing services to their communities. Moreover, public access democratizes knowledge because people from all walks of life can benefit from NIH-funded studies without having to deal with financial or geographic barriers. It will be especially impactful in economically depressed regions in the world. Furthermore, public access increases the transparency of the funded projects, which enhances people's trust in science and boosts the return on the federal government's investments in the research enterprise.
The UChicago Library applauds the NIH for continuing the free pathway for policy compliance by means of depositing the author-accepted manuscript (AAM) in PubMed Central. Some researchers seem to have the misconception that compliance requires publishing in fee-based open access journals. To ensure that funded researchers are aware of the free pathway and understand the definition of AAM, the NIH may want to proactively provide grantees with information about them immediately after awarding the NIH funds. The NIH can also remind grantees that their institutions' research offices and libraries are available to offer assistance with policy compliance. In addition, we unconditionally support the language in the draft policy that payments charged to funded researchers for submitting their AAMs to PubMed Central will not be covered by NIH funds because they do not constitute legitimate publication expenses. This practice will deter publishers from purposefully creating a new fee for what they have been doing to support compliance with the NIH Public Access Policy. On the whole, the free pathway for policy compliance and the disallowance of publishers' fees for PubMed Central submissions will ensure that grantees can make the best use of their NIH funds to conduct their studies and to academically support graduate students and/or postdoctoral scholars on their research teams.
Enabling broad reuse of research outputs in general can propel new discoveries and innovation in various domains. Therefore, the UChicago Library encourages the NIH to explicitly authorize the public to make the fullest possible reuse of publications stemming from NIH-funded

research. SPARC (Scholarly Publishing and Academic Resources Coalition, https://sparcopen.org/) has proposed that the following language be added to the "Government Use License and Rights" section of the NIH Public Access Policy:
"NIH hereby exercises its right under this license to authorize members of the public to reuse the work for any purpose so long as the authors and the original publisher receive attribution in a reasonable manner."
The UChicago Library endorses the proposal. Alternatively, if the NIH considered requiring grantees to apply a Creative Commons Attribution 4.0 (CC BY 4.0) International License (https://creativecommons.org/licenses/by/4.0/) to their publications, it would facilitate much greater downstream reuse because the License's clear and explicit terms may lead to significant volume of research that occurs outside of academia. Moreover, we believe that computational processing of NIH-funded research publications with a CC BY 4.0 International License can potentially generate momentous positive impacts societally, scientifically, educationally, and economically.
The UChicago Library recommends that the NIH consider making funded research publications deposited in PubMed Central also available in digital repositories maintained by grantees' institutions. Doing so will elevate the online visibility and discoverability of the publications and reduce the reliance on a single access point. It will also extend the reach of the publications across different disciplines, potentially facilitating interdisciplinary collaboration and augmenting the overall impact of the funded research. Additionally, it will align with the LOCKSS (Lots of Copies Keep Stuff Safe) principle and safeguard the long-term access to and preservation of the publications. To prevent the burden that a grantee has to deposit their publication multiple times, the NIH can collaborate with the U.S. Repository Network (https://sparcopen.org/our-work/us-repository-network/) to investigate the possibility of operationalizing interoperability between PubMed Central and other digital repositories.
Last but not least, as the Office of Science and Technology Policy's Nelson Memo highlights the utility of persistent identifiers (PIDs), the UChicago Library recommends that the NIH specify its preferred PIDs to be used in the metadata of the funded research publications. Ideally, the preferred PIDs are based on the characteristics highlighted in the report, Developing a US National PID Strategy (https://doi.org/10.5281/zenodo.10811008), by the ORFG PID Strategy Working Group. A coherent and systematic approach to persistent identification of authors and contributors (for example with ORCID IDs), all research outputs, research organizations, and awards, will reduce administrative burden while increasing accountability, discoverability, and transparency of the PID-referenced parties/entities. It will also reveal the connections among the stakeholders of a funded study, facilitate accurate attribution of credit, and contribute to research information management. In other words, using PIDs will result in more efficient communications in the research ecosystem.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
SPARC has recommended that explicit authorization for public reuse of NIH-funded research publications be incorporated in two places in the Guidance:
1. In the statement NIH requires of authors submitting manuscripts to PMC, add to the end:

"I acknowledge that this includes the right of NIH to authorize members of the public to reuse the work for any purpose so long as the authors and the original publisher receive attribution in a reasonable manner."
2. In the sample language NIH recommends that authors attach to manuscripts, add to the end: "Members of the public are authorized to reuse this work for any purpose so long as the authors and the original publisher receive attribution in a reasonable manner."
The UChicago Library supports the recommendation because the addition of the language will ensure that grantees and readers of the publications understand the permission of broadest possible reuse. As noted in the previous section, the UChicago Library prefers that the NIH consider requiring grantees to apply a Creative Commons Attribution 4.0 (CC BY 4.0) International License to their publications in order to facilitate downstream reuse as much as possible. If the NIH decides to go in this direction, we recommend that a CC BY 4.0 licensing statement be added to the two abovementioned places in the Guidance.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
The UChicago Library thanks the NIH for providing this Guidance. The identification of unallowable costs and the list of factors to consider when assessing publication costs are illuminating. As fee-based open access journals continue to raise their article processing charges, this Guidance helps NIH grantees make informed decisions regarding how to prepare their research budgets judiciously. To remind grantees of available pathways to policy compliance, we recommend that the NIH reiterate in the Guidance the option of depositing the author-accepted manuscript in PubMed Central. Otherwise, the focus on publication costs may unwittingly lead funded researchers to think that they are required to publish in fee-based open access journals in order to be in compliance with the Public Access Policy. This perception may translate into less funding reserved for research activities. It may also be co-opted by publishers to justify and promote expensive open access agreements with institutions.

Uploaded File:

Description:

Submit date: 8/18/2024

I am responding to this RFI: On behalf of an organization

Name: Maria T. Abreu, M.D., AGAF

Name of Organization: American Gastroenterological Association

Type of Organization: Professional org association

Type of Organization-Other:

Role: Medical provider

1) **Provide any comments on the Draft Public Access Policy below:**
The American Gastroenterological Association (AGA) appreciates the opportunity to provide comments on the NIH Draft Public Access Policy. AGA is a 501(c)(3) nonprofit medical association representing 16,000 members who are involved in all aspects of the science, clinical practice, and advancement of digestive health and disease. In addition to serving our membership, we also publish five peer-reviewed publications and award over $2 million annually in research funding. As a publisher and funder, AGA fully supports the spirit of public access to the results of federally funded research. However, we believe that elements of the NIH Draft Public Access Policy – including the Government Use License and Rights guidance and the misconception that compliance with the policy is "free" – will have significant, unintended consequences that would be harmful to researcher-authors, institutions, and publishers (particularly those that are society-based) and counter the agency's intended impact of this updated policy. Overall, we urge NIH to consider partnerships with professional societies and publishers to leverage their existing efforts to enhance public access, ensure research integrity, and disseminate the results of federally funded research rather than pursuing efforts siloed within the agency.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
As a publisher, AGA facilitates the peer review process and ensures works published in our journals meet a variety of research integrity measures. Following publication, AGA retains the copyright associated with the final manuscript or publication. Two of our five journals are "gold" open-access journals and the other three journals fully support "green" open-access publishing in compliance with the current NIH public access policy as well as the proposed update to the policy. AGA and its publishing partner, Elsevier, safeguard each manuscript to ensure that content published in our journals isn't misappropriated or misused. This model works well for researcher-authors, their institutions, and publishers alike and ensures NIH funding results in high-quality publications.
Unfortunately, the draft Public Access Policy would require researchers to grant government use rights to NIH upon acceptance of funding. Further, it would require that "those submitting Manuscripts to PubMed Central will provide a license to NIH that mirrors the Government Use License as part of a revised Manuscript Submission Statement granting NIH the right to (1) make Manuscripts publicly available in PubMed Central upon the Official Date of Publication and (2) make Manuscripts available in Machine-readable formats to support accessibility and facilitate

text mining, consistent with current practice." The proposed policy would allow others (including government employees) to create derivative or altered works, in some cases without attribution to the author or publisher, and potentially in ways that are inappropriate or inaccurate. This would undermine the safeguarding provided by publishers.

AGA further encourages NIH to establish a minimum funding threshold or level of participation at which the Public Access Policy would apply. As currently drafted, the policy would require all NIH-funded researchers regardless of the amount of funding to hand over their rights to the NIH, but also allow NIH to "authorize others" (who are not clearly defined in the policy) to create derivative works. This is not only a violation of copyrights held by the authors and the publishers, but a possible vehicle for spreading misinformation. The agency has not communicated within the Public Access Policy how it plans to prevent misappropriation or misrepresentation of the original manuscript in derivative works, nor a method by which authors, publishers or the public can report such transgressions.

AGA strongly opposes this proposal, and at minimum encourages you to establish limits on the manner in which works can be reproduced or altered; requirements for attribution to the original author or publisher; and guidelines regarding the extent to which authors and publications, as applicable, must provide consent to the use or alteration of the publication. We also request that the NIH clarify its plan for enforcement should derivative or altered works misappropriate or misrepresent the original manuscript on which it is based and encourage the agency to work in partnership with publishers (including professional societies) who are already investing significant resources in safeguarding content that they publish.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Currently, researchers have a choice in whether they publish in "gold" open-access journals or through a "green" open-access route. This choice exists because publishers can subsidize the costs of the services they provide (e.g., peer review, research integrity checks, copyediting, production, and depositing into public repositories such as PubMed Central) through other means such as subscriptions. Though the NIH contends that compliance with the draft Public Access Policy is "free," the policy applies to manuscripts accepted by a journal that has gone through peer review and integrity checks that are not "free."

Further, the choice to publish "green" open access will become obsolete when more and more content becomes immediately accessible at no cost and there is no reason for libraries or individual users to subscriptions. Without subscriptions subsidizing the operational expenses associated with publishing a manuscript in a journal, reputable journals will begin to convert to "gold" open access where the article processing charges (APCs) paid by authors is the primary source of revenue. Though the NIH contends that its policy does not dictate any particular business model, the unfortunate reality is that the agency's actions will drive market forces that will change the industry and ultimately disempower authors from having a choice in how and where they publish their federally funded research. As noted in our previous comments, the proposed policy could also exacerbate inequities that disproportionately harm early-career researchers and those from under-resourced regions or institutions.

Finally, we note that the draft Public Access Policy would now apply to manuscripts resulting from funding (in whole or in part) by NIH that are accepted for publication in a journal on or after October 1, 2025. This may result in researchers with active grants or agreements with NIH

incurring (additional) publication costs that were not budgeted for in the initial award, should they choose to publish in “gold” open access journals to comply with the policy. AGA urges you to revise this policy such that it only applies to grants awarded after a certain date, or dedicate additional funding for unanticipated publishing costs as a result of the Public Access Policy.

Uploaded File:

Description:

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Katherine Eve

Name of Organization: Elsevier

Type of Organization: Other

Type of Organization-Other: Publisher

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**

Sustainable models and support for gold open access

We acknowledge that under the terms of NIH's draft public access policy, researchers will be required by NIH to make peer-reviewed article versions immediately available and asked to retain copyright. We also welcome the fact that NIH's definition of Journals includes that they are intended to be "published indefinitely." Prerequisite for this is the use of sustainable models. We will therefore enable researchers to comply with NIH's policy through the gold open access (pay-to-publish) model. Gold open access is a sustainable publication model, which reimburses publishers for their continued investment and innovation to ensure the quality, integrity, discoverability and archiving of research in perpetuity; goals shared by the NIH and public. The gold open access model has already been widely adopted by the research community and successfully implemented in many countries.

Conversely, we are unable to support approaches that aim to make subscription articles immediately and freely available, including approaches that require authors or their funders to retain rights via 'rights-retention'-like strategies. Such approaches are not sustainable in the long term given they undermine the subscription model on which they depend. This position is shared by the vast majority of journals and publishers. (ref: https://www.stm-assoc.org/rightsretentionstrategy/) It is also noteworthy, given OSTP's and NIH's emphasis on access to peer-reviewed versions, that deposited versions will not necessarily reflect the latest version, including important post-publication corrections and updates that are made to the Version of Record hosted on the publisher's platform. We therefore disagree with the draft policy's repeated emphasis of this route to compliance over and above other more viable publication models supported by publishers.

Researchers should not be placed in the difficult position of having to choose between sharing their work in their preferred way (which may include publishing in a fully gold open access journal) and complying with their funder's policy. Researchers should have the freedom to publish in their journal of choice, that will provide the best readership, reach and impact for their work, a policy goal shared by NIH and OSTP.

We therefore recommend that NIH adopts more balanced and neutral language in its policy as to publication model to support compliance. Specifically, the policy should make clear to researchers that publishing via the gold open access model remains an equal and viable option alongside other routes. This will better ensure compliance with the policy, support researcher freedoms to publish in the journal venue of their choosing, and ensure that NIH does not

encroach on market principles by directing researchers on the type of publication model or publisher value-added services they should use. This point is further explored under section 3, Comments on the Draft Guidance on Publication Costs, below.

Furthermore, policies that emphasize a single approach have the potential to create burdens for NIH researchers in determining how to comply with the policy where they are collaborating with other researchers who are subject to different funder policies, and with business and industry. A less restrictive and more business model-agnostic approach would better facilitate both collaborations and projects funded by multiple sources.

Further specific comments on the draft policy

Definitions

We suggest further contextualizing the proposed definition of "Official Date of Publication" with an explanation that this refers to the point when the article has volume/ issue numbers and pagination to provide additional clarity for researchers.

Regarding definitions for article versions, we recommend referring to the National Information Standards Organization (NISO) Journal Article Versions standard to avoid confusion as to the versions being referenced (ref: https://www.niso.org/publications/niso-rp-8-2008-jav, currently under review).

Scope

The applicability of NIH's new policy for all Accepted Manuscripts from October 1, 2025, will prove problematic for the tranche of awards that are already in flight before this date, given provision will not have been made for researchers to effectively plan how to comply with future policy requirements at the time of budgeting. We suggest the policy apply to new grants awarded from the effective date.

Further aspects of the draft policy are covered under the below sections.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**

We disagree with NIH's proposal to mandate researchers it funds to grant NIH wide-ranging rights to manuscripts, including to make derivative versions. There is no legal basis for this provision given the derivative work right in the draft policy language exceeds what is provided for by regulations that permit a federal agency to reserve a non-exclusive license in a work, including 45 CFR 75.322(b) referred to in the policy (ref: https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-75/subpart-D/subject-group-ECFR78b08d9c95aad03/section-75.322). Indeed, it is noteworthy that during a recent update to the Office of Management and Budgeting (OMB) guidance, 2 CFR 200.315 (b), OMB did not extend the license beyond permitting federal agencies to provide access to a manuscript in a federal repository (ref: https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR8feb98c2e3e5ad2/section-200.315). This is therefore inconsistent with NIH's stated principle that the license it is being granted should 'mirror' the Government Use License.

Additionally, we note that the Senate Appropriations Subcommittee on Commerce, Justice, Science, and Related Agencies (CJS) Senate Report for fiscal year 2025, emphasizes researchers' academic freedoms and directs OSTP to instruct federal agencies not to limit grant recipients' ability to copyright, freely license, or control their works (ref: https://www.appropriations.senate.gov/download/fy25-cjs-senate-report). The House CJS has recently raised similar concerns (ref:

https://docs.house.gov/meetings/AP/AP00/20240709/117502/HMKP-118-AP00-20240709-SD002.pdf). Additionally, the OSTP Public Access Memorandum, dated 25th August 2022, indicates that the implementation of its provisions should be consistent with applicable laws (including copyright law) (ref: https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf).

Moreover, public access policies should ensure that their goals around access to research are balanced with the need to ensure the integrity and veracity of the scholarly record – priorities we all share. This provision gives NIH the authority to revise authors' works at will and in line with a government agenda. The very inclusion of such a provision undermines public trust in an editorially independent scholarly record. Additionally, this provision could be used to enable ingestion of authors' works into Generative Artificial Intelligence (Gen AI) tools. AI brings new challenges to the world of research and publishing norms, and researchers are concerned about their work being misinterpreted and misused, or not being appropriately attributed or contextualised, within Gen AI tools. Crediting the work of others through referencing/ citations not only ensures recognition of individuals, but also provides provenance for findings and transparency, which underpins the research process. We therefore strongly recommend that NIH remove the derivative right from its draft policy given the considerable implications.

Further, NIH's requirement for researchers to grant it Government Use rights upon acceptance of funding puts undue burdens on researchers, who are placed in the position of having to either concede their academic freedoms to disseminate their future work in the way that they choose, or decline funding. Additionally, elements of the article may fall outside the author's copyright e.g., another author's figure they obtained permission to include; such article elements would need to be exempt. In line with this, we again recommend that NIH removes the derivative right from its draft policy.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

We welcome that NIH's draft policy allows researchers to budget 'reasonable' costs for publishing gold open access against their awards, which will be critical for grantees to be able to comply with NIH's policy and to publish in their preferred journal. However, we are concerned by the strong emphasis throughout the proposed policy on posting of the Manuscript to PubMed Central as a 'free' route to compliance, given that most publishers don't support this route, as outlined above under Section 1. Moreover, this is not a wholly 'free' route given the substantial amount of investment made by publishers to develop a write-up of an author's research into a peer-reviewed manuscript accepted for publication. As mentioned above, where researchers are required to make their work immediately and freely available, we will enable this through the gold open access (pay-to-publish) model.

Publishing gold open access requires funding through either Read and Publish agreements with institutions, or by encouraging researchers to use their own resources, such as funding from a grant. Researchers based at less well funded institutions, and early career researchers, are less likely to be able to obtain funds to publish their work open access unless they actively budget to do so as part of their grant.

We recommend that NIH provide its grantees with clear and consistent guidance to budget for the costs of publishing gold open access. This is vital to ensure researchers have the academic freedom to disseminate their work in their journal of choice and avoid compounding existing

inequities, which would inevitably result from NIH obfuscating the ability of authors to budget for gold open access publishing.
Additionally, the various guidelines and rules around what costs are deemed reasonable are complex and potentially confusing, creating a burden for researchers and their institutions to establish 'reasonableness.' Researchers themselves are best placed to assess what is reasonable, given their unique circumstances, and the publication options that are available to them that afford the best reach, readership and impact for their work. NIH should confirm, for researchers' reassurance, that researchers have ultimate authority over the decision for assessing 'reasonableness.'

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/Elseviers-Response-to-89-FR-51537.docx

Description: Elsevier's full response to 89 FR 51537 (with introduction)

Submit date: 8/19/2024

I am responding to this RFI: On behalf of myself

Name: Romaine F. Johnson

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/Letter-to-NIH-Trio.docx

Description: Comment on new rules.

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Heather Goodell

Name of Organization: American Heart Association

Type of Organization: Professional org association

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   Thank you for the opportunity to respond to the National Institute of Health (NIH) Draft Policy on Public Access of Federally Funded Research. The entirety of these comments is from the American Heart Association, a voluntary organization dedicated to fighting heart disease and stroke. Among other activities, we fund and publish research.
   We will address several issues posed by the draft policy including:
   - Need for author education by NIH
   - Value added by publishers to the accepted manuscript version of papers
   - Research integrity and trust in the American scientific enterprise
   - Applicable article types

   The majority of manuscripts deposited into PubMed Central are done either via bulk deposit by journal publishers or one-by-one by journal publishers on behalf of authors. An education campaign may be warranted to ensure grantees understand the changes. For example, authors will need to determine if journals will continue to bulk deposit and if not, what steps they need to take to ensure the article is deposited. Additionally, education of grantees may also be needed around the October 1, 2025 date. Current grantees may need to budget for fees that they did not anticipate. Authors may also need education that compliance extends beyond the closure of the grant even though the draft policy does not allow for publication fees at that time.
   Certain Article Types Should Not Be Included
   We are disappointed that the draft policy failed to clarify whether specific article types would be exempt. Our journals frequently invite experts to write commentaries, perspectives, state-of-the-art reviews, and educational content to help clinicians put the research into the context of their daily practice and to help patients understand the implications of the results. These opinions may also highlight limitations of the study or areas that require further exploration. No one would assert that these invited articles are the work product of a research grant, however funded researchers are incentivized to connect as many manuscripts as possible to a grant.
   We ask that the policy be restricted to articles detailing the results of original research.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   Publishers have facilitated the goals of the NIH, under congressional requirements, to make publicly available the results of research as accepted by journals within 12 months of

publication. This new policy goes too far in assuming rights that Congress has not authorized, that the Office of Management and Budget (OMB) has specifically not claimed and is contrary to copyright law. Further, federal purpose is a non-statutory claim.

As the NIH is aware, journals not only facilitate the timely peer review by our expert physician/scientist editors of submitted manuscripts leading to improvements to the manuscripts, but journals staff and/or physician/scientist editors also routinely conduct an intensive integrity review (was the trial registered, were IRB approvals completed, were CONSORT standards followed, is the manuscript free of plagiarism, did all authors contribute, were financial disclosures included, are the figures free of inappropriate manipulation, has the accompanying data been made available to the public, etc.). These research integrity tools require staff, vendors, platforms, and extensive trainings for staff and physician/scientist editors.

Further, our expert physician/scientist editors ensure that abstracts, titles, and conclusions accurately represent the results of the research. The editors also facilitate biostatistical reviews of content in addition to the standard peer review. It is not uncommon for submitted manuscripts to go through more than one review cycle. In fact, it is extremely rare that revisions would not be requested, triggering further review of those changes.

Societies such as the American Heart Association have a vested interest in helping the authors improve their manuscripts to be the best output possible. This work benefits us, benefits the authors, benefits the clinicians and patients they treat, and ultimately benefits the NIH. And yet, it is this version of the manuscript that the policy takes, makes public with no opportunity for embargo, and now requires reuse and derivative rights to. This policy severely undervalues the work that journals and societies like ours put into the improvement of submitted manuscripts.

While we appreciate that the draft policy does not limit publisher's ability to license content by requiring a CC BY license, the NIH has essentially taken those rights without any requirement for attribution.

This policy draft would give the NIH the right to reproduce papers, create derivative works, and allow others to do the same on the version of the manuscripts that journals have invested resources in to improve. The NIH should educate authors on what this means to their rights to their manuscripts.

It is extremely concerning that the NIH is requiring researchers, some of whom may have minimal federal funding associated with a manuscript, to hand over rights to the NIH that may allow others (not defined or limited) to reproduce AND create derivative works of the accepted manuscript. In essence, this draft policy could allow a third party or the government to recreate our journals in a different format or create new products with the content with no attribution to the author or the publisher. This is a direct violation of copyrights held by the authors and the publishers who accepted the work and possesses a significant risk of perpetuating misinformation.

More concerning is that the NIH is reserving the rights to alter the content. While we expect it is not the intent of the NIH to modify published research papers, as written, the policy allows for this possibility. As presented in the draft policy, the NIH would have the right to alter the results described in a manuscript to fit a political agenda or add inappropriate content to a paper—without the consent, and yet under the byline, of an author.

Our journals are seen as trusted sources of clinical content directly affecting patient care. The American Heart Association journals take that role seriously through our manuscript reviews, our conflict-of-interest policies, and our processes for handling issues of research integrity. Our journals serve a mission to attract and disseminate the highest quality and most impactful clinical content to the communities we serve and the public.

This draft policy requiring authors to deputize the NIH to extend to others the right to use or alter content without permission and without attribution removes safeguards and puts the reputations of our journals, our societies, and our researcher members at risk.

Further, this draft policy would allow the NIH to grant permission to third parties to ingest our copyrighted content into online indices and AI tools. AI companies are already taking our full text content out of PubMed and using it to train their AI tools without our permission, without attribution, and without any remuneration. This is an area where societies could use support from our government instead of allowing the government to enable this unauthorized use of our content.

Updates, corrections, and retractions of content already confuse the archive of literature when content is reproduced, reposted, and derivative works created without attribution or notification to the copyright holders.

At a time when public trust in science is fragile and trust in government institutions is at historically low levels, a policy that allows the government to manipulate scientific research papers carries unintended consequences that may erode trust even further. Researchers, patients, and policymakers trust that the content in PubMed and PubMed Central come from sources that carefully review and publish content that is accurate and impactful.

Using non-statutory “federal purpose” language and declaring a “Government license” is unprecedented and unnecessary for the purpose of providing the public with access to the accepted manuscripts.

As has been noted in the 2025 report from the House Subcommittee on Commerce, Justice, Science Appropriations that accompanied their budget, “Researchers should have the right to choose how and where they publish or communicate their research and should not be forced to disseminate their research in ways or under licenses that could harm its integrity or lead to its modification without their express consent.”

In fact, when our members are given a choice between a Creative Commons Attribution Only license (CC BY) or a more restrictive version that does not allow for derivatives or use in commercial activities (CC BY NC-ND), authors overwhelmingly select the more restrictive licenses.

The NIH draft policy takes an extremely bold step in requiring rights to a version of the manuscript that has been improved, vetted, and given a branded stamp of approval by our non-profit scientific organizations. By requiring these rights to journal peer-reviewed and approved content, this policy not only infringes on the authors’ right to retain and control the rights they want to confer, but also infringes on the rights of the publisher of the journal.

As a a society with a non-profit mission, we stand ready to continue to support a green open access approach to making the NIH policy work—even with shortened embargoes. However, we cannot support a zero-embargo green model if the NIH insists on outsourcing the quality control of manuscripts produced by NIH grantees to our journals, usurping rights to reproduce and

create derivative works from the content and infringing on our ability to recoup our expenses through subscriptions or other access models.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

We continue to be concerned that this policy draft will force more and more journals to flip to an Article Processing Charge funded open access model. If journals do not have the ability to recoup expenses through subscriptions because of zero embargo and have added concerns about the rights the NIH are requiring, moving to an APC model may provide a more sustainable revenue stream.

While the NIH has always contended that they are "business model agnostic," this policy fails to take into consideration the obvious market forces that will affect the industry. Because this policy extends the deposit requirements beyond the grant closing date and yet does not allow for researchers to use NIH grant money to pay publication fees for those papers, the policy adds a burden to the researchers. Hastening a move to more APC funded open access will be extremely expensive for US Institutions, funders and authors as well as exacerbate the inequalities inherent in the APC model of open access globally as well as with under-resourced domestic institutions, many of which support diverse students and investigators.

Deposit of Accepted Papers is Not Free

An argument could be made that a policy that requires authors to deposit a preprint (manuscripts prior to peer review) into PubMed Central is free. However, that is not this policy. This draft policy requires that manuscript deposits undergo extensive quality checks and rounds of improvements prior to deposit. These activities, as explained elsewhere, are not free. Publisher agreements with the NLM require that publishers deposit "electronically readable versions of full-text journal articles and other journal content, at no expense to NLM" and "in XML format, using a mutually agreed upon DTD." Producing these formats and developing workflows for a subset of manuscripts to be delivered to the NLM, with associated metadata, incurs expense and staff resources.

Devaluing subscriptions by imposing zero-embargo on the quality approved and journal branded content comes at expense—in the form of loss of revenue-- for the journals and non-profit societies. To date, the NIH has not provided an Economic Impact Statement on the financial impact of this draft policy on American societies and publishers. This policy as drafted will disproportionately affect smaller societies, particularly those whose journals are not sustainable as fully APC funded open access journals.

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I am responding to this RFI: On behalf of an organization

Name: David Schuster

Name of Organization: Binghamton University

Type of Organization: University

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   The Draft Public Access Policy advocates for unembargoed access to NIH-funded research and is a crucial step in fast-paced public health industry research and development. By providing free access to biomedical research, the policy ensures that researchers and healthcare providers have immediate access to the latest, often groundbreaking, information, significantly contributing to the public good.
   Our pharmacy school recently discovered new medications. Unembargoing this research finding would help doctors and other researchers have direct access to this critical information. Often, hospitals may not have subscription rights to the latest publications, especially in rural America. Opening this information to the public not only benefits the medical community but also empowers individuals in the community. It may help someone in a community with Parkinson's to share developments with their doctor and offer life-changing knowledge.
   This policy provides the right direction for making articles more accessible and unencumbering authors from fees when submitting them to PubMed Central(PMC). This ensures publication costs do not hinder the researcher's ability to comply with the policy. The legal contracts universities must sign to consider transformative agreements are complex and challenging, so any clarifications from the NIH in reducing barriers are critical to helping researchers. Free compliance with depositing articles to PMC makes this vital information publicly available and reusable.
   In addition, the suggested language for the "Government Use License and Rights" should clarify the current concerns of researchers and authors. "NIH hereby exercises its right under this license to authorize members of the public to reuse the work for any purpose so long as the authors and original publisher reasonably receive attribution."
   The proposed language for the "Government Use License and Rights" is a significant step forward. It clarifies the rights of the NIH and allows universities to showcase the work being done at their institutions by enabling submission to local repositories. This further promotes the discovery and access to publicly funded research and aligns with the U.S. Repository Network's goals of achieving the desirable characteristics of digital publication.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**

It would be a tremendous help to incorporate language into the policy that explicitly authorizes the public to reuse publications generated from NIH-funded research with proper attribution. The statement should also include the reuse of publication guidance in two places.
1) In the statement, NIH requires authors submitting manuscripts to PMC; and
2) In the sample language, NIH recommends that authors attach to manuscripts.
These suggestions help users and authors understand how works can be reused and ensure that the public can broadly reuse the work.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
It is essential to have language and guidance on nonallowable publisher fees that further help determine reasonable costs. A pay-to-publish model creates inequality in distributing new information to hybrid subscription/open-access publication avenues. With these changes and guidance, NIH ensures a wider free path to compliance and enhanced access to publicly funded research. Working with publishers on campus-wide transformative agreements to reduce fees for authors has been legally challenging for universities and contracts. The proposed language provides administrators of libraries and universities with authoritative language to use as part of the negotiation process and an additional source of support for why these types of contracts are critical.

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Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Andrew Bostjancic

Name of Organization: Taylor & Francis

Type of Organization: Other

Type of Organization-Other: Private

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Jonah McAllister-Erickson

Name of Organization: West Virginia University Libraries

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
WVU Libraries (or WVU) commends the NIH for eliminating the embargo period on publications resulting from NIH funded research. Providing immediate and free public access to biomedical research will ensure that the public, researchers, and healthcare providers have the latest information available to effectively understand and address public health challenges. WVU is an R1 institution that spent approximately 6.5 million dollars on collections in 2023, with 90% of the expenditure dedicated to subscriptions. Yet there are many important health sciences titles that WVU cannot afford to subscribe to. This limits clinicians and researchers affiliated with the university from accessing thousands of articles, until they are made publicly available through PubMed Central. In part to bridge that divide WVU Libraries requests roughly 22,000 items through Interlibrary Loan per year many of which were to support medical research.
We also commend the NIH for clarifying that an article is considered published when it is first made available in a finally edited version. Often, we see articles in their final published form that are released ahead of print but are not assigned to an issue for several months after being made available on the journal's website, which creates an additional unnecessary delay in public access to NIH funded research.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
WVU urges the NIH to add to the Public Access Policy an explicit right for the Public to re-use publications in whole or in part so long as they provide appropriate attribution to the author and publisher. This would be best accomplished through the requirement of a Creative Commons license by author.
Much of the best scientific work is built on already existing scholarship, immediate public access is a step in the right direction, but merely being able to read scientific scholarship only advances knowledge so far.
Within the scholarly community there is a great deal of confusion when one is required to request permission to re-use previously published works. This is compounded by confusion between Open Access, where the work is licensed under a Creative Commons license, and Public Access. Many researchers at WVU are shocked to discover that they have to request permission to re-use, figures, tables and other visualizations for some articles that are freely available through PubMed Central. Not only does requesting permission require time and effort, and in some instances when permission cannot be secured requires a duplication of effort to re-create visualizations, it can also cost money. Although many publishers have policies that allow some

gratis re-use of figures, such as the STM Permission agreement, some publishers such as the American Medical Association routinely charge fees for the re-use of figures and tables, even for their own authors re-using materials in their thesis or dissertation. Adding an explicit re-use right through the requirement of a Creative Commons license would remove another barrier to scientific exploration.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
WVU appreciates the restatement of the types of publisher fees that will NOT be considered allowable costs (article development charges, charges for peer review, PMC deposit charges etc.) as well as the guidance in assessing whether costs are reasonable, including their impact on institutional budgets, given that significant publishing activity occurs after the performance period of an award, and thus without the ability to use NIH funds.
As fees that some publishers charge for Open Access, continue to increase, out pacing inflation, with the maximum APC for fully OA journals at $8,900, and Nature now a hybrid journal toping $12,290 we expect to see decreasing institutional ability to support APCs especially when coupled with other budgetary constraints. , For example, our university's budget model does not centralize costs such as this and due to recent budget cuts the WVU libraries had to discontinue our Open Access Author Fee Fund which sought to advocate for and encourage open publishing. The trend towards higher APCs will also lend itself to greater inequality between authors based on their institutional resources, as well as between more senior research with robust grant funding and new career researchers.
Despite our budgetary constraints WVU continues to invest in Open Access, but supporting collective funding strategies, such as Diamond Open Access, and Subscribe to Open (S2O), as well as alternative models of research communication such as the use of pre-print servers, depositing version of an article in our institutional repository.
We think that it is crucial that the NIH ensures that there is always a free (beyond ensuring that deposit in PubMed Central is free) path to compliance with the Public Access mandate, as well as more robust guidance on when and when not to pay fees required by some publishers.

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Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Agathe Farrage

Name of Organization: American Psychiatric Association

Type of Organization: Other

Type of Organization-Other: Medical Association

Role: Medical provider

1) **Provide any comments on the Draft Public Access Policy below:**
On behalf of the American Psychiatric Association (APA), the national medical specialty society representing over 38,900 psychiatric physicians and their patients, we thank you for the opportunity to comment on the National Institutes of Health's request for information regarding the draft public access policy.
APA Publishing is the world's premier publisher of books, journals, and multimedia on psychiatry, mental health, and behavioral science. In total we provide content in 6 journals, and 25 books each year. We offer authoritative, up-to-date, and affordable information geared toward psychiatrists, other mental health professionals, psychiatric residents, medical students, and the general public. APA's publishing division supports the organization in its wider mission to advance and represent the profession of psychiatry, ensuring that we serve the professional needs of our members, and promote universal and equitable access to the highest quality of care mental health patients.
APA supports a flexible, functioning, sustainable ecosystem for scholarly communication where a range of business models is available to provide equitable opportunities both for authors to publish their research in high-quality journals, and for readers to access that output.
APA takes very seriously the critical work of publishing articles that are seen as a trusted resource of content for all psychiatrists and mental health professionals who need to stay on the cutting edge of best practices in the diagnosis and treatment of patients with mental illnesses. APA therefore continues to invest in an infrastructure that supports intensive peer review, additional biostatistical review, as well as research integrity tools to monitor conflicts of interest, financial disclosures, and plagiarism checks. In addition, journals maintain strict guidelines on authorship criteria and standards for reporting and recording clinical trial and research participant data. It is a concern that it is this version of the manuscript, in which APA has invested significant resources, that the policy would require APA provide with no embargo. In addition, it is of paramount importance that APA protects the intellectual property and rights of our authors and it is therefore a concern that the draft policy gives the NIH rights to reproduce the work of our authors without attribution, to change the content, and to allow the creation of derivative works. Such changes, without author review or approval, would undermine the integrity of the work and risk introducing errors and misinformation at a time when trust in the scientific record is under considerable strain. New research and evidence-based practices help clinicians advance the health of patients. If information is distorted or

selected on a predisposed premise patients may not receive the highest quality care and at worst are put at risk.

APA supports a "green open access approach" and will maintain its current process that delivers accepted articles from NIH-funded research to PubMed Central on behalf of our authors to enable this new draft policy. A zero embargo, however, will serve to devalue subscriptions, limit APA's ability to recover the significant expense of the publication and archiving process, and ultimately force a move to an article-publication-charge (APC) business model. APA cannot support the proposed model because it may result in fewer options for authors to publish their work and will have a deleterious financial impact on our journals that would put the Association's mission at risk.

Finally, APA is concerned that the date on which implementation of this new policy is due to start has been brought forward to 1 October 2025. Given the required technical changes, as well as the necessary communication to and education of authors, APA requests additional time for developing an effective implementation plan.

APA is happy to continue this conversation with you to find mutual areas of agreement that maintain the integrity of our published output, and delivers a sustainable scholarly communication system. If you have questions, please contact Simone Taylor, Chief of Publishing at staylor@psych.org.

Sincerely,

Marketa M. Wills, MD, MBA, FAPA
CEO & Medical Director

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Jennifer Crosswhite

Name of Organization: National Council on Family Relations

Type of Organization: Professional org association

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
RE: ‘‘Draft NIH Public Access Policy and Request for Information” regarding governmental use license and rights and publication costs. [89 FR 51537] [NIH- 2024-13373]
Dear Ms. Leeds,
Thank you for the opportunity to share our views on the Draft NIH Public Access Policy. We appreciate this important feedback mechanism and look forward to working with NIH to deliver meaningful outcomes that advance open science and research. We support the objectives of the Draft NIH Access Policy, and we hope to work with NIH to ensure that academic societies who publish journals and own the rights to published articles are considered when finalizing policies.
The National Council on Family Relations (NCFR) was founded in1938 and is the oldest nonprofit (501c3), nonpartisan, professional academic society focused solely on understanding families through interdisciplinary research, theory, and practice. NCFR's mission is to provide an educational forum for family researchers, educators, and practitioners to share in the development and dissemination of knowledge about families and family relationships, establish professional standards, and work to promote family well-being. One of our core values is to create and catalyze leading-edge research, theory, and practice.
We commend the NIH for thinking through how the public may access NIH-funded published findings easily. It is important that published research findings are easily and equitably available to improve the health of individuals and families. We agree that OA research can accelerate future research, lead to collaborations, and allow others to stay up to date with critical advances.
As a partner with Wiley, we support Wiley’s belief that, to be truly equitable and effective, any well-informed public access policy should adhere to the following principles:
- Endorse the final published Version of Record (VoR) as the article format which will deliver the full benefit of OA to the scientific community and society at large;
- Include a Federal funding mechanism that recognizes the cost of peer-review, editing, publication, distribution, and long-term stewardship of articles, alleviating the administrative and financial burden of publishing costs from universities, libraries, and individual researchers; and
- Leverage the many services currently provided by publishers to advance discovery and innovation, thereby avoiding a duplication of efforts and investments already made in support of OA.

Timeline of Public Access Policy Applicability and Noncompliance

According to NIH Draft Public Access Policy, “NIH is not proposing an end date for applicability to manuscripts arising out of awards. Non-compliance with the NIH Public Access Policy may be considered by NIH regarding future funding decisions for the recipient institution.” We certainly understand the need to develop timelines and respond to the 2022 OSTP Memorandum. We appreciate that “NIH is committed to working with the research community to prepare for the implementation of the final Policy.”

It would be helpful to the research community and academic societies for NIH to provide guidance on:

- How to comply with the Policy when NIH-supported researchers submit articles for publication long after their NIH funding has ended.
- How noncompliance will be monitored and enforcement measures will be implemented in a manner that is financially sustainable, transparent, and equitable. It is essential to recognize that smaller organizations

may have a reduced capacity to engage with regulators to ensure compliance. Smaller entities often lack the resources, such as legal counsel and specialized compliance teams, to navigate the complexities of the public access landscape effectively. Consequently, smaller entities may be unaware of specific requirements or unable to meet them adequately, leading unintentionally to non-compliance and potentially resulting in a disproportionate number of negative funding decisions affecting these institutions.

- Whether the noncompliance consequences apply to all authors on the one published Manuscript or the principal investigator(s) only.
- How long the compliance requirements will be in place. Even after the grant has ended, the previously funded researcher remains on the hook for paying publication costs for any resulting work even though funds are no longer available. A failure to do so will reflect poorly on any future applications for funding. An end date for compliance is encouraged.
- How noncompliance will affect future funding decisions. If noncompliance means that an individual will no longer be granted NIH funds, that should be said. It will be helpful for authors and academic societies to have clear guidelines and avoid striking fear. However, withdrawing funding as a penalty for unintentional noncompliance would impede scientific progress rather than facilitate it. We urge the NIH to provide clear, detailed guidelines and robust support mechanisms to ensure that all institutions, regardless of size, can comply with the policy on an equal footing. This approach will help to avoid inequitable outcomes and support the overarching goal of fostering broad and inclusive access to publicly funded research. It is also crucial to recognize that the implementation of new funding guidelines, along with the necessary updates to infrastructure and publishing workflows, demands substantial time, effort, and investment from publishers and academic societies. The introduction of varying or conflicting policies would further complicate this process, potentially making it unfeasible without resorting to time-consuming and error-prone manual workflows. To facilitate this transition, NIH should offer clear and easily understandable compliance guidelines and assign dedicated personnel within agency funding offices to provide direct assistance. We advise that any policy that does not allow adequate time for journals and publishers to update their systems and processes will be less effective.

Policy Effective Date

The Draft NIH Public Access Policy shortened the effective date to October 1, 2025, to allow capturing all Manuscripts accepted for publication regardless of whether the award or contract is new or ongoing.

The language used makes clear that requirements will apply to all existing grant recipients rather than just those funded after the policy is implemented ("This approach has the benefit of capturing all Manuscripts accepted for publication regardless of whether the award or contract is new or ongoing"). This retroactive implementation directly disadvantages grant recipients who were not given the opportunity to budget for the necessary publication charges. Those researchers will instead need to pay the newly required expenses of APCs out of their existing funds, requiring the sacrifice of things such as purchasing equipment or paying salaries. It also rapidly advances the timetable for journals to get ready for these massive changes, as all papers will be subject to the new policy, rather than phasing it in over time through new grants.

Rapidly adjusting the timetable is not equitable to smaller organizations (scientific partners) as they do not have the staff to track NIH and other agencies' plans to address the Policy. Thus far, no plans have been provided that address all agencies and dates. It will be difficult for smaller organizations to comply.

Relatedly, the October 1, 2025, deadline differs from other Federal agencies. Such an inconsistent approach to

implementation will create increased regulatory burdens for organizations by complicating the already complex landscape that organizations must navigate to ensure compliance. Without a comprehensive Federal repository that catalogs key information, organizations face significant difficulties in tracking and adhering to varying requirements, leading to potential non-compliance and administrative inefficiencies. We request greater clarity across the agencies.

To address these concerns, we urge NIH to reconsider its policy effective date and establish a unified article database in coordination with other agencies, which provides: (1) clear documentation of public access policies by agency; (2) updates on major changes and key compliance obligations; and (3) a detailed timeline of policy effective dates. By developing and implementing such a resource, the Federal government can alleviate regulatory burdens, streamline compliance efforts, and advance equity and inclusion efforts by supporting organizations in fulfilling public access requirements effectively and efficiently.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**

Rights in Manuscripts

We appreciate the purpose of having all NIH grant-funded published research available OA and agree with that intent. We can also understand requiring a statement to be included on said articles allowing the articles to be published in PubMed.

However, according to the NIH Draft Guidance on Governmental Use License and Rights, authors

will transfer all rights to the government. Specifically, the draft policy says "By accepting NIH funding, the

recipient grants to NIH, as the funding agency, a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others

to do so. This includes making Manuscripts publicly available in PubMed Central upon the Official Date of Publication."

The meaning and purpose of "a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so" is unclear. The language does not describe what types of purposes for such a right would be appropriate. This language raises important questions about regulatory overreach and compliance with copyright laws. It seems, the language was included to allow the Manuscript to be submitted to PubMed, which is currently allowable under the stated policies. It is also possible that the language was designed to ensure that program officers and grant panels could use copyrighted material during grant analysis or for broader internal agency purposes. There also appears to be interest from some within the Administration to test whether this language could be used by the Federal government to supersede exclusive rights of copyrights holders who received Federal grants.

The Federal Copyright Act is a direct exercise of Congress's constitutionally sanctioned power to "promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." It explicitly grants copyright owners a range of exclusive rights, including the right to reproduce their works, distribute copies to the public, and prepare derivative works based on their original creations. We rely on these protections to maintain the integrity and economic viability of the works we publish with Wiley, our publisher. On the contrary, "Federal Purpose language" emanates from the Code of Federal Regulations (2 CFR §200.315 (b)). In citing 2 CFR §200.315 (b)(b) as authority for Federal agency public access plans, agencies assume powers with regard to copyright that belong to Congress under the Constitution and are exercising them in a manner that is inconsistent with both the letter and spirit of the Congressional exercise of those powers in the enactment of the Copyright Act. Neither the Constitution nor the Copyright Act authorizes Federal agencies or departments to issue regulations that restrict or eliminate the exercise of such
exclusive rights by copyright owners, including as conditions for the receipt of Federal funding or in any other regulatory context.

Public access mandates did not exist at the time the "Federal purpose" regulation was proclaimed, and the extension of this regulation raises considerable questions.

Retaining Rights to Articles

In response to the public comments, NIH said it would clarify how NIH-supported investigators may retain sufficient rights to NIH-supported peer-reviewed Manuscripts. NIH proposed to develop language that NIH- supported investigators may use for submission of their peer-reviewed Manuscripts to journals to retain rights to make the peer-reviewed Manuscript available in PubMed Central without an embargo period. NIH Draft Public Access Policy, however, did not clarify how NIH-supported investigators may retain sufficient rights. Nor does the draft policy discuss the rights of academic societies as the copyright owners of Final Published Articles. It is critical that NIH provide clarification on how NIH-supported investigators and academic societies who publish may retain their sufficient rights to the Final Published Articles.

One potential unintended consequence of transferring all rights to NIH is that authors and academic societies may choose not to seek NIH grants to avoid the proposed transfer of rights.

This potential outcome is not equitable as those individuals and publishers would not have equal access to NIH grants. This unintended consequence becomes problematic for the journals, societies, and authors who typically publish NIH-funded research and publish in our high-profile journals. There needs to be a compromise between NIH and the publishers and academic societies to protect the integrity of journal articles and our intellectual property.

As the current owner of articles published in Journal of Marriage and Family, Journal of Family Theory & Review, and Family Relations, the move from publishers holding the rights of the journals to that of NIH will hinder our work. As the owner of said journals, we reuse the content in myriad ways (e.g., republishing the articles in other NCFR publications). Removing our ownership of those articles impacts our academic society and business.

Would we now have to ask NIH for permission to republish the articles in another NCFR publication? Doing so would add unnecessary barriers to increasing the visibility of said research. It would be acceptable for the statement to read “By accepting NIH funding, the recipient grants to NIH, as the funding agency, a royalty-free, nonexclusive and irrevocable right to reproduce and publish.” We also recommend that a statement be included stating the rights of academic societies to reproduce and republish in accordance with their current business practices.

Related, with these rights being transferred to NIH to use the work for Federal purposes, what happens if someone uses the peer-reviewed Manuscript in a way that conflicts with the Final Published Article? How will NIH ensure that the research is used in a manner consistent with the Final Published Article? We fully support Wiley’s recommendation: Endorse the final published VoR as the article format which will deliver the full benefit of OA to the scientific community and society at large.

Governmental Use of Articles and the Creation of Derivatives

We are particularly concerned about the language in the proposed copyright transfer statement that says, “or otherwise use the work for Federal purposes, and to authorize others to do so” and “includes the right to create derivative works.”

NIH's quest for derivative rights poses a risk of disrupting the scientific record and undermining scientific integrity. Having this broad of a license allows anyone in the Federal government, or those authorized by the Federal

government, to create derivatives and use the work as they deem. The possible alteration of the scholarly record without notifying or obtaining approval from rights holders could result in a record that diverges from the official VoR. What assurances can you provide that will prevent government officials from making derivatives of the published findings that no longer are accurate? What guidance can you provide that will assure that the scientific research is used in a manner that is consistent with ethical science and that is consistent with the Final Published Article? Clarification is also requested as to whether the Federal government could sell the article rights to others.

Relatedly, “the right to reproduce, publish, and otherwise use” poses a significant threat to the integrity of content and the foundation of scientific research the US has championed for decades and raises concerns about potential interference, both political and apolitical. This provision could create an environment where Federal agencies, subject to the political views of

an administration, may be directed to alter “controversial” scientific and medical research to align with political agendas rather than scientific evidence.
Such a scenario would undermine the credibility and reliability of scientific research, which relies on the objective and unbiased dissemination of findings. If Federal agencies are instructed to modify or selectively reproduce works to align with political messaging, it could erode public trust in scientific information. This potential for alteration and manipulation of research jeopardizes the integrity of individual studies and places at risk the broader scientific community's efforts to advance knowledge and address critical issues based on sound research.
As suggested in the Federal Registrar, a statement is needed on NIH-funded articles to make the Manuscript publicly available. Given the problems associated with transferring all article rights to NIH, we highly recommend that the statement be amended to only allow articles to be publicly available on PubMed and nothing more.
Further, we need assurance that the content of said article is not used for other purposes than making the article OA. Nonexclusive right to reproduce, publish, and otherwise use the work for Federal purposes, to authorize others to do so, and to create derivatives is too broad of a license and is not something that NCFR, as the current rights holder of journal articles, is comfortable with permitting.
We urge NIH to revise the rights statement to include only making the article publicly available on PubMed.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

We appreciate the intention to monitor publication costs so that it is equitable for all individuals, including those who are less resourced, to publish. It is also helpful for “reasonable costs” to include all publication fees (e.g., OA fees). It is unclear what other reasonable publication costs are included. Guidance on what is and is not included as a reasonable cost, and that is equitable and clear would be very helpful. For example, are article submission fees an allowable, reasonable cost? What other costs are reasonable?
We appreciate the list of unallowable costs, and many are appropriate. Some questions arise though about some unallowable costs:

- Peer review: The draft guidelines indicate that peer review cannot be paid for through the grant when there is not a resulting publication. Does that mean that the grant will pay for peer review when there is a resulting publication? How does the grant money move from the authors to that of the editorial office who invites individuals to conduct the peer review? Are other author services acceptable (e.g., translation
services) when there is a resulting publication? What happens if the article is anticipated to be published, the services are paid for, and the article does not get published? Clearer guidance would be helpful.
- Duplicative costs (e.g., fees the university already pays for; transformational agreements). How will duplicative costs be monitored and enforced?

It would be most helpful to be thoughtful and proactive now about processes so that grantees and professional societies are not negatively impacted by the new guidelines.
It is important to consider, in the broadest sense, the financial burdens and unrealistic expectations. For example,

- Open and public access comes with costs for both researchers and publishers. As it stands, OSTP's public access guidance creates an unfunded and likely unsustainable mandate, resulting in emerging Federal agency policies that place a range of obligations and burdens on researchers and their institutions while failing to account for the essential, substantial investment publishers make to ensure that the scientific record is both timely and trustworthy. We urge NIH to recognize that all public access business models have costs and require some form of funding to ensure they are sustainable, be that through the subscription model or an OA model. There are no cost-free routes to public access. Should Wiley ever stop submitting the VoR articles to PubMed, that responsibility could fall to professional societies, like NCFR, which do not have the structure or finances to support such a requirement.
- The costs of open research are also becoming clear to universities and research institutes. Survey results published by the Council on Government Relations in May 2023 suggest that for mid-size to large research institutions, the projected cost of storing and maintaining scientific research data in accordance with the new NIH Data Sharing and Management Policy exceeds over $1 million annually per institution.
- Reasonable costs could be different between the various stakeholders. How will this process be balanced with publishers, universities, researchers, society partners etc.? What are the tradeoffs? Could this new process lower the number of grants available? How will this mandate be funded? How will the various stakeholders be supported and to what degree? Changing the funding flow will change the landscape of the publishing process and will change relationships between stakeholders. For example,
- Removing the embargo period could drive publishers to business models that charge fees to make articles openly and immediately available, and as these fees rise, so will inequity for lower-resourced institutions and investigators. Additionally, the removal of the embargo and subsequent diminished subscriptions could have a significant negative effect on publisher (and academic society) operations, leading to limited choices for authors of where to publish, which in turn would limit accessibility, or even increase ''predatory'' publishing.
- The funding burden switches to that of universities as universities are increasingly signing transformative agreements (TAs). Concerns emerge around how universities will try to recoup the lost income. Will the universities have to increase tuition, thereby impacting students and their families? Any tweaks made to the business model will create ripple effects throughout the ecosystem. Any future policy should ensure that Federally funded authors who are not covered under an institutional agreement should also have access to funding that will allow them to publish the VoR OA in their journal of choice, and to make their works available to the widest possible audience.
- There are concerns about the overall effect the proposed changes will have on the ecosystem and an erosion of journal revenue. Requiring immediate public access to published research will result in an erosion of subscriptions for publishers. In turn, article processing charges (APCs) will be increased to
offset the loss of subscription revenue.
- Increased APCs will impact researchers who will have to pay for such APCs out of their grants or out of pocket. In both cases, money will be diverted away from research to pay APCs. While researchers can budget for publication fees in their grant proposals, without additional funds at the agency level, this will result in either less money for research or fewer grant

recipients. In either case, there will be implications for US R&D policy and an economic impact. Equity and integrity issues emerge.

- Further, revenue received from our society journals is essential for the operations, services, and products key to the mission of the organization, including our activities relating to improving diversity, equity, and inclusion. Any reduction in journal publishing revenues will negatively impact our ability to sustain high-quality publishing activities and to engage their member communities in a meaningful way.
- Federal agencies will also be impacted through increased monitoring and digital archiving costs. Additionally, there are the more indirect (but very real) costs associated with research fraud, which have been enabled by author-pays OA models. Sadly, the Nelson Memo will likely encourage more fraud simply by shifting more journals to Gold OA.
- The policy will further affect research societies, more of whom are seeking relationships with the larger commercial publishers (few of which are US companies) due to the economies of scale needed to participate in TAs. The Nelson Memo will result in more TAs and thereby accelerate this consolidation, which can be clearly seen in the increasing market share (as measured by article output) of the top five publishers. This consolidation has implications for jobs at societies and at smaller publishers in the US, many of which are being shifted outside the US.

We highly encourage NIH to work with publishers, academic societies, and universities to determine the best path forward to answer these questions equitably. Specifically, it would be good to work with publishers to understand the publishing model and/or discipline-specific requirements and explore currently existing cost assessments. However, it is important that the appearance of dictating business models is avoided so as not to interfere with a publisher's and academic societies' ability to remain in business.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/Federal-Registrar-Comments-89-FR-51537-NIH-2024-13373.pdf

Description: RE: ''Draft NIH Public Access Policy and Request for Information" regarding governmental use license and rights and publication costs. [89 FR 51537] [NIH- 2024-13373]

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Angela Cochran

Name of Organization: American Society of Clinical Oncology

Type of Organization: Professional org association

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**

Dr. Tabak,

Thank you for the opportunity to respond to the National Institute of Health (NIH) Draft Policy on Public Access of Federally Funded Research. The American Society of Clinical Oncology (ASCO) is the is the world's leading professional organization for physicians and oncology professionals caring for people with cancer. We own six clinical oncology journals, including the Journal of Clinical Oncology—the highest cited clinical oncology journal.

ASCO publishes practice-changing clinical trial results, clinical care perspectives and research, and treatment guidelines. We believe that our members and everyone involved in the care of cancer patients benefit from the research published in our journals, including those studies funded by the NIH.

As we emphasized in our previous comments about the NIH Draft Plan, a green open access route (posting of accepted manuscripts) with a short embargo has allowed us to sustain our journal business operations while making journal articles widely available. ASCO journal revenue, like at most societies, funds programs such as editorial fellowships, scholarships and merit awards, travel to scientific meetings, leadership development programs, educational programs, global health initiatives, advocacy for NIH funding, and more.

We remain concerned that this draft policy, with new stipulations for the NIH to retain the right to distribute, alter, create derivative works, and authorize third parties to do the same, exacts harm not only to the sustainability of our journal programs, but also inadvertently opens the door to serious issues of research integrity, medical misinformation, and copyright infringement. More on these topics are detailed below.

At the time of the Draft Plan, many organizations requested more time to facilitate communication, education, and technical changes required to implement this policy. We encourage the NIH to produce an education campaign to ensure grantees understand the changes. Authors will need to determine if journals will continue to bulk deposit and if not, what steps they need to take to ensure the article is deposited. Additionally, grantees receiving funding now will be publishing results of this work after the implementation date, and yet have not had the opportunity to review and understand the new criteria. How to accommodate compliance with any papers that may be published after the closure of the grant period will also need to be considered.

The majority of manuscripts deposited into PubMed Central are done either via bulk deposit by journal publishers or one-by-one by journal publishers on behalf of authors. As the current

Publisher Participation Agreements between the National Library of Medicine (NLM) and publishers will be invalidated as of October 1, 2025, new agreements will need to be negotiated. We remain concerned that there will not be enough time to roll out an implementation plan by October 1, 2025.

We are disappointed that the draft policy failed to clarify whether specific article types would be exempt. ASCO journals frequently invite experts to write commentaries, perspectives, state-of-the-art reviews, and educational content to help clinicians put the research into the context of their daily practice and to help patients understand the implications of the results. These opinions may also highlight limitations of the study or areas that require further exploration. As funded researchers are incentivized to connect as many manuscripts to their grant activities as possible, it is not uncommon for an author to claim funding support on manuscripts of opinion. However, no one would assert that an editorial is the work product of a grant. As such, we are once again asking that the policy be restricted to articles detailing the results of original research directly funded by the NIH.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**

ASCO has facilitated the goals of the NIH, under congressional requirements, to make publicly available the results of research as accepted by journals within 12 months of publication. This new draft policy goes too far in assuming rights that Congress has not authorized, that the Office of Management and Budget (OMB) has specifically not claimed, and is contrary to copyright law. Further, federal purpose is a non-statutory claim.

As the NIH is aware, journals not only facilitate the timely peer review by our expert physician editors of submitted manuscripts leading to improvements to the manuscripts, but journals staff and/or physician editors also routinely conduct an intensive integrity review (e.g. was the trial registered, were IRB approvals completed, were CONSORT standards followed, is the manuscript free of plagiarism, did all authors contribute, were financial disclosures included, are the figures free of inappropriate manipulation, has the accompanying data been made available to the public, etc.). These research integrity tools require staff, vendors, platforms, and extensive trainings for staff and physician editors.

Further, our expert physician editors ensure that abstracts, titles, and conclusions accurately represent the results of the research. The editors also facilitate biostatistical reviews of content in addition to the standard peer review. It is not uncommon for submitted manuscripts to go through more than one review cycle. In fact, it is extremely rare that revisions would not be requested, triggering further review of those changes.

ASCO has a vested interest in helping the authors improve their manuscripts to be the best output possible. This work benefits the evidence-driven decisions we make on behalf of the public, benefits the authors' work and careers, benefits the decisions of clinicians and the patients they treat, and ultimately benefits the NIH. And yet, it is this version of the manuscript that the policy takes, makes public with no opportunity for embargo, and now requires reuse and derivative rights to. This policy severely undervalues the work that journals, societies like ASCO, and our members put into the improvement of submitted manuscripts.

While we appreciate that the draft policy does not limit our ability to license content by requiring a CC BY license, the NIH draft policy requires that we share those rights without any requirement for attribution.

This policy draft would give the NIH the right to reproduce papers, create derivative works, and allow others to do the same on the version of the manuscripts that journals have invested resources in to improve and validate.

It is extremely concerning that the NIH is requiring researchers, some of whom may have minimal federal funding associated with a manuscript, to transfer rights to the NIH that may allow others (not defined or limited) to reproduce AND create derivative works of the accepted manuscript. In essence, this draft policy could allow a third party or the government to recreate our journals in a different format or create new products with the content with no attribution to the author or the publisher. This is a direct violation of copyrights held by the authors and the publishers who accepted the work and possesses a significant risk of perpetuating misinformation.

More concerning is that the NIH is reserving the rights to alter the content. While we expect it is not the intent of the NIH to modify published research papers, as written, the policy allows for this possibility. As presented in the draft policy, the NIH would have the right to alter the results described in a manuscript to fit a political agenda or add inappropriate content to a paper—without the consent, and yet under the byline, of an author.

Our journals are seen as trusted sources of clinical oncology content directly affecting patient care. We take that responsibility seriously through our manuscript reviews, our conflict-of-interest policies, and our processes for handling issues of research integrity. This draft policy requiring authors to deputize the NIH to both use and extend to others the right to use or alter content without permission and without attribution removes those safeguards and puts the reputations of our journals, ASCO, and our researcher members at significant risk.

Further, this draft policy would allow the NIH to grant permission to third parties to ingest our copyrighted content into online indices and AI tools. AI companies are already taking our full text content out of PubMed and using it to train their AI tools without our permission, without attribution, and without any renumeration. This is an area where societies could use support from government agencies instead of the government potentially enabling this unauthorized use of our content.

At a time when public trust in science is fragile and trust in government institutions is at historically low levels, a policy that allows the government to manipulate scientific research papers carries unintended consequences that may erode trust even further. Researchers, patients, and policymakers trust that the content in PubMed and PubMed Central come from sources that carefully review and publish content that is accurate and impactful.

Using non-statutory “federal purpose” language and declaring a “Government license” is unprecedented and unnecessary for the purpose of providing the public with access to the accepted manuscripts.

As has been noted in the 2025 reports from both the House Subcommittee on Commerce, Justice, Science Appropriations and the Senate Appropriations Committee Commerce-Justice-Science that accompanied their budgets, “Researchers should have the right to choose how and where they publish or communicate their research and should not be forced to disseminate

their research in ways or under licenses that could harm its integrity or lead to its modification without their express consent."

In fact, when our members are given a choice between a Creative Commons Attribution Only license (CC BY) or a more restrictive version that does not allow for derivatives or use in commercial activities (CC BY NC-ND), 75% of authors select the more restrictive licenses.

The NIH draft policy takes an extremely bold step in requiring rights to a version of the manuscript that has been improved, vetted, and given a branded stamp of approval by our non-profit scientific organizations. By requiring these rights to journal peer-reviewed and approved content, this policy not only infringes on the authors' right to retain and control the rights they want to confer, but also infringes on ASCO's rights as owner of the journal.

ASCO stands ready to continue to support a green open access approach to making the NIH policy work—even with shortened embargoes. However, we cannot support a zero-embargo green model if the NIH insists on outsourcing the quality control of manuscripts produced by NIH grantees to our journals, usurping rights to reproduce and create derivative works from the content, and infringing on our ability to recoup our expenses through subscriptions or other access models.

Further, ASCO is fortunate to have many NIH funded researchers among our membership. We cannot support a policy that restricts the abilities of our members to choose where, how, and under what licenses they publish their research, regardless of where and how they choose to disseminate their findings.

We urge the NIH to review the rights language in this draft policy and consider the serious consequences of implementing a policy as drafted. The stated goal of the NIH has been to make research results and underlying data accessible to the public. Those goals can be met without introducing confusing reuse and modification rights that will need to be managed by the NIH.

3) Provide any comments on the Draft Guidance on Publication Costs below:

An argument could be made that a policy that requires authors to deposit a preprint (manuscripts prior to peer review) into PubMed Central is free. However, that is not this policy. This draft policy requires that manuscript deposits undergo extensive quality checks and rounds of improvements prior to deposit. These activities, as previously explained, are not free.

Publisher agreements with the NLM require that publishers deposit "electronically readable versions of full-text journal articles and other journal content, at no expense to NLM" and "in XML format, using a mutually agreed upon DTD." Producing these formats and developing workflows for a subset of manuscripts to be delivered to the NLM, with associated metadata, incurs expense and staff resources.

Devaluing subscriptions by imposing zero-embargo on the quality approved and journal branded content comes at the expense of loss of resources for the journals and non-profit societies to contribute their value-add to the gold-standard scientific peer review process. To date, the NIH has not provided an Economic Impact Statement on the financial impact of this draft policy on American societies and publishers. This policy as drafted will disproportionately affect smaller societies, particularly those whose journals are not sustainable as fully APC funded open access journals.

Further, this draft policy, particularly with the rights being assumed by the NIH on the peer reviewed content, will hasten a flip to open access publishing supported by Article Processing Fees. While the NIH continues to contend that fees can be included in grant proposals, the NIH has not accurately estimated what the costs will be after October 1, 2025.
Thank you again for this opportunity to provide comments on this important change in policy.

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Description:

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Katherine Klosek

Name of Organization: Association of Research Libraries (ARL)

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
The Association of Research Libraries (ARL) is a nonprofit membership organization of research libraries and archives in major public and private universities, federal government agencies, and large public institutions in the US and Canada. ARL's work on open access includes supporting institutions in managing and sharing federally funded research data, and improving our collective understanding of institutional expenses for public access to research data. ARL appreciates NIH's long history of providing public access to scholarly publications resulting from the research it supports, and welcomes the opportunity to comment on the National Institutes of Health (NIH) Draft Public Access Policy.
ARL applauds NIH for eliminating the 12-month embargo period, in alignment with the Office of Science and Technology Policy (OSTP) memorandum on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research. It is critical that publicly-funded research be made available freely and immediately.
We appreciate NIH clarifying that compliance with the policy is free. The free pathway for compliance aligns with ARL's previous comments on the NIH draft public access plan, in which we suggested the agency "clarify for investigators that there is no charge for manuscript deposit into PMC, and that publishing charges by journals are not public-access compliance fees." It is critical that researchers have options for compliance that do not require researchers to pay publishing fees. In the final version of the policy, NIH may wish to consider including language encouraging researchers to deposit their manuscripts into institutional repositories as well, as an additional free pathway for public access.
It is in the interest of researchers and institutions to make their research available for reuse without unnecessary restrictions to support the larger research ecosystem. As such, we agree with other commenters in the research community that it will be useful for NIH to include clear instructions for researchers to prepare and submit manuscripts, and to clarify that there will not be additional requirements for researchers.
The proposal to continue making articles available in formats that allow for machine-readability and through assistive devices will ensure that people with disabilities can access federally funded research using assistive technologies, and facilitate the use of computational research methods on the corpus of NIH-funded works. We ask that NIH clarify whether it is the responsibility of the agency, or the researcher to create accessible, machine-readable formats. In the final policy, NIH should reference the specific accessibility laws and standards that

support making content accessible for people who use assistive technology.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
In previous comments to OMB, ARL affirmed that under the federal purpose license created by 2 CFR 200.315, federal agencies have a non-exclusive, irrevocable, worldwide, royalty-free license to exercise all rights under copyright for works that they fund. Such licensing is compatible with US copyright law. The federal purpose license encompasses the bundle of exclusive rights codified in Section 106 of the US Copyright Act, and confers maximum flexibility to federal agencies to reproduce, publish, or otherwise use federally-funded works. The federal purpose license allows the government the ability to authorize others to use work funded by Federal grants. Under 2 CFR 200.315, NIH can explicitly condition federal funding on researchers granting NIH a non-exclusive license to make Manuscripts publicly available in PubMed Central, and to make Manuscripts available to the public in machine-readable formats to support accessibility and facilitate text mining.
Public Law 110-161 further authorizes NIH to explicitly condition federal funding on researchers granting NIH a non-exclusive license to make Manuscripts publicly available in PubMed Central, and to make Manuscripts available to the public in machine-readable formats to support accessibility and facilitate text mining, consistent with current practice. This draft policy is an opportunity to be explicit about the activities that this license allows; as such, NIH may wish to add "computational use" to the list of uses.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
In previous comments on the NIH draft policy, ARL suggested the agency "clarify for investigators that there is no charge for manuscript deposit into PMC, and that publishing charges by journals are not public-access compliance fees." We appreciate that clarification in this policy.
The issue of federal grants covering post-closeout costs is unresolved for the research community, and is certainly not unique to NIH. Agencies may wish to collaborate with libraries and research institutions to study how publication costs could be funded after a grant has ended, to address situations in which an article is accepted and a fee is due after the grant money is spent or is the term of the grant has ended. Such a solution might also cover costs related to research activities, like peer review or copyediting.

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Description: ARL comments on NIH 2024 Draft Public Access Policy

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Ashley Farley

Name of Organization: Bill & Melinda Gates Foundation

Type of Organization: Other

Type of Organization-Other: Private Funder

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   It is commendable that the NIH is updating its Public Access Policy to eliminate the embargo period on publications resulting from NIH-funded research. It is critical for funders to take a strong stance on ensuring immediate and barrier free access to tax-payer research. If there are any lessons learned from the COVID19 pandemic, prioritizing the access and reuse of research is one of the most important. This demonstrated the need for reform of the traditional academic publishing system which struggled to meet the community's urgent needs. Making necessary changes to timely access can help safeguard that we are better prepared to respond to the next crisis.
   We strongly support the proposed language in the draft Public Access Policy that clearly states that submission of manuscripts to PubMed Central (PMC) remains free for authors and that any fee requested during the publication process for submission to PMC (e.g., “article development charges” or similar) is not an allowable cost.
   Many researchers mistakenly assume that compliance with the new policy requires the payment of a publication fee to a journal. We particularly appreciate that the draft policy outlines a compliance option for authors that does not require authors to pay a fee of any kind and welcome the language underscoring that any fee requested during the publication process for submission to PMC (e.g., “article development charges” or similar) is not an allowable cost for NIH grants. To help mitigate continued confusion, we encourage the agency to review the language in the draft policy and to add clarifying language where appropriate to ensure that researchers and institutions do not end up paying unnecessary publication fees.
   However, we note that the Memorandum also asks agencies to clarify exactly what use and reuse rights should accompany these articles, and we recommend that the NIH explicitly authorize the public to fully reuse publications resulting from its research. In the experience of the Gates Foundation and rights retention, we have witnessed first hand how difficult it can be for authors to retain their rights. As individuals they have limited support and power to strongly enforce rights retention against publisher requirements. Undoubtedly, broader institutional support will increase their chances of success.
   We suggest that the agency add the following language to the “Government Use License and Rights” section of its draft policy:

"NIH hereby exercises its right under this license to authorize members of the public to reuse the work for any purpose so long as the authors and the original publisher receive attribution in a reasonable manner."
This will both provide necessary clarity on reuse rights and enable NIH to make all research articles available under terms that allow for full reuse and secondary analysis.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
As noted above, we recommended that NIH add specific language to the policy authorizing the public to fully reuse the research articles resulting from its funded research. We also recommend that NIH support this policy language by adding similar language in two additional places in its accompanying Guidance documents.

First, we recommend that the agency add language to the statement that NIH requires when authors upload manuscripts to PMC that indicates that they acknowledge NIH's right to authorize members of the public to reuse their work for any purpose so long as the authors and the original publisher receive attribution.

Second, we ask that the agency include a sentence in the sample language that NIH recommends authors attach to their manuscripts that clearly indicates that members of the public are authorized to reuse their work for any purpose so long as the authors and the original publisher receive attribution in a reasonable manner.

Incorporating language that explicitly authorizes public reuse in these two places will ensure that both authors and users of these publications fully understand that the public is empowered to make broad reuse of the work.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
As open access publisher fees continue to increase, this Guidance will be increasingly important to scrutinize these unchecked costs and reduce the inequities that result when authors are required to pay to publish. It can also encourage the development and adoption of alternative models for research communication (including preprints; Publish, Review, Curate models; Diamond Open Access models; etc) which provide important opportunities for the research community to incentivize and reward a much wider variety of research outputs.
We applaud the NIH for providing researchers a no-fee option for compliance through deposition of a final accepted manuscript at PubMed Central). However, we also recognize that many authors will still choose to publish their articles in open access journals that require payment of a publication charge.
We appreciate that the accompanying Guidance documents include information to help grantees assess whether the publication costs levied are "reasonable," as well as information on the types of publisher fees that will not be considered allowable costs (e.g., "article development charges'') under the updated policy. Our main concern is the potential cost of

complying with this updated policy. In the experience of the foundation it is nearly impossible to calculate a reasonable cost for the below reasons:

Overall, the true cost of publishing is not clear to the community and many commercial publishers refuse to participate in price transparency work organized by the community. Publishers that have embraced price transparency and current research on the topic have shown that the true cost to process and publish an article is much less than the market rate. Researchers have very little price awareness and will struggle to account for these costs in their grant budgets, which will add an administrative burden. The foundation covered APCs from a central fund for its grantees and the administrative effort to achieve this for several thousand papers a year required multiple staff, banking information exchanged between financial departments, a constantly monitored tracking system, and many rounds with publishers to obtain the information needed to determine eligible articles.

It is also critically important that NIH's policy and guidance do not inadvertently undermine new and innovative models for research communication that are emerging. Models like preprints, the "Publish, Review, Curate" model, and Diamond Open Access provide important opportunities for the research community to incentivize and reward a much wider variety of research outputs and not limit the ability for researchers to be credited only for publication of an article in a "reputable" journal.

We thank NIH for the opportunity to provide feedback on this draft public access policy and accompanying guidance.

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Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: James C. Appleby, BSPharm, MPH, ScD (hon)

Name of Organization: Gerontological Society of America

Type of Organization: Professional org association

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   We appreciate the Draft Guidance on Publication Costs specifically related to clarification of reasonable costs and other unallowable costs. In particular, we appreciate the clarification that in cases where an institution already pays a fee that would cover publication costs are unallowable because costs may not be double charged or inconsistently charged as both a direct and indirect cost. (GPS 7.4). Furthermore, as noted in our April 2023 response to the RFI NIH Plan to Enhance Public Access to the Results of NIH Supported Research, we respectfully request NIH to monitor evolving costs and impacts on affected communities in an effort to ensure equity and accessibility of publications. Analyses of and reporting on costs paid by institutions or researchers for publication should examine potential variability in costs across disciplines, career stages, and institution types, as well as variability based on researcher backgrounds.

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I am responding to this RFI: On behalf of an organization

Name: Meagan Phelane

Name of Organization: American Association for the Advancement of Science

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
The American Association for the Advancement of Science (AAAS) welcomes the opportunity to submit comments in response to the National Institutes of Health Draft Public Access Policy ("draft Policy"). We are pleased that NIH continues to engage stakeholders across the enterprise on public access – including by joining AAAS in 2023 for a session with early-career researchers, society publishers, and academic administrators – and we are also pleased to see that many of our comments on the NIH Public Access Plan were considered in the development of the new draft Policy.
AAAS, a multidisciplinary non-profit association of scientists at all levels of the scientific enterprise, publishes the Science family of journals. Our mission is to advance science, engineering, and innovation throughout the world for the benefit of all.
Peer-reviewed research published by the Science family of journals is open to the public without embargo using a green open access model (involving authors depositing their accepted manuscript) for five of our journals and a gold open access model for one. Our journals require published authors to make their data immediately accessible in approved repositories, crucial for scientific reproducibility. Authors may also share their accepted manuscripts ("Manuscripts") immediately upon publication.
We continue to engage not only with Science family authors about our approaches to public access, but also with the broader scientific community. The feedback we receive about our predominant approach (green open access) is overwhelmingly positive – from all corners of the globe. This is in no small part because authors' ability to pay to publish is a growing concern; related impacts to scientists have only begun to be studied, including by AAAS, and they are significant.
AAAS applauds the NIH for its leadership in emphasizing authors' ability to publish in its approach to public access policy development – and for considering how to balance this essential component of the scientific ecosystem with reader access to research. The ability to comply by depositing the Manuscript via green open access is critical to mitigate issues associated with author- and institution-borne costs for publishing open access, including article processing charges (APCs).
AAAS also applauds NIH for its flexible approach to licensing; as acknowledged in the draft Policy, "A particular license is not needed to achieve the Policy's goal of making Manuscripts available." This is important. A paper's underlying data should be available, so other scientists can reproduce the work, but a particular license is not required to facilitate public access.

As AAAS reflects on the practical implications of the 2022 OSTP Memorandum and the draft NIH Policy on the research ecosystem, we have several recommendations. First, in the NIH Policy, we would strongly encourage revision to language that suggests the business model used to provide access to original peer-reviewed research does not matter; in fact, some open access business models create new hurdles for authors – and freeze in place existing inequities. While there may be no best route to public access, some models definitely cause more harm than others. The NIH, the biomedical research ecosystem, and – most importantly – patients have a big stake in ensuring that the business model used to implement access does not have consequences counter to NIH's mission and goals. Second, as we know NIH is focused on minimizing compliance burdens on authors, we recommend that the effective date of the policy should be with respect to new grants, rather than to the acceptance date of a publication. Finally, while we commend NIH for its flexible approach to licensing, we raise concerns more generally – as we look to the future – about the breadth of open license types often used in open access publishing. Some of these licenses challenge authors' ability to ensure the accuracy of downstream uses of their works.

AAAS is pleased to offer its response to the NIH's draft Policy in this document on the three concerns briefly outlined above. Below, we provide recommendations to ensure the Policy fully achieves NIH's goals for public access while maintaining authors' ability to publish, minimizing author burdens, and prioritizing the accuracy (and credibility) of downstream communication of research. AAAS is committed to collaborating with NIH, other federal research agencies, and OSTP to finalize public access policies and supportive publishing models that achieve these goals.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**

AAAS applauds NIH for its flexible approach to licensing; as acknowledged in the draft Policy, "A particular license is not needed to achieve the Policy's goal of making Manuscripts available." However, we want to raise concerns more generally – as we look to the future – about the breadth of open license types increasingly used in open access publishing. Some of these, like the CC BY license, challenge authors' ability to ensure the accuracy of downstream uses of their works. There are key concerns with CC BY Licenses that AAAS (and others) have identified. Namely, research under this license can be modified and misrepresented. Also, research can be modified and used to support a finding/initiative with which its original authors disagree. In both cases, because of the CC BY license, publishers cannot intervene to help authors. But authors are not monitoring these issues themselves, in many cases; they would rather have someone else (e.g., journal, funder, etc.) do this for them. Thus, the CC BY license creates both unintended consequences and an additional burden on researchers. Related problems are only likely to grow in an AI-driven world where openly licensed content is reused more often, in different ways, online. Such breaches of integrity create obstacles for improving trust in the science NIH is working to make publicly accessible.

In a lot of ways, use of the CC BY license in scholarly publishing has been an experiment. Determining the full impact of this license type on the integrity and accuracy of the downstream communication of scientific research will require time. During this period, AAAS recommends that NIH articulates in its Policy the possibility that open license types could lead to reuses that

adversely impact the integrity of published work. (AAAS is currently undertaking a survey of researchers to understand their experiences with open licenses and would be glad to share results.) To prioritize scientific integrity, AAAS would also encourage NIH to recommend broad use of a CC BY-NC-ND (nonderivative) license, in the final Policy.
Any license policy encouraged for federally funded work should make determining the applicability of the policy as straightforward as possible for authors, institutions and journals. As well, the rights reserved to the federal government through such a policy should meet the stated goals and intentions as first outlined by NIH; in other words, they should not only facilitate public access but also ensure authors maintain choice in where to publish.

3) Provide any comments on the Draft Guidance on Publication Costs below:

Per the NIH draft Policy, authors comply if they deposit their accepted manuscripts ("Manuscripts") to PubMed Central without an embargo. (The Manuscript is defined as the author's final version that has been accepted for journal publication and includes all revisions resulting from the peer review process. AAAS appreciates that this definition recognizes the importance of peer review, a process managed by journals, and one critical for upholding the quality of research disseminated.) AAAS applauds NIH for its focus on this approach, which is consistent with green open access. (AAAS does recognize that some publishers have concerns about the sustainability of pursuing green open access; we have been participating in discussions about alternative approaches that also do not transfer the cost burden to scientists.)
AAAS does note several places in the Policy where the language states that implementation could best minimize burdens by ensuring flexibility in business models, licensing, and implementation processes. Ensuring flexibility for licensing and implementation processes will minimize author burdens, but the same is not true for business models. Models involving APCs, the predominant form of gold open access, create new author burdens.
Relatedly, the draft Policy suggests there is not one best route, or business model, to provide access to original peer-reviewed research and data. While none of the existing business models is perfect, gold open access is far less equitable to scientists, with significant financial and professional impacts depending on one's institution, discipline, career stage, geography or gender. These results have been clear, including in AAAS's 2022 survey of more than 400 U.S.-based researchers. And researchers around the world are increasingly speaking up to vocalize their inability to pay these fees without making significant trade-offs, perhaps most notably those that are detrimental to their career progression.
AAAS recommends that the NIH Policy transparently conveys the financial and professional challenges around gold open access, for authors. Rather than minimizing burdens to authors, gold open access stands out for creating them anew. We strongly discourage bolstering support for a fully funded gold open access route as a predominant means of achieving public access. This is essential to ensuring that, regardless of a scientist's geographic location, institutional affiliation, academic rank, or identity, they can publish world-changing science.
Finally, in the "Points to Consider […] in Assessing Reasonable Costs," section of the Policy, we were glad to see the last bullet, which encouraged monitoring the sustainability of costs over time in terms of the "library budget, laboratory budget, etc." If APC-supported open access

continues to exist in the journal ecosystem, it is crucial to monitor how related fees accrue for authors and institutions – particularly as the number of papers published increases, and so, too, the number of open access journals. All analysis of and reporting on publication costs should examine potential variability in costs across disciplines, career stages, and institution type, as well as based on researchers' backgrounds and characteristics.

Critically, not all gold open access journals are created equal in terms of quality checks and standards. Some perform minimal quality checks, at best, before publishing new work for public consumption. Thus, we encourage NIH to emphasize the importance of monitoring the following questions:

- Are there significant differences among open access models in their impact on the overall quality of the research enterprise? Are some more likely to perpetuate predatory practices or cost-saving practices that contribute to research integrity issues?
- If research funds that would normally support research activity are diverted to publication, it is possible that research activity and output – and ultimately the pace of discovery – will decline?

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/FINAL_AAAS-response-to-NIH-RFI-on-public-access_August-2024.pdf

Description: AAAS response to NIH RFI on public access

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Helen Burstin, MD, MPH

Name of Organization: Council of Medical Specialty Societies

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   See attached

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   See attached

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   See attached

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/CMSS_Comment-Submission_NIH-Proposed-Guidelines-Response_August-2024.docx

Description: CMSS Comments on Updated NIH Proposed Guidelines

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Jody Bailey

Name of Organization: Emory University Libraries

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
At Emory Libraries, we were pleased to see the 2022 White House Office of Science and Technology Policy (OSTP) recommendations regarding public access to results of federally funded research. We are similarly now pleased that the National Institutes of Health (NIH) has drafted a new policy to implement these recommendations and given us the opportunity to submit these comments. In particular, the elimination of the embargo period will be greatly beneficial to all constituents needing immediate access to these critical research results, many of which involve information that can mean life or death for U.S. citizens. At Emory University, the Libraries financially support access to over 1,000 databases with millions of peer-reviewed journal articles and other crucial information resources, but that access is extended only to members of our campus community. The 24,000+ employees in the greater Emory Healthcare system cannot access all these research databases because the cost for us to include them as users would be prohibitive. Access to recent results of federally funded research for many private healthcare practitioners and other individuals in our community outside of Emory University and Healthcare and across the nation is not feasible for similar reasons.

   Furthermore, we believe it is critical to maintain a no-cost pathway to sharing the results of federally funded research since many researchers cannot pay article processing charges (APCs) for their work to be published open access, nor can they pay article development charges just to submit their work to a journal or to PubMed Central (PMC). Ensuring that funded researchers can comply with the NIH public access policy by providing and enforcing a cost-free path to publication and sharing will promote equity for researchers at all types of institutions across the world.
   Because Emory faculty members strive to be at the cutting edge of research in the medical field, these policy updates will be greatly beneficial to those whose work is funded by NIH grants. The results of Emory faculty research will be made accessible to the global community immediately upon publication, giving them greater opportunities for collaboration and influence in their fields, which further benefit the Emory community by drawing interest from additional researchers and potential students.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
A government use license accomplishes the policy's baseline goal of making manuscripts publicly and immediately available, but access to this research without the explicit authorization

to reuse it significantly limits how educational institutions like Emory can draw on our nation's investment in biomedical research to train the next generation of medical professionals or to provide effective continuing education. It is increasingly common for Emory faculty to develop teaching materials tailored to specific learning objectives using local examples in lieu of exorbitantly priced textbooks developed for a broad international audience. We urge the NIH to add language to the public access policy that specifically authorizes the public to reuse articles resulting from its funded research in whole or in part, which would permit educators to combine articles, or sections of articles, to develop up-to-date, customized teaching materials. A clear authorization for reuse would also allow instructors to incorporate publicly funded research articles into continuing-education courses delivered online to students who have no access to library databases due to common licensing restrictions.

As well as amending the policy itself to provide explicit authorization to reuse publicly funded articles in whole or in part, we recommend the addition of similar language to the statement the NIH requires of authors submitting manuscripts to PubMed Central and to the statement that the NIH recommends that authors attach to their manuscripts. Prominent clarification that publicly funded research articles may be reused by the public, especially for educational purposes, will ensure the greatest possible impact of federal investment in biomedical research.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

As mentioned above, we believe it is important to maintain a no-cost pathway to sharing the results of federally funded research. We are gratified to see that the NIH has continued to ensure a free path to compliance with the newest OSTP memo, thus continuing the NIH's commitment to reducing inequalities stemming from fee-based publishing models. For researchers, particularly those without or with only minimal institutional support, immediate availability of their author manuscript on PMC may be an effective and positive alternative to paying an APC.

Across our campus, current APC expenditures at Emory are approximately $1.5 to $2 million, and our researchers can sometimes cover their APC payments from their own discretionary or internal research funds; those who have grant funding can draw on it if sufficient funds remain after all other expenses are paid. For those who have no other sources, Emory Libraries established the Open Access Publishing Fund. However, dramatically rising APC costs have negatively affected the Emory Libraries' budget for this fund. Launched in 2012, this fund has paid APCs in full or in part for more than 381 articles. The fund currently receives well over a hundred applications per year, and the approval rate hovers near 60%. In the early years of the fund, our maximum award of $1,500 covered 100% of the APC for most successful applicants. Currently, however, that maximum award fully covers an average of only 22% of our applicants' APCs.

To this end, we are pleased to see that the guidance on draft publication costs encourages researchers to consider sustainability in terms of library and laboratory budgets and expected publication expenditures in relation to an NIH award. This guidance will become increasingly important as the cost of APCs continues to rise and will hopefully encourage researchers to consider alternative publishing models.

Uploaded File:

Description:

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Claire Stewart

Name of Organization: University of Illinois Urbana-Champaign

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   See attached file.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   See attached file.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   See attached file.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/NIH-Response-Final-CS.pdf

Description:

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Carter Alleman

Name of Organization: American Society for Pharmacology and Experimental Therapeutics (ASPET)

Type of Organization: Professional org association

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   ASPET strongly recommends simplifying definitions in the draft policy. In the current proposed draft, three definitions are used to describe a single piece of written material: "manuscript," "final published article," and "article." NIH included "article" as a response to a clarification question concerning the scope of the draft plan. Instead of clarifying, NIH created a definition that encompasses both that of "manuscript" and "final published article," thus creating unnecessary confusion for the research community.
   Moreover, in the draft policy's definition of "manuscript." it states:
   The 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. (Emphasis added).
   Although ASPET appreciates that NIH recognizes that the manuscript is the result of the peer review process, we are concerned that NIH is expanding the sphere of peer review to encompass preprints, conference proceedings, book chapters, editorials through the inclusion of "supplemental material." This expansion would add administrative burdens on scientists. As previously stated, ASPET recommends explicitly specifying what "supplemental material" entails. If it entails more than the traditional understanding of materials present in a journal publication, NIH needs to explicitly state this as well as what it expects for reporting and allow the community to comment.
   ASPET strongly encourages NIH to remove "article" and "final published article" as the definitions do not accomplish the clarification of what is covered by the NIH Public Access Policy. The Policy applies to "any Manuscript accepted for publication in a journal." NIH has defined "manuscript." Additional clarifications within the definition are appreciated, however no additional definitions need to be created.
   Scope and Effective Date
   ASPET finds the effective date of October 1, 2025, to be arbitrary, and shortens the time that NIH can effectively aid the research community for implementation date. Should NIH revise its effective date to December 31, 2025, this would allow NIH an added three months of preparation time to create a policy that aligns with the intent of the OSTP Memorandum. As it stands, there would be little under a year for NIH to communicate its final Policy to the research community and aid in the transition. The research community has already had enough shifting caused by the OSTP Memorandum and the impact on its publishing capabilities.
   Compliance and Enforcement

ASPET asks that NIH publish a plan that details its implementation plan and allows for public comments. With so many different moving parts within the publishing world, time is not on the side of publishers and scientific societies to implement the Policy. Clear, concise, and detailed policies and plans are necessary to not only remove the burden, but also allow for clarity on what is expected by all parties.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
ASPET appreciates the need for publicly sponsored research to be accessed within the public arena and supports authors ability to have academic freedom to choose how their findings will be delivered, including a journal of their choice as well as license for reuse. Several times throughout the Plan the terms "derivatives" and "reuse rights" appear without clear definitions which lead to concerns about misrepresentation of findings that could be used to impeach the investigator, funding agencies, and scientific integrity.
The use of "derivatives" could potentially allow irresponsible AI owners and even responsible AI owners to use content without providing credit to authors or allowing the misrepresentation to exist without anyone knowing. The policy goal of the Plan is to open research to the public, not allow it to be manipulated for other purposes. We strongly ask that any derivative rights be removed in the final policy. We also strongly recommend that there be included stronger intellectual property protections against intrusive AI and nefarious agents repurposing or misrepresenting findings within the given findings

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
ASPET appreciates the strides that NIH has taken to allow "allowable costs" to be considered. We also commend the "Other Unallowable Costs" section and "Points to Consider" additions to aid authors and institutions. Yet ASPET is still concerned that NIH is not watching the expansive growth in new publishing models and open access infrastructure. NIH's push to open access has created disparities impacting communities and researchers from historically excluded backgrounds, early-stage investigators and lower-resource institutions. Without a step to open access, business models have been disruptive, and that disruption has been passed on to those authors. NIH should include sections that outline how it will support these groups. NIH has a role and responsibility to make open access equitable to all. The worst outcome is not that research is behind a paywall for a year, it is that research is never published due to high costs, or an author is forced to publish some place where the discovery will languish away from sight.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/ASPET-Comments-RFI-NIH-Draft-Public-Access-Policy-8.2024.pdf

Description: ASPET Comment Letter to RFI

Submit date: 8/19/2024

I am responding to this RFI: On behalf of myself

Name: Amy Pham

Name of Organization: University of San Diego

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Dr. Cable Green

Name of Organization: Creative Commons

Type of Organization: Other

Type of Organization-Other: Nonprofit stewarding the open licenses legal infrastructure the world uses to share knowledge

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   see attached word document

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   see attached word document

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   see attached word document

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/Creative-Commons-Comment-NIH-Draft-Public-Access-Policy.docx

Description: Creative Commons Comment - NIH Draft Public Access Policy.docx

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Angela Cochran

Name of Organization: American Society of Clinical Oncology, American College of Physicians, NEJM Group, American Society of Anesthesiologists, American Thoracic Society, American Gastroenterological Association, Endocrine Society, American Academy of Neurology, American Psych

Type of Organization: Professional org association

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**

Thank you for the opportunity to respond to the National Institute of Health (NIH) Draft Policy on Public Access of Federally Funded Research. The entirety of these comments represents 12 non-profit, US based, medical Societies that publish some of the top clinical journals.

We will address several issues posed by the draft policy including:

- Rights of researchers to determine reuse of content
- Value added by publishers to the accepted manuscript version of papers
- Research integrity and trust in the American scientific enterprise
- Applicable article types
- Implementation date

The Earlier Implementation Date is Problematic

At the time of the Draft Plan, many organizations requested more time to facilitate communication, education, and technical changes required to implement this draft policy. We encourage the NIH to produce an education campaign to ensure grantees understand the changes. Authors will need to determine if journals will continue to bulk deposit and if not, what steps they need to take to ensure the article is deposited.

Also, grantees receiving funding now will publish results of this work after the implementation date and have not reviewed and understood the new criteria. How to accommodate compliance with any papers that may be published after the closure of the grant period will also need to be considered.

The majority of manuscripts deposited into PubMed Central are done either via bulk deposit by journal publishers or one-by-one by journal publishers on behalf of authors. As the current Publisher Participation Agreements between the National Library of Medicine (NLM) and publishers will be invalidated as of October 1, 2025, new agreements will need to be negotiated. We remain concerned that there will not be enough time to roll out an implementation plan by October 1, 2025.

Certain Article Types Should Not Be Included

We are disappointed that the draft policy failed to clarify which specific article types would be subject to the policies and which would not. Our journals frequently invite experts to write commentaries, perspectives, state-of-the-art reviews, and educational content to help clinicians put the research into the context of their daily practice and to help patients understand the

implications of the results. These opinions may also highlight limitations of the study or areas that require further exploration.

As funded researchers are incentivized to connect as many manuscripts to their grant activities as possible, it is not uncommon for an author to claim funding support on manuscripts of opinion. However, no one would assert that an editorial is the work product of a grant. As such, we are once again asking that the policy be restricted to specific articles detailing the results of original research funded by the grant and not inclusive of any work a grantee publishes over the course of the grant period.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**

Publishers have facilitated the goals of the NIH, under congressional requirements, to make publicly available on PubMed Central the results of research as accepted by journals within 12 months of publication. This new draft policy goes too far in assuming rights that Congress has not authorized, that the Office of Management and Budget (OMB) has specifically not claimed and is contrary to copyright law. Further, federal purpose is a non-statutory claim.

As the NIH is aware, journals not only facilitate the timely peer review by our expert editors, most of whom are physicians, of submitted manuscripts leading to improvements to the manuscripts, but journals staff and/or editors also routinely conduct an intensive integrity review (including appropriate trial registration, required IRB approvals, adherence to CONSORT and other reporting standards, plagiarism checks, authorship criteria, disclosure of financial relationships and other potential conflicts of interest, checking that figures are free of inappropriate manipulation, adherence to data sharing requirements, etc.) These research integrity tools require staff, vendors, platforms, and extensive trainings for staff and editors. Further, our expert editors ensure that abstracts, titles, and conclusions accurately represent the results of the research. The editors also facilitate methodological and biostatistical reviews of content in addition to the clinical content review. It is not uncommon for submitted manuscripts to go through more than one review cycle. In fact, it is extremely rare that revisions are not requested, triggering further review of those changes.

Non-profit medical societies have a vested interest in helping the authors improve their manuscripts to be the best output possible. This work benefits us, benefits the authors, benefits the clinicians and patients they treat, and ultimately benefits the NIH. The proposed policy would require societies to provide this version with its vastly added value to the public with no opportunity for embargo and loss of control over rights for reuse or creation of derivatives. This draft policy severely undervalues the work that journals and societies like ours put into the improvement of submitted manuscripts.

While we appreciate that the draft policy does not limit publisher's ability to license content by requiring a CC BY license, the NIH has essentially taken those rights without any requirement for attribution.

This policy draft would give the NIH the right to reproduce papers, create derivative works, and allow others to do the same on the version of the manuscripts that journals have invested resources in to improve.

It is extremely concerning that the NIH is requiring researchers, some of whom may have minimal federal funding associated with a manuscript, to hand over rights to the NIH that may

allow others (not defined or limited) to reproduce AND create derivative works of the accepted manuscript. In essence, this draft policy could allow a third party or the government to recreate our journals in a different format or create new products with the content with no attribution to the author or the publisher. This is a direct violation of copyrights held by the authors and the publishers who accepted the work and possess a significant risk of perpetuating misinformation. More concerning is that the NIH is reserving the rights to alter the content. While we expect it is not the intent of the NIH to modify published research papers, as written, the draft policy allows for this possibility. As presented in the draft policy, the NIH would have the right to alter the results described in a manuscript to fit a political agenda or add inappropriate content to a paper—without the consent, and yet under the byline, of an author.

Our journals are seen as trusted sources of clinical content directly affecting patient care. As scientific and clinical practice societies, we take that role seriously through our manuscript reviews, our conflict-of-interest policies, and our processes for handling issues of research integrity. Our journals and our non-profit organizations serve a mission to attract and disseminate the highest quality and most impactful clinical content to the communities we serve and the public.

As stewards of the research published in our journals, we manage permission requests on behalf of our authors, and it is not uncommon to receive requests that are inappropriate. Safeguarding science from industry spin or ideological cherry picking of data points is another way that we expend resources on ensuring the integrity of the content.

This draft policy requiring authors to deputize the NIH to extend to others the right to use or alter content without permission and without attribution removes those safeguards and puts the reputations of our journals, our societies, and our researcher members at significant risk. Further, this draft policy would allow the NIH to grant permission to third parties to ingest our copyrighted content into online indices and AI tools. AI companies are already taking our full text content out of PubMed Central and using it to train their AI tools without our permission, without attribution, and without any renumeration. This is an area where societies could use support from our government instead of allowing the government to enable this unauthorized use of our content.

At a time when public trust in science is fragile and trust in government institutions is at historically low levels, a policy that allows the government to manipulate scientific research papers carries unintended consequences that may erode trust even further. Researchers, patients, and policymakers trust that the content in PubMed and PubMed Central come from sources that carefully review and publish content that is accurate and impactful.

Using non-statutory “federal purpose” language and declaring a “Government license” is unprecedented and unnecessary for the purpose of providing the public with access to the accepted manuscripts.

As has been noted in the 2025 reports from both the House Subcommittee on Commerce, Justice, Science Appropriations and the Senate Appropriations Committee Commerce-Justice-Science that accompanied their budgets, “Researchers should have the right to choose how and where they publish or communicate their research and should not be forced to disseminate their research in ways or under licenses that could harm its integrity or lead to its modification without their express consent.”

In fact, when our members are given a choice between a Creative Commons Attribution Only license (CC BY) or a more restrictive version that does not allow for derivatives or use in commercial activities (CC BY NC-ND), authors overwhelmingly select the more restrictive licenses.

The NIH draft policy takes an extremely bold step in requiring rights to a version of the manuscript that has been improved, vetted, and given a branded stamp of approval by our non-profit scientific organizations. By requiring these rights to journal peer-reviewed and approved content, this draft policy not only infringes on the authors' right to retain and control the rights they want to confer, but also infringes on the rights of the publisher of the journal.

As a collective group of clinical medical publishing societies and consistent with our non-profit missions, we stand ready to continue to support a "green open access" approach to making the NIH policy work—preferably with an embargo. However, we cannot support a green model if the NIH insists on outsourcing the quality control of manuscripts produced by NIH grantees to our journals, usurping rights to reproduce and create derivative works from the content and infringing on our ability to recoup our expenses through subscriptions or other access models. Further, as scientific societies that represent NIH funded researchers, we cannot support a policy that restricts the abilities of our members to choose where, how, and under what licenses they publish their research.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

We continue to be concerned that this policy draft will force more and more journals to flip to an Article Processing Charge funded open access model. If journals cannot recoup expenses through subscriptions because of zero embargo and have added concerns about the rights the NIH are requiring, moving to an APC model may provide a more sustainable revenue stream. While the NIH has always contended that they are "business model agnostic," this draft policy fails to take into consideration the obvious market forces that will affect the industry. Because this draft policy extends the deposit requirements beyond the grant closing date and yet does not allow for researchers to use NIH grant money to pay publication fees for those papers, the draft policy adds a burden to the researchers. Hastening a move to more APC funded open access will be extremely expensive for US Institutions and authors as well as exacerbate the inequalities inherent in the APC model of open access globally as well as with under-resourced domestic institutions, many of which support diverse students and investigators.

Deposit of Accepted Papers is Not Free

An argument could be made that a policy that requires authors to deposit a preprint (manuscripts prior to peer review) into PubMed Central is free. However, that is not this policy. This draft policy requires that manuscript deposits undergo extensive quality checks and rounds of improvements prior to deposit. These activities, as explained elsewhere, are not free. Publisher agreements with the NLM require that publishers deposit "electronically readable versions of full-text journal articles and other journal content, at no expense to NLM" and "in XML format, using a mutually agreed upon DTD." Producing these formats and developing workflows for a subset of manuscripts to be delivered to the NLM, with associated metadata, incurs expense and staff resources.

Devaluing subscriptions by imposing zero-embargo on the quality approved and journal branded content comes at expense—in the form of loss of revenue-- for the journals and non-profit societies. To date, the NIH has not provided an Economic Impact Statement on the financial impact of this draft policy on American societies and publishers. This policy as drafted will disproportionately affect smaller societies, particularly those whose journals are not sustainable as fully APC funded open access journals.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/Response-to-NIH-RFI-on-Public-Access-Draft-Policy.pdf

Description: Comments on Draft NIH Policy from 12 Societies

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Karen S. Quigley

Name of Organization: Society for Psychophysiological Research

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   See letter

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   See letter

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/SPR-Letter-of-Response-to-the-Nelson-Memo_Aug_2024_FINAL.docx

Description: Letter from the Society for Psychophysiological Research (resent)

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: John Burger

Name of Organization: Association of Southeastern Research Libraries (ASERL)

Type of Organization: Professional org association

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   The Association of Southeastern Research Libraries support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. We believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.
   Thank you for your wise leadership on this important matter!
   Kind regards,
   John Burger, Executive Director
   Association of Southeastern Research Libraries (ASERL)
   540 Asbury Circle, #316
   Atlanta, Georgia 30322

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File:

Description:

Submit date: 8/19/2024

I am responding to this RFI: On behalf of myself

Name: Lisa German with input from Shannon Farrell, Shanda Hunt, Nancy Sims, J.D., Alicia Hofelich Mohr, P.hD., Allison Langham-Putrow, Ph.D., and Wanda Marsolek

Name of Organization: University of Minnesota

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   We appreciate the opportunity to provide comments to NIH on the Draft Public Access Policy. Our response follows the organization of the Draft Plan.
   --Definition of "manuscript"--
   We are concerned about the proposed definition of "Manuscript" in the draft policy. As demonstrated in public comments on Rights in Manuscripts, the terms "preprint", "author-accepted manuscript", and the journal "version of record" are commonly used to distinguish between versions of an article. Even if the provided definition of Manuscript is in the Notice of Grant Award, researchers may find the term confusing. NISO RP-8-202x [National Information Standards Organization (NISO). (2024). "NISO RP-8-2008, Journal Article Versions (JAV): Recommendations of the NISO/ALPSP JAV Technical Working Group," https://www.niso.org/standards-committees/jav-revision.], defines the following states for an article as it is drafted and moves through the peer review process:
   AO: Author's Original
   SM: Submitted Manuscript
   AM: Accepted Manuscript
   PF: Proof
   VoR: Version of Record
   Colloquially, "manuscript" is often taken to mean either the "Author's Original" or "Submitted Manuscript" by researchers—the version of the article before peer review (which may or may not have been shared publicly as a "preprint").
   We suggest NIH consider using "Accepted Manuscript" or "Author Accepted Manuscript" to mean the "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", instead of "Manuscript".
   Similarly, NIH might consider using "Version of Record" in place of "Final Published Article".
   Under the Requirements section of the Draft Plan, the version that researchers are required to deposit in PubMed Central, the term "final peer-reviewed Manuscript" is introduced, which does not appear in "Definitions." Again, we would recommend the use of "Accepted Manuscript" here.
   --Peer review--

Researchers might benefit from a clearer definition of "peer review" in regard to the definition of "journal". For example, if researchers were to release research findings of funded research in a non-peer review outlet, such as a white paper, dissertation, or other gray literature source, would those documents be subject to this policy?

--"Official Date of Publication"--

We thank NIH for included a definition of "Official Date of Publication" to clarify that it is the first time when the article first appears online *or* in print. However, there is conflicting mention of the acceptance date. The definition for "Official Date of Publication" is "The date on which the article is first made available in final, edited form, whether in print or electronic (i.e., online) format". The term "Official Date of Publication" is used in the example language NIH provides for authors to include in the Manuscript. However, the following language is in the first bullet of the "Requirements" section: "Submission of an electronic version of the final peer-reviewed Manuscript to PubMed Central upon its acceptance for publication, for public availability without embargo upon the Official Date of Publication".

Acceptance occurs before the article is published, online or in print. NIH should clarify if authors are to submit their author-accepted manuscript immediately upon acceptance, when it first appears on the journal's website, or when it appears in print. We recommend making it clear whether it is the author's responsibility to determine if their journal will automatically deposit into PMC. If the journal does not automatically deposit the Version of Record, then authors should deposit the Accepted Manuscript to PMC upon acceptance and no later than the date of publication. Note that authors may not be aware of the date when their article is first published. Some journals notify authors when it is available online and others do not communicate with authors after the final proofs have been submitted.

--Implementation date--

We are pleased to see that NIH will implement the new Public Access Policy on October 1, 2025 for all grantees. It will simplify compliance processes for researchers and those who support them by having one deadline (upon publication) for making their article publicly accessible. We would appreciate active communication from NIH to grantees starting immediately upon the issue of the final Public Access Policy.

As described in our response to question 2, we suggest clarifying the use of the language provided in "Guidance for Communicating Rights in Manuscripts" (https://www.federalregister.gov/d/2024-13373/p-125). If this language must be included when the article is submitted, it will not be possible for all authors who submitted their article before October 1, 2025 to comply. The length of time between article submission, acceptance, and publication is highly variable (it can reach lengths over one year) and authors will be unable to predict whether articles submitted after the final version of the Public Access Policy is published will be accepted before or after October 1, 2025.

We also encourage NIH to use this opportunity to strongly encourage authors to use persistent identifiers to track their articles, including using ORCids for author identification, DOIs of manuscripts when published, and Research Organization Registry numbers (RORs) for affiliation and funder identification. This facilitates tracking, findability, and compliance with the 2022 OSTP "Guidance to Make Federally-Funded Research Freely Available Without Delay" as well as related Federal Research Security and Research Integrity Policies.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**

We applaud NIH on the inclusion of the Government Use License in the Draft Plan as a means for researchers to share their work without paying article processing charges (APCs). This ensures that there is an equitable path to compliance, available to all authors regardless of the amount of funding they have available. It also enables maximum use of taxpayer money to support research, rather than for paying publisher charges.

--Timeline of usage--

In "Guidance for Communicating Rights in Manuscripts", NIH helpfully provides a statement authors can include in their manuscript (https://www.federalregister.gov/d/2024-13373/p-125). Related to the concerns outlined in our response to question 1, it is unclear when authors should use this language. Should the statement be included in the submitted version? Or are authors expected to add this to their accepted manuscript, post-peer review? In which cases might authors not include it? We recommend clarifying the language in this section of the policy.

--Publisher systems--

We have concerns about the use of the recommended license language given limitations of publisher manuscript submission systems. In many cases, authors only have the choice to "click through" statements agreeing to transfer their copyright to the publisher. Clarification for how authors can insert or append publisher contracts with the provided language would be helpful.

--Clarify purpose of licenses from authors--

We understand the proposed guidance to affirm that a license exists as a basic condition of grant funding that enables government use (i.e., the Government Use License (GUL)), and that the GUL allows for public access sharing of articles resulting from NIH funding.

The proposed guidance suggests that authors should include a statement in their manuscripts affirming the Government Use License. We think this is a good suggestion.

The proposed guidance then also suggests the inclusion of what seems to be a separate license from authors to PubMed Central (PMC). This separate license seems to provide an additional layer of rights assurance for PMC beyond the existing Government Use License, and possibly an additional reminder for authors about their public access obligations under grant conditions. However, some authors may find it confusing to be required to execute a license to PMC, especially if they have already included a statement in their manuscript affirming the GUL.

We suggest that additional information be provided to authors about any license requested at the time of submission to PMC. One possible way to do that would be to provide information around that license explaining that it is an additional assurance around rights, and/or that it is a reaffirmation of shared rights required as part of the grant agreement.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**

--Clarification on reasonable, allowable, allocatable, and consistent--

There is ongoing research and data collection on what are reasonable and actual costs for publications—we recommend that NIH use language that aligns with the current standard guidelines (reasonable, allowable, allocatable and consistent) until there is more information

about specific guidelines. It also is worth emphasizing that allowable and reasonable costs for direct charge to grants may change from the timeline of budget development to publication.
We greatly appreciate that NIH has emphasized the no-fee methods to public access policy compliance. We recognize that authors may still choose to publish in journals that require payment of an article processing charge (APC) for publication; that is, for fully open access journals that charge APCs. NIH should consider adding more emphasis that APCs for hybrid journals are unnecessary for compliance with the policy. Communication and education around this point are crucial to ensure authors understand they do not need to pay to meet open access requirements.
We propose NIH might be more specific about what is "reasonable" to ensure that the Policy does not introduce more inequities into the publishing system. The work of Butler et al. shows how APC prices increased between 2019 and 2023, with an average (of hybrid and fully OA APCs) of $2,860 across publishers, and a maximum of $11,600 in 2023.[1] In 2024, the APC for Nature increased to $12,290. Again, NIH should emphasize to authors that hybrid APCs are not required for compliance with the NIH policy; this will ensure that taxpayer money is spent on research, not publication.
In considering NIH-funded articles, the average APC for the top journals in which UMN authors publish is close to the average reported in OSTP's June 2024 Updated Report to the U.S. Congress on Financing Mechanisms for Open Access Publishing of Federally Funded Research[2], $3800. We estimate up to 2500 articles based on NIH-funded research may be published by UMN authors each year, which would cost taxpayers over $9.4 million if APC payment were to be required. With our collections budget of approximately $18 million, the University Libraries would be unable to cover the cost with APCs for funded authors, without creating deep inequities for unfunded versus funded authors. (Our authors publish roughly 8000 to 9000 articles per year; even if our entire budget were spent on APCs, we would not be able to support all authors.)
If it is not possible to define a "reasonable" APC at this time, we suggest that NIH should monitor APC prices. This could be done through tracking where NIH-funded authors publish and how often their articles are published OA (i.e., paid hybrid or published in a fully OA journal), monitoring broader trends in APC prices, or through a pilot project to monitor costs for a set of grants.
--Other publisher charges--
We appreciate that NIH has provided clear prohibition of use of grant funding to pay publishers for activities other than publishing articles. Subsidizing publisher business models in this way would be a poor use of taxpayer money. Like many who work in open/public access, we were disappointed when the American Chemical Society (ACS) introduced its "article development charge" (ADC), for which authors pay $2500 at the time of submission. With this model, if the article is rejected, the author is not refunded the money; if the article is accepted, the author is allowed to deposit the article in a repository (e.g., PMC) without an embargo or they can pay an APC that is discounted by the amount paid for the ADC. The Policy is clear that fees for submission or services such as peer review are not allowable costs. However, more clarification would be useful. For example, with the ACS model, if the article is accepted and the author opts to pay the remaining APC for hybrid OA, would they be able to expense the full amount paid (i.e., treating the ADC as part of the eventual APC paid)?

"Transformative" agreements and institutional support for open access

OSTP's June 2024 Updated Report to the U.S. Congress on Financing Mechanisms for Open Access Publishing of Federally Funded Research [2] provides discussion of transformative agreements and the growth in their numbers. "Transformative" agreements were meant to transform hybrid journals to full OA; they allow corresponding authors from the participating institution to publish OA in hybrid journals without paying an APC, sometimes fully OA journals are also included under the agreement.

We have concerns about providing support or encouragement for these types of agreements and the expectations that publishers might place on institutions to enter into these agreements to enable researchers to meet funders' public access requirements. We are already hearing from publishers that APCs will not be a problem for authors because they expect the author's institution will enter into an agreement to cover APCs for their institution's authors or the author will be able to receive a waiver. However, waiver policies are usually limited to authors from low or middle income countries; publishers typically expect authors from high income countries to pay APCs, especially if they have received grant funding, regardless of the amount. These agreements are inherently inequitable. They benefit only authors at participating institutions, but they are costly and are unaffordable for many institutions. They are also specific to individual publishers. Large research institutions like the University of Minnesota would not be able to enter into agreements for every journal in which our NIH-funded researchers would publish.

Some publishers have suggested that libraries should "access" grant funding (through direct or indirect costs) to pay for the additional costs. This does not align with the University of Minnesota Libraries' principles on open access, but we are aware of some institutions who do request authors provide grant funding to support agreements. If transformative agreements become a dominant model for OA publishing, we suggest NIH might provide clarification on if and how grant funding can be used to support them. Would contributions from NIH-funded researchers to agreements that combine access to subscription materials ("reading" access) and publication charges be an allowable expense? Authors generally do not know exactly how many articles they publish and where they will publish at the start of the fiscal year and would be taking the chance of using grant funding to support agreements that they will not take advantage of.

Some agreements are "capped": the institution receives credits for a predetermined number of articles. In some cases the cap is lower than the expected output and authors with grant funding may be encouraged to use their funding to pay an APC outside of the agreement. If the cap is exceeded, authors typically have the option to pay an APC to make their article open access. Would the APC be an allowable expense in these cases? It would not be feasible or equitable for institutions to manage a capped agreement to maintain a reserved pool of credits for NIH-funded authors.

We have also seen a university system develop a model in which authors have the option to use their grant funding to contribute to an APC, however, the library would pay the entirety if the author was unable or unwilling to contribute. Would contributing to an APC be an allowable expense, if it might otherwise be paid through another source from within the institution?

Support for diamond and other non-APC-based OA models

We appreciated the discussion of non-APC-based business models for open access publishing in OSTP's June 2024 Report. Countries in Latin America, Central America, South America, and the Caribbean have used diamond OA publishing models, where the journal is free for all readers and free for all authors to publish, for decades (e.g., ScieELO and Redalyc). Support for Diamond OA has been increasing in Europe over the last few years: Science Europe, cOAlition S, OPERAS, and the French National Research Agency published an Action Plan for Diamond Open Access [3]. We have also seen statements of support for OA models that do not rely on author payments from library deans from some of the most prestigious universities in the US [4] and researchers in the United Kingdom [5].

The University of Minnesota strongly supports fee-free OA publishing models. Through our Libraries Publishing Services, we publish journals, scholarly monographs and other research products using the diamond OA model [6]. We provide financial support for diamond OA from other journals and are strong supporters of the subscribe-to-open model. These models work best for publishers that are working in partnership with libraries and researchers, typically non-profit, society publishers. We encourage NIH to consider supporting these types of OA publishing models, potentially through direct grants to diamond OA publishers, support for meetings among publishers to develop models, and educating NIH-funded researchers about diamond OA and other APC-free journal options.

[1] Butler, L. A., Hare, M., SchÃ¶nfelder, N., Schares, E., Alperin, J. P., & Haustein, S. (2024). An open dataset of article processing charges from six large scholarly publishers (2019-2023). arXiv preprint arXiv:2406.08356.

[2] White House Office of Science and Technology Policy. (2024). Updated Report to the U.S. Congress on Financing Mechanisms for Open Access Publishing of Federally Funded Research: A report by the White House Office of Science and Technology Policy. https://www.whitehouse.gov/wp-content/uploads/2024/06/2024-Report-to-Appropriations-Committee-on-Scholarly-Publishing-and-Public-Access-Implementation.pdf

[3] Ancion, Z., Borrell-DamiÃ¡n, L., Mounier, P., Rooryck, J., & Saenen, B. (2022). Action Plan for Diamond Open Access. Zenodo. https://doi.org/10.5281/zenodo.6282403

[4] Meisel, J.S., Reimer, T., Thornton, A., Westbrooks, Kroch, C.A., E.L., Mehrer, S., Salem, J., Whitehead, M., Long, E.M., Bourg, C., Constantinou, C., Jarvis, A., Rockenbach, B., & Keller, M.A. (2023). Ivy Plus Libraries weigh in on OSTP guidance on access to federally funded research. MIT Libraries News & Events. https://libraries.mit.edu/news/libraries-support-3/34036/

[5] Eglen, S., et al., An open letter from UK researchers to UK library directors regarding the UK's reliance on read-and-publish deals with journal publishers. https://docs.google.com/document/d/1ZAlPDvECb5Zm1pqAf0I1f0sjcBqPbkPGMvGIhaCz6lM/edit#heading=h.5k64npqo1jn0

[6] University of Minnesota Libraries. (n.d.). Libraries Partnerships for Open Access. Libraries partnerships for open access https://www.lib.umn.edu/services/open-access/oa-partnerships#sustainable

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Description:

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Tom Ciavarella

Name of Organization: Frontiers

Type of Organization: Professional org association

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
In judging the delivery models to abide by public access requirements, the NIH must make a robust and transparent assessment to compare those models for efficiency, scalability, and public value for money, guided by the objective of discoverability that underlies public access. In all such aspects, Gold Open Access delivers. We stand ready to support the NIH and its partners in the federal government. It is vital we back responsible publishing efforts for the good of open science and to meet the public appetite for accountability, transparency, and trust.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
Gold Open Access provides clear protections for authors' rights. Frontiers articles are published under the Creative Commons attribution (CC-BY) license, allowing others to distribute, remix, adapt, and build on the articles – with the expectation that attribution is given to the articles' original creators. While it is standard practice for subscription paywall publishers to require that authors surrender their work's copyright, all authors in all Frontiers journals retain all their rights; copyright is not transferred to Frontiers. The Frontiers Gold OA, CC-BY approach delivers truly open science that is freely and permanently available for anyone to view, download, and disseminate in interoperable, machine-readable formats, allowing all authors to commercially manage their intellectual property as they wish.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
Gold Open Access delivers the NIH's desired results for public access in an efficient, effective, and affordable way. It is vital that the funding of public access is as scalable and as good a value for money as possible, and in our view, Gold OA is the best way of securing that outcome. It offers a simple, transparent, and competitive means to unlock the benefits of fully accessible science and does so more effectively than the Green OA option. As such we believe that the NIH, in allowing for compliance through either a Green or Gold model, should express a preference for Gold OA.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/Frontiers_response_NIH_2024-08-19.pdf

Description: Frontiers response to Request for Information on the National Institutes of Health Draft Public Access Policy (89 FR 51537)

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Jennifer Brogan

Name of Organization: Wolters Kluwer

Type of Organization: Other

Type of Organization-Other: Publisher

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   Please refer to attached PDF.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   Please refer to attached PDF.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   Please refer to attached PDF.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/Wolters-Kluwer-NIH-RFI-Response-08.19.24.pdf

Description: Wolters Kluwer Response to NIH Draft Public Access Policy

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Josh Kerr

Name of Organization: American Association of Hip and Knee Surgeons

Type of Organization: Professional org association

Type of Organization-Other:

Role: Medical provider

1) **Provide any comments on the Draft Public Access Policy below:**
   AAHKS shares the NIH's goals of ensuring the broad availability of trustworthy and impactful research findings, as well as equity in publication opportunities for NIH-supported investigators. Accordingly, we agree that publicly funded research should be publicly accessible without an embargo period. Doing so will remove resource-barriers for health care practitioners seeking to improve the quality of care delivered to their patients by referencing the latest peer-reviewed publications. In addition to promoting equity, this change will help support independent practices and mitigate concerning trends in health care consolidation.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   AAHKS welcomes that the Draft Public Access Policy continues to allow for reasonable costs associated with publication to be requested in the budget for the project as direct or indirect costs. Hip and knee surgeons across the country depend on highly credible, practice-specific research journals to continue to advance the standard of care. Allowing for reasonable publications costs will enable these journals to continue performing critical services (e.g., peer review) as the 12-month embargo period is lifted and timely access to NIH-funded research becomes more equitable.
   Furthermore, to help ensure equity in publication opportunities for all NIH-supported investigators, AAHKS supports guidance clarifying that funds for publication should remain available after the end of the grant period.

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Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Lorin Jackson

Name of Organization: NNLM Region 2

Type of Organization: Other

Type of Organization-Other: NNLM Region 2 Regional Medical Library

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   We appreciate how this emphasizes the importance of health information accessibility for all. How will NIH work to accommodate accessibility needs (sight impairment, physical disability, language needs, digital literacy, etc.) through its online platform?

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   We suggest exploring partnerships with public libraries to enhance engagement and dissemination of information. Public libraries are best positioned to understand their community's needs, making them ideal partners for achieving strategic goals. The NNLM can also partner in discussing enhancing engagement and dissemination of information through virtual open forums. How can the NIH leverage relationships with the NNLM and public libraries for Government Use Licenses and Rights?

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   We recommend providing free training and user-friendly resources to help the general public and community organizations access NH content. We stress the need for accessible and understandable information, including clear parameters and responsibilities for the NNLM and its members involved in providing work or research.

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Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Kelsey Badger and Julia Behnfeldt

Name of Organization: The Ohio State University

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/nih-public-access-rfi_osu-response_20240819.pdf

Description: Response letter

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Jennifer E. Beamer

Name of Organization: United States Repository Network (USRN)

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/USRN-Comments-on-NIHs-draft-public-access-policy-guidance-.pdf

Description: USRN Comments on NIH's draft public access policy & guidance .pdf

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Jay Flynn

Name of Organization: John Wiley & Sons

Type of Organization: Other

Type of Organization-Other: Access Partnership

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/Wiley-Response-to-NIH-Draft-Public-Access-Policy-August-2024.pdf

Description:

Submit date: 8/19/2024

I am responding to this RFI: On behalf of myself

Name: Rachel Caldwell

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan which will make grant-funded research immediately available to the public for free. As an academic librarian, I especially support the NIH's use of the Federal Purpose License in support of authors' right to deposit their works as it is a straightforward approach. The FPL will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Victoria Tiase

Name of Organization: Alliance for Nursing Informatics

Type of Organization: Professional org association

Type of Organization-Other:

Role: Medical provider

1) **Provide any comments on the Draft Public Access Policy below:**
   Please see the attached letter for our comments.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/ANI-Comments_Public-Access-Plan-2024.pdf

Description:

Submit date: 8/19/2024

I am responding to this RFI: On behalf of myself

Name: Gillian Goldberg

Name of Organization: University of the Pacific Holt-Atherton Special Collections and Archives

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   I support the NIH draft plan to make grant-funded research immediately available to the public for free. The NIH's use of the Federal Purpose License in support of authors' right to deposit their works for this purpose is particularly welcome. I believe NIH is proposing an effective, consistent, and straightforward approach, which will avoid overburdening researchers and universities with legal complexity or additional cost.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

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Description:

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: New York University

Name of Organization: New York University

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**

August 19, 2024
Lyric Jorgenson, PhD
Director, Office of Science Policy and
NIH Associate Director for Science Policy
The National Institutes of Health
6705 Rockledge Drive, Suite 630
Bethesda, MD 20892
NYU Comments Response to Request for Information on the NIH Draft Public Access Policy
Dear Dr. Jorgenson,
On behalf of New York University (NYU) we would like to express our gratitude for the opportunity to provide feedback to the Request for Information (RFI) regarding the NIH Draft Public Access Policy. The New York University Libraries is a global organization that advances teaching, learning, research, and scholarly inquiry in an environment dedicated to the open exchange of information. As participants in the educational mission of an interconnected, multi-agency, global institution, we prioritize equitable access to information and resources, as well as embrace principles of intellectual freedom and open access. NYU scholars and scientists are on the forefront of medical research and support the open distribution of research discoveries that have real-world positive impact on human health and well-being. As you consider your plans to adapt the Draft Public Access Policy, we wanted to raise the following points, which collectively address many of the questions in your RFI.
Comment Field #1: Draft Public Access Policy
NYU thanks the National Institutes of Health (NIH) for its leadership on public access policy and commends NIH for eliminating the embargo period on publications resulting from NIH-funded research. Providing immediate and free access to biomedical research is a strong belief of ours to ensure that our researchers have the latest information at their fingertips to effectively address our most pressing public health challenges and the world-leading research our institution produces can reach the widest audience. We support NIH's intention to make it easy for researchers to comply with the draft policy. Long-term we hope that NIH will continue to monitor the impacts of the policy to ensure that institutions and researchers do not bear undue burdens in publishing biomedical research and that the publishing ecosystem remains vibrant with diverse journal options for our readers and authors.
Comment Field #2: Draft Guidance on Government Use License and Rights

We encourage the NIH to more explicitly clarify in the policy and in PubMed user guidance that manuscripts submitted to PubMed will be available to the public for fair use. Fair reuse is critical for our researchers, including our students and postdoctoral fellows, as they advance discovery through text and data mining and use publication materials in educational courses.

Comment Field #3: Draft Guidance on Publication Costs

We appreciate NIH's intention to make compliance with the new policy as free as possible for authors, researchers, and institutions. At NYU we are investing greatly in enabling our researchers to pursue open access sustainably, equitably, and with a focus on high quality research. This has included open access agreements with some publishers. We hope that NIH will foster innovation around these principles and keep an eye to the impact of the policy on equity, sustainability, and quality. Reasonable publication costs should continue to be allowable so that researchers have maximum choice in where to publish and amplify their research. NIH should assess how costs are impacting institutions and researchers as well as how these costs impact NIH grant sizes, success rates, or other downstream effects. We also encourage exploring alternative ways to share research, such as preprints or Diamond Open Access models.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   n/a

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   n/a

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/NYU-NIH-Public-Access-Policy-RFI-Response-Aug-2024.pdf

Description: NYU Comments on NIH Public Access Policy RFI

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Juliane Baron

Name of Organization: Federation of Associations in Behavioral and Brain Sciences (FABBS)

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
FABBS applauds and shares the NIH's commitment to making federally funded research available to the public. Please see our Open Science Statement (https://fabbs.org/wp-content/uploads/2024/03/FABBS-Open-Science-Statement.pdf).
The policy refers narrowly to "biomedical research." FABBS recommends updating this to "biomedical and behavioral research" to match the current NIH strategic plan, which is "to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability" (https://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2021-2025-508.pdf).
FABBS appreciates the emphasis on equity in this policy (e.g., making content accessible for those using assistive technologies), however, we caution that equal public access via PubMed Central (PMC) will not ensure equitable access. In comments submitted to last year's public access RFI, FABBS noted barriers, beyond the ability to download a particular article (https://osp.od.nih.gov/wp-content/uploads/2023/06/NIH_Public_Access_to_the_Results_of_NIH-Supported_Research_RFI_FINAL_508.pdf). Apparently, other stakeholders share this concern: "making information available is necessary but not sufficient to meet goals concerning equitable access. Consumers of the information resulting from NIH-supported studies need to be able to process and understand what they are reading." Despite this acknowledgement, the new policy does not concretely address these concerns. FABBS urges NIH to address this issue while finalizing the policy, rather than taking a wait-and-see approach.
As we know, not all NIH-funded projects produce results that lend themselves to a publishable article. FABBS encourages NIH to think through opportunities for capturing null findings, doing so would help document the return on investment and potentially promote research efficiency by building on previous research questions.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**
FABBS encourages NIH to differentiate between commercial/for-profit publishers and society publishers. FABBS member societies rely on journal revenue for a wide range of critical services that support their disciplines, for example: mentorship programs, offsetting the costs of conference attendance, professional development opportunities, etc often most benefitting

early career and scholars from underrepresented communities. FABBS is concerned about the ability for scientific societies to continue these valuable activities.
The current RFI focuses on article processing charges (APCs) as the primary alternative to the subscription model. FABBS contends that APCs will continue to have disparate and unintended consequences for researchers and encourages NIH to continue to explore additional models.

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Description: The Federation of Associations in Behavioral and Brain Sciences (FABBS) represents 29 scientific societies and 60 university departments whose scientific members and faculty share a commitment to advancing knowledge in the sciences of mind, brain, and behavior.

Submit date: 8/19/2024

I am responding to this RFI: On behalf of myself

Name: Craig C. McLauchlan

Name of Organization: Illinois State University

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   Although Illinois State University has a small number of NIH grantees, we appreciate the use of the Federal Purpose License in the Public Access Policy Draft and believe it will help grantees comply with the requirement to make research outputs immediately publicly available.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   Illinois State University has entered into open access publishing agreements with several publishers, but comprehensive open access publishing is not sustainable given the library's flat budget. We also acknowledge that payment-based open access publishing can perpetuate inequities in the scholarly communication landscape and exclude authors from low-income countries and under-resourced institutions. Accordingly, we encourage the NIH to define reasonable publication costs, consider capping per-article publication costs, and otherwise push back against commercial publishers' exploitation of payment-based open access publishing to increase their considerable profit margins.

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Description:

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Felice J. Levine

Name of Organization: American Educational Research Association

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
   AERA supports the ongoing work to update the NIH public access policy for publications to remove the embargo period to make NIH-funded publications available to align with the 2022 White House Office of Science and Technology Policy memorandum, Ensuring Free, Immediate, and Equitable Access to Federally Funded Research.
   Overall, we encourage consistency and alignment with other federal agencies in the process for making available applicable peer-reviewed scholarly publications that have support from federal funding. This is especially important in cases where funding from additional agencies (e.g., Institute of Education Sciences [IES] or National Science Foundation [NSF]) contributed to research findings in peer-reviewed scientific publications. In education research, it is not uncommon for multiple federal agencies to fund research that results in a peer-reviewed publication. In addition, we recommend that there should be flexibility for authors to submit either the final peer-reviewed manuscript or the final published article (version of record). We urge NIH to be consistent in allowing for the submission of applicable publications to PubMed Central to be made at the time of acceptance of publication with the author accepted manuscript, which would align with the public access policies at NSF and IES.
   We also recommend that requirements for publications include a direct object identifier (DOI) for articles supplied by the publisher. We also are encouraging of authors' obtaining a persistent author identifier (e.g., ORCID) that NIH can include to accompany the article. This stipulation would also be consistent with the IES and NSF Public Access Plans.
   AERA also supports the language that is included in the third bullet point under "Government Use License and Rights" that authors are not expected to provide rights to the Final Published Article to leave flexibility to provide the author accepted manuscript. NIH should also continue to work with publishers directly to the extent possible to form agreements with journal publishers to submit applicable journal articles to PubMed Central as one way to decrease burden and cost for the NIH-funded author and to reduce confusion on copyright.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   We strongly support NIH grants including funds as reasonable costs to cover article processing fees for open access journals and for related fees that subscription-based journals assess to authors to provide immediate open access. We understand and support the draft guidance not

allowing costs for submission of NIH-funded peer-reviewed scholarly publications to PubMed Central where there are no attendant fees. The draft guidance could make clear that NIH-funded authors should not be penalized for submitting manuscripts to peer-reviewed journals where they may need to pay for article processing fees.

Uploaded File:

Description: Please see attached comment on behalf of the American Educational Research Association.

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Barbara E Bierer MD

Name of Organization: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

Type of Organization: Health care delivery organization

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**

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.
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.

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.
- 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.

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) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**

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) **Provide any comments on the Draft Guidance on Publication Costs below:**
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.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/MRCT-Center-comments-NIH-Draft-Public-Access-Policy.pdf

Description: A letter encompassing much of what was said above.

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Raechel McKinley

Name of Organization: American Society for Biochemistry and Molecular Biology

Type of Organization: Professional org association

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
The draft public access policy provides clearer and more concise guidance than the current public access policy by clarifying the rights of authors. However, the NIH should consider expanding and clarifying several definitions in the policy:
   - The current definition of "article" does not specify that the paper must be peer reviewed. This sparks concern because documents like preprints may not undergo peer review. To prevent any confusion, the ASBMB recommends that the NIH clarify that publicly deposited preprint content is not peer-reviewed and should not fall under the "article" category.
   - However, the public access policy's scope should explicitly state that articles are affirmatively peer re-reviewed.

   Overall, the ASBMB recommends that NIH use language similar to NSF's Public Access Plan 2.0 when discussing manuscripts, articles and peer review.
   Moreover, unless NIH does make clear that publicly available articles are peer reviewed, the requirement that content be machine-readable could open the door for incorrect information being used to train artificial intelligence algorithms or large language models. Specifically, manuscripts that have not benefited from independent peer review, i.e. become a finalized article if accepted, may be more likely to include incorrect information. Given the proliferation of AI tools that ingest and "learn" from publicly available scientific databases, ASBMB recommends that the NIH investigate, anticipate and remediate the potential harmful implications of those AI tools' ready access to content that has not undergone peer review. ASBMB also raises significant concerns associated with large-scale AI acquisition of copyrighted works and the consequences for ASBMB members and scientists whose work is appropriated and used, without a clear understanding on how these royalties would be redistributed.
   Under the compliance and enforcement section of the policy, the NIH should be more specific about who is considered a claimant. The NIH should also clarify what non-compliance means. The policy puts the responsibility of complying on institutions. The agency should state how the non-compliance of one author affects other authors at the same institution. The ASBMB recommends the addition of a section in the FAQs to elaborate on the consequences for individual investigators when and if another investigator at the same institution does not comply with the policy.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**

The ASBMB supports the draft guidance. The Society commends the NIH for clarifying that researchers maintain the rights.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
The draft guidance on publication costs raises concern regarding caps on publication-related costs. The capping of publication-related costs can subject the scientific community to the risk of predatory publishing, including article processing charges from disreputable journals. In addition, capping costs may hinder publishing societies from supporting programs and operations related to their mission.
The NIH Draft Public Access Policy indicates reasonable, allowable costs associated with publication may be requested in the budget for the project as direct or indirect costs. ASBMB commends this language and recommends that it be incorporated in the final public access policy as it makes allowable costs clearer to authors.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/ASBMB-Response-to-the-NIH-Draft-Public-Acess-Policy.pdf

Description: Attached are formal comments from the American Society for Biochemistry and Molecular Biology

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Deborah Motton

Name of Organization: University of California system

Type of Organization: University

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
   Please see attached comment letter for comments.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   Please see attached comment letter for comments.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   Please see attached comment letter for comments.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/UC-Comment-Letter-on-Draft-NIH-Public-Access-Policy_final_8.19.24.pdf

Description: Please see attached comment letter submitted on behalf of the University of California.

Submit date: 8/19/2024

I am responding to this RFI: On behalf of an organization

Name: Tayler Williams

Name of Organization: American Medical Informatics Association (AMIA)

Type of Organization: Professional org association

Type of Organization-Other:

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/NIH-RFI-Draft-Public-Access-Policy-AMIA-Comments.pdf

Description: General comments and observations by the American Medical Informatics Association.

Submit date: 8/19/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Scientific researcher

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/Untitled-document-1.pdf

Description: Comments 89 FR 51537

Submit date: 8/20/2024

I am responding to this RFI: On behalf of an organization

Name: Kaia Motter

Name of Organization: Springer Nature

Type of Organization: Other

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/SN%20response%20to%20Request%20for%20Information%20on%20the%20National%20Institutes%20of%20Health%20Draft%20Public%20Access%20Policy%20(89%20FR%2051537)%20FINAL.pdf

Description:

Submit date: 8/20/2024

I am responding to this RFI: On behalf of an organization

Name: Emily Besser

Name of Organization: American Society of Transplant Surgeons & American Society of Transplantation

Type of Organization: Other

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/AST-ASTS%20statement%20on%20OA-c.pdf

Description:

Submit date: 8/21/2024

I am responding to this RFI: On behalf of an organization

Name: Casey Rojas

Name of Organization: New England Journal of Medicine

Type of Organization: Other

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
We appreciate this opportunity to comment on the Draft Public Access Policy.
The New England Journal of Medicine (NEJM) has published peer-reviewed research and interactive clinical content for physicians, educators, and the global medical community since 1812. As the oldest continuously published medical periodical, NEJM is recognized as the gold standard for current research and best practices in medicine. Our mission is to bring health care professionals the most reliable biomedical research and clinical information to inform their practice and improve patient outcomes. NEJM and its related publications—NEJM AI, NEJM Catalyst, and NEJM Evidence—are published by the Massachusetts Medical Society, an independent, nonprofit medical publisher.
As the most widely read, cited, and influential general medical journal and website in the world, it's vital for NEJM to publish accurate and timely clinical evidence. Our editors and peer reviewers work through a painstaking process with authors to ensure that findings are accurate and not overstated or exaggerated in any way. We are extremely concerned that the proposed public access policy from the National Institutes of Health (NIH) allows for derivative reuse of NEJM articles. By allowing others to modify clinically directive content like ours the NIH policy increases the likelihood that the research results will be misrepresented and misused.
Imagine what would happen if an adaptive article incorrectly translated the clinical application of the research. Think of the implications if medicine was prescribed to an unintended patient group because clinical trial population data were left out of a derivative of an NEJM article. Consider the impact to human health if information about adverse events were excluded from derivative works. Not only could this policy add to mistrust in science, but it's also harmful to our authors and the physicians using this information to treat their patients and puts the reputation of the NIH at risk by jeopardizing public health.
In addition to introducing a zero-month embargo on research content, adding a government use and derivative rights clause to the proposed NIH Public Access Policy impacts the long-term sustainability of our publications. As a nonprofit organization, proceeds from publishing operations are reinvested in enhancing journal content through plain language summaries, videos, and podcasts so that busy clinicians can correctly apply trusted health evidence to patient care.
On a final note, the current public access statute, Public Law 110-161, Division G, Title II, Section 218, does not include any language authorizing a derivative works requirement. It's unclear to us what authority the NIH has for extending the policy and believe this additional condition

should be removed.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
The New England Journal of Medicine is a small volume, high-quality publication. Each year, our editors filter through thousands of submitted manuscripts, rigorously vetting clinical trials and health research to select only the best for publication. Each manuscript accepted for publication benefits from hundreds of hours of work by medical editors, statistical experts, manuscript editors, illustrators, proofreaders,
and production staff, who work to ensure that every paper meets exacting standards before it publishes in the Journal.
NEJM provides healthcare professionals and the patients they serve with trusted clinical evidence. What we publish has a direct and immediate impact on human health. Our independent, non-biased review process ensures research findings are not overstated, prevents miscommunication of health evidence, contests misinformation promoted by self-serving organizations, and engenders public trust in the scientific enterprise. A subscription model works best for our high-touch peer review and manuscript editing publishing ethos.
The valuable intellectual property enhancements from NEJM and the systems we have invested in to deliver them come at a substantial cost. A reader-pays model is the only model that can finance our comprehensive process. Moreover, a broad one-size-fits-all approach does not work for all authors and publishers. We firmly believe that authors should be able to choose where to publish. A subscription model is the most equitable approach for ensuring that all authors can publish in NEJM regardless of their financial means.
If NIH authorizes derivatives, authors will no longer have control over how their research is interpreted and publishers lose oversight of the integrity of the scholarly record. At a time when partisanship is rampant, the freedom to create derivative works without author review or unbiased scrutiny may lead to political influence in the representation of the findings, could introduce errors, and in the case of medical research, could affect patient outcomes and public health. The reputation of the NIH and other government research agencies could also be affected.
As we look to the future, even more resources are needed to scrutinize new technologies like artificial intelligence in medicine, deliver practice-changing advances in health care, and educate the next generation of physicians. Prohibiting reuse of research outputs without permission and protecting subscriptions best supports NEJM in its mission to publish the most impactful medical advances and improve patient care in the United States and around the world.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
As a not-for-profit medical publisher, we value our reader-pays business model, which allows us to continuously invest in subject-matter experts, statistical reviews, innovations in science communication, professional publishing talent, and editorial and production systems to ensure that New England Journal of Medicine remains a trusted resource for health care professionals. Our model gives NEJM editorial independence to ensure that conclusions are not overstated or misleading, that results are put into the proper context for treating patients, and that a dispassionate peer-review process has informed all editorial selections. We do all of this without charging our authors any fees to submit or publish in the Journal—something that would take

valuable research dollars away from the actual research. Our commitment is to publishing practice-changing evidence without contributing to the growing cost of research to funders like the NIH.

Thank you for this opportunity to comment on the proposed NIH Public Access Policy. NEJM is ready to assist in advising on policy updates and welcomes further dialogue. Please reach out to Casey Rojas at crojas@mms.org with any questions or to continue this discussion.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/NEJM-Group-NIH-RFI-submission-Public-Access-Licensing-8.14.24.pdf

Description:

Submit date: 8/21/2024

I am responding to this RFI: On behalf of an organization

Name: Paul Fakes

Name of Organization: ASME

Type of Organization: Other

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/ASME-NIH-RFI-Response%20July%202024.pdf

Description:

Submit date: 8/21/2024

I am responding to this RFI: On behalf of an organization

Name: Miriam Quintal

Name of Organization: Society for Industrial and Applied Mathematics

Type of Organization: Other

Type of Organization-Other:

Role: Institutional official

1) **Provide any comments on the Draft Public Access Policy below:**
2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
3) **Provide any comments on the Draft Guidance on Publication Costs below:**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/SIAM-NIH-Open-Access-RFI-Response-August-2024.docx

Description:

Submit date: 8/30/2024

I am responding to this RFI: On behalf of an organization

Name: David Knutson

Name of Organization: Public Library of Science (PLOS)

Type of Organization: Other

Type of Organization-Other: Open Access Scholarly Publisher

Role: Member of the public

1) **Provide any comments on the Draft Public Access Policy below:**
   PLOS is a nonprofit, Open Access (OA) publisher empowering researchers to accelerate progress in science and medicine by leading a transformation in research communication. We've been breaking boundaries since 2001, and we propelled the movement for OA alternatives to subscription journals. We consider the NIH policy (and the policies of other federal agencies) as a crucial step in supporting the goal of ensuring public access to knowledge.

2) **Provide any comments on the Draft Guidance on Government Use License and Rights below:**
   PLOS welcomes the public access to research outputs enabled by this policy. Making research publicly accessible is important for increasing inclusion and is a step towards achieving a goal of the Universal Declaration of Human Rights, namely that 'everyone…has the right to share in scientific advancement and its benefits'.
   However, we would go a step further and grant full re-use rights to publications to all under a CC BY license. This approach allows researchers to be identified as the originator of the work while allowing others to build upon it. In the spirit of scientific exploration, CC licenses do not license only for the exceptions or uses that we see now, but to enable future leaps in discovery and innovation for the benefit of society as a whole.
   In practical terms, we encourage streamlining of licensing to reduce administrative burden and simplify compliance, while ensuring that authors retain the right to be identified as the originators of their work and to re-use their own publications.

3) **Provide any comments on the Draft Guidance on Publication Costs below:**
   PLOS acknowledges that we have a vested interest in guidance provided by the NIH with regards to compliance with publication costs.
   While we support the policy overall, PLOS is concerned about the language in the draft policy In its current form, in particular where it states that submission of manuscripts to PubMed Central (PMC) remains a free route to compliance.
   PLOS understands and appreciates the NIH perspective that organizations should not profit from the activity of deposition. However, PubMed Central only accepts submissions of either (a) a peer reviewed author version; or (b) a final published article. Positioning this as a 'free' route to compliance and placing the focus solely on the deposition fee, devalues the work that comes prior. It infers that publication costs are associated only with the post-peer review stages of the

publication process, i.e. production, publication, dissemination and archiving. This is not an accurate picture.

An article's lifecycle from submission to deposition must pass through many touchpoints before this stage. At PLOS (and many other publishers) these steps include at minimum: research integrity checks, quality/methodological rigor assessment and peer review. The activities of quality assessment and peer review are valuable, and it should be recognized that these have associated costs. As such the authors, or authors' institutions, may incur fees arising from these costs, whether as fees associated with an individual article, or as part of an agreement with an institution. We encourage the NIH to allow such fees to be covered under this policy.

PLOS shares publicly the breakdown of value ascribed to each process stage in line with the cOAlition S price transparency framework. This illustrates the distribution of value associated with fees paid for different stages of the publication process.

PLOS welcomes the draft policy position that where agreements exist between publishers and institutions to cover publication costs, there should be no additional costs for compliance with NIH policy. We also support the proposal that there should be no differential pricing for publications subject to the NIH's Public Access Policy.

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Description: