

Compiled Comments - Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH- Supported Research

Guide Notice Number: NOT-OD-23-091

February 21, 2023 – April 24, 2023

Table of Contents

1. [Aaron W Dobbs](#)
2. [Natalie Moffett](#)
3. [University of Oregon Libraries](#)
4. [Mayank Verma](#)
5. [Gail Johnson](#)
6. [Daniel Gorelick](#)
7. [Peter L. Elkin, MD](#)
8. [Anonymous](#)
9. [Kenneth Pawlak](#)
10. [Bobby Hollingsworth](#)
11. [Anonymous](#)
12. [Center for emerging and neglected diseases uc berkeley](#)
13. [Sandra Poulson](#)
14. [Adam Armstrong](#)
15. [Federico Leva](#)
16. [Catherine Christian-Hinman](#)
17. [Anonymous](#)
18. [Sonal Sathe](#)
19. [Anonymous](#)
20. [Tiffany Atkins](#)
21. [Damien Camany](#)
22. [Peggy Lentz](#)
23. [Rebecca Braddock](#)
24. [Thurman McGarian](#)
25. [Stephen J. Kron](#)
26. [Peggy Lentz](#)
27. [Christopher Marcum](#)
28. [Aligning Science Across Parkinson's](#)
29. [Ana Chicas-Mosier](#)
30. [Andrea Bertke](#)
31. [Federation of American Societies for Experimental Biology](#)
32. [NC State University](#)
33. [Jessica Moise](#)
34. [Luella Allen-Waller](#)
35. [Elizabeth McNally](#)
36. [cOAlition S](#)
37. [Robert Weinberg](#)
38. [Nils Walter](#)
39. [Clifford B. Saper, MD, PhD](#)
40. [Amy Wright](#)
41. [Anonymous](#)
42. [Lynn Brielmaier](#)

43. [Gail A. Bishop](#)
44. [Mr. Stephen P. Panossian](#)
45. [Phil Hurvitz](#)
46. [Andriy Fedorov](#)
47. [Robin Ely MD](#)
48. [Bill & Melinda Gates Foundation](#)
49. [American Academy of Neurology](#)
50. [American Society of Colon & Rectal Surgeons/ Journal Diseases of the Colon & Rectum](#)
51. [Sonal Sathe](#)
52. [Steve Pieper](#)
53. [Peer Community In](#)
54. [Libraries and Sponsored Projects Administration](#)
55. [Carl Tuttle](#)
56. [Open Research Funders Group](#)
57. [Public Knowledge Project](#)
58. [Steven D. Smith](#)
59. [Mark Peifer](#)
60. [NC State University Libraries](#)
61. [John Vaughen](#)
62. [Duke University](#)
63. [American Psychological Association](#)
64. [American Society of Clinical Oncology, American College of Physicians, NEJM Group, American Heart Association, American Diabetes Association, American Society of Anesthesiologists, American Urological Association, American Thoracic Society, American Gastr](#)
65. [University of Illinois Chicago](#)
66. [European Bioinformatics Institute EMBL-EBI](#)
67. [The American Society for Cell Biology](#)
68. [Massachusetts Medical Society - New England Journal of Medicine \(NEJM\)](#)
69. [ORCID](#)
70. [Association of American Medical Colleges](#)
71. [American Chemical Society](#)
72. [AcademyHealth](#)
73. [Oregon State University Libraries and Press](#)
74. [American Association for the Advancement of Science](#)
75. [Public Library of Science \(PLOS\)](#)
76. [Frontiers Media Inc](#)
77. [The American Association of Immunologists \(AAI\)](#)
78. [Congress of Neurological Surgeons](#)
79. [Northern Illinois University](#)
80. [ASAPbio](#)
81. [American Thoracic Society](#)
82. [American Society for Microbiology](#)
83. [Elsevier](#)

84. [American Society for Investigative Pathology](#)
85. [STM \(The International Association of Scientific, Technical and Medical Publishers\)](#)
86. [Council of Medical Specialty Societies](#)
87. [Alliance for Nursing Informatics](#)
88. [Association of American Universities](#)
89. [The Alliance for Aging Research](#)
90. [American Society for Pharmacology and Experimental Therapeutics](#)
91. [The Ohio State University](#)
92. [Association of American Publishers](#)
93. [Medical Library Association & Association of Academic Health Sciences Libraries](#)
94. [Taylor and Francis Group](#)
95. [Huntsman Cancer Institute](#)
96. [American Urological](#)
97. [Springer Nature](#)
98. [Copyright Clearance Center](#)
99. [American Society for Radiation Oncology](#)
100. [Copyright Clearance Center](#)
101. [Research Data Access and Preservation Association](#)
102. [American Gastroenterological Association](#)
103. [American Society for Nutrition](#)
104. [Crossref](#)
105. [Simon Bacon](#)
106. [Data Discovery Collaboration](#)
107. [American Society of Hematology](#)
108. [Center for Open Science](#)
109. [Case Western Reserve University Libraries](#)
110. [American Medical Informatics Association](#)
111. [Epilepsy Foundation](#)
112. [Massachusetts Institute of Technology - MIT Libraries](#)
113. [OASPA](#)
114. [Wolters Kluwer](#)
115. [Research Organization Registry \(ROR\)](#)
116. [Association of Research Libraries](#)
117. [Wiley](#)
118. [Seventeen Science Societies](#)
119. [The Allen Institute](#)
120. [Society for Industrial and Applied Mathematics \(SIAM\)](#)
121. [Women's Health Issues](#)
122. [U.S. Repository Network](#)
123. [American Society of Mechanical Engineers](#)
124. [Association of Public and Land-grant Universities](#)
125. [COGR](#)
126. [American Association for Cancer Research](#)
127. [University of California Office of the President](#)

128. [Carrie Nelson and Cameron Cook](#)
129. [Arizona State University -ASU Library](#)
130. [American Association for Dental, Oral, and Craniofacial Research](#)
131. [Figshare \(Digital Science\)](#)
132. [American Society of Clinical Oncology](#)
133. [Jonathan Saunders](#)
134. [Creative Commons](#)
135. [The Gerontological Society of America](#)
136. [American College of Radiology](#)
137. [SPARC](#)
138. [Federation of Associations in Behavioral and Brain Sciences](#)
139. [Booz Allen Hamilton, Inc.](#)
140. [Robin Puett](#)
141. [Gary McDowell](#)
142. [American College of Rheumatology](#)
143. [Fully OA Publishers](#)

Submit date: 2/21/2023

I am responding to this RFI: On behalf of myself

Name: Aaron W Dobbs

Name of Organization: US Citizen and Member of the Public

Type of Organization: Other

Type of Organization-Other: Member of the Public

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Upon publication, *all* US government funded (especially NIH) research results and publications derived therefrom shall be submitted by the author indexed in PMC (or successor resources). Researchers are encouraged to publish wherever they wish, with the stipulation that the results of the research and any publications derived therefrom shall be publicly indexed in PMC (or successor resources).

2. Steps for improving equity in access and accessibility of publications.

Upon publication, *all* US government funded (especially NIH) research results and publications derived therefrom shall be made publicly available in the Public Domain. Researchers are encouraged to publish wherever they wish, with the stipulation that the results of the research and any publications derived therefrom shall be in the Public Domain.

3. Methods for monitoring evolving costs and impacts on affected communities.

Acknowledging current profitability levels of major research publishers, *all* US government funded (especially NIH) research results and publications derived therefrom should not be subject to publication fees. If this position is too extreme, then a one-time payment for publication should be funded by NIH, not to exceed the 10-year average of the journal issue subscription price divided by the 10-year average page count of each article in an issue.

4. Early input on considerations to increase findability and transparency of research.

Submit date: 2/22/2023

I am responding to this RFI: On behalf of myself

Name: Natalie Moffett

Name of Organization: Student - Washington State University

Type of Organization: Not applicable

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

2. Steps for improving equity in access and accessibility of publications.

The websites fonts sizes can vary wildly, making them larger and more consistent would be better. Prefer bolding and underlining to differentiate titles/authors/section headings. Avoid italics when possible.

3. Methods for monitoring evolving costs and impacts on affected communities.

Publications should announce where your application fees go -what percentage pays for reading and fact checking, how much is spent on formatting or printing, and how much is simply getting kicked into a publishers coffers.

4. Early input on considerations to increase findability and transparency of research.

Washington vs Wichita State Universities can be hard to tell apart, I imagine similar problems occur at Other universities and can make it difficult to track down research and scientists for follow-up questions.

Submit date: 2/22/2023

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

Name: Alicia Salaz

Name of Organization: University of Oregon Libraries

Type of Organization: University

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Allowing federal funds to be used to pay individual author publication charges (APCs) to support 'gold' open access publishing is helpful to the funded author in the short-term, but fuels inflationary price increases to APCs that negatively impact all authors across the research publication system in the US and around the world and entrench growing inequities in access to publishing. As a professional information steward, I have serious concerns about continuing this policy, and would encourage NIH and Other federal agencies to consider expanding and encouraging "green" open access deposits for compliance, for instance, depositing an accepted version of a manuscript into PMC, or a local institutional or disciplinary repository. NIH dollars should go directly towards supporting these government, non-profit, or academy-owned infrastructures, and not to individual researchers to take to the non-competitive publishing marketplace.

A very large percentage of federally funded APC fees go directly to for-profit publishers, whose profit margins on scientific publishing have regularly exceeded 30-40%. Meanwhile, subscription read fees for scholarly journal databases as public and publicly-funded academic libraries across the nation continue to climb. At the system level, this is not a good or effective use of public money or good stewardship of taxpayer funds.

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

Is information gleaned from monitoring actionable? APC fees from for-profit publishers have already inflated to excessive levels. For-profit publishers say they offer discounts and waivers to provide equitable access to publishing. This is highly misleading. The availability, hoops, hurdles, and administrative overhead required to know about and secure these waivers is prohibitive. Our Library strongly advocates for NIH to pursue policies that move towards low-cost, open public infrastructures for sharing the products of publicly funded research (such as PMC); thereby driving down market demand both for for-profit journal subscriptions and open access publishing charges, and hopefully lowering costs for consumers and producers of publicly funded research across the board.

4. Early input on considerations to increase findability and transparency of research.

Submit date: 2/23/2023

I am responding to this RFI: On behalf of myself

Name: Mayank Verma

Name of Organization: UTSW

Type of Organization: University

Role: Scientific researcher

- 1. How to best ensure equity in publication opportunities for NIH-supported investigators.**
- 2. Steps for improving equity in access and accessibility of publications.**
- 3. Methods for monitoring evolving costs and impacts on affected communities.**

Journals fees should be capped for NIH dollar expenses.

- 4. Early input on considerations to increase findability and transparency of research.**

Submit date: 2/24/2023

I am responding to this RFI: On behalf of myself

Name: Gail Johnson

Name of Organization: University of Rochester

Type of Organization: University

Role: Scientific researcher

- 1. How to best ensure equity in publication opportunities for NIH-supported investigators.**
- 2. Steps for improving equity in access and accessibility of publications.**

In principal I agree that having published works immediately available is good. However, depending on the journal, the cost of open access publishing can be prohibitively expensive. Unfortunately NIH cannot put caps on the amount journals can charge, which would solve the problem (point 3 below). Alternatively a possible solution would be that if the paper has been uploaded to a preprint server such as bioRxiv then publishing using the subscription model with an embargo period should be allowable.

- 3. Methods for monitoring evolving costs and impacts on affected communities.**
- 4. Early input on considerations to increase findability and transparency of research.**

Submit date: 2/24/2023

I am responding to this RFI: On behalf of myself

Name: Daniel Gorelick

Name of Organization: Baylor College of Medicine

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

One option is to modify the NIH Public Access Plan to allow grantees to post manuscripts as preprints on a server like bioRxiv or medRxiv. This would immediately make results from NIH-funded research freely accessible. Preprints are free to post and free to read but are not

peer-reviewed. Following posting of a preprint, scientists are free to submit their manuscript for peer-review and publication

in any journal, whether subscription or open access. This would minimize the compliance burden on NIH-supported researchers and also maintains the flexibility of NIH-supported researchers to publish their final, peer-reviewed manuscript in any journal. For details on the advantages and limitations of this idea, see the attached PDF.

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

In the proposed policy, NIH-funded publications would be deposited in PubMed Central immediately following publication. People could read peer-reviewed manuscripts for free immediately following publication without waiting for a 12 month embargo to elapse.

Advantages: All NIH-funded research would be free to read immediately to anybody in the world.

Disadvantages: This policy does not address article publication costs (APC) to scientists. Journal publishers would be free to set APCs as they wish, with no maximums, as is the case currently. Scientists would need to find ways of paying the APCs, using either grant money, institutional funds or personal funds.

The attached PDF discusses ways to reduce these APCs and still maintain open access, either by having NIH pay APCs directly to journals, by having NIH cap the amount of grant money to be used to pay APCs (eg no more than \$3000 per manuscript), by the NIH publishing more journals that would be free to read and free to publish (similar to the existing Environmental Health Perspectives, published by NIEHS), or some combination of these policies.

4. Early input on considerations to increase findability and transparency of research.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/Gorelick-OpenAccess-Proof-Final.pdf>

Email: gorelick@bcm.edu

Submit date: 2/24/2023

I am responding to this RFI: On behalf of myself

Name: Peter L. Elkin, MD

Name of Organization: University at Buffalo

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Encourage authors to site Data sets that they utilized in their research in addition to articles.

In order to best understand datasets made available encourage researchers when possible to collaborate the data providers.

2. Steps for improving equity in access and accessibility of publications.

once accepted for publication encourage journals and authors to post the pre-print to a pre-print server.

3. Methods for monitoring evolving costs and impacts on affected communities.

Have a monitoring program that collects ongoing data for data driven decision making.

4. Early input on considerations to increase findability and transparency of research.

This is a good step forward. It falls short in a few areas.

1. By giving a HIPAA exception you guarantee poor compliance with the aim of this regulation. Instead what you should have done is to establish required methods for sharing of de-identified and separately for limited datasets with proper authentication and security and privacy. This would exponentially increase compliance with the intent of this policy.

2. You did not go far enough to specify interoperability. APIs for the most part provide only syntactic interoperability. There are considerable issues with administrative code sets. The federal government should require the use of ontology to move toward semantic interoperability. This would require SNOMED CT, LOINC and RxNorm be used to code clinical data and the sequence ontology and UniProt for molecular data. Additionally clinical data should be provided in one of the three most common observational database formats (OMOP, i2b2 or PCORNet).

Email: elkin@buffalo.edu

Submit date: 2/25/2023

- 1. How to best ensure equity in publication opportunities for NIH-supported investigators.**
- 2. Steps for improving equity in access and accessibility of publications.**
- 3. Methods for monitoring evolving costs and impacts on affected communities.**
- 4. Early input on considerations to increase findability and transparency of research.**

Email: lancejr38@outlook.com

Submit date: 2/26/2023

I am responding to this RFI: On behalf of myself

Name: Kenneth Pawlak

Type of Organization: Other

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

When will the public reading room be reopened?

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

4. Early input on considerations to increase findability and transparency of research.

Email: k.pawlak@comcast.net

Submit date: 2/26/2023

I am responding to this RFI: On behalf of myself

Name: Bobby Hollingsworth

Name of Organization: Harvard Medical School

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

I agree that authors should have some semblance of choice in publication medium; however, the existence of prestige signalling through journal title has allowed bloated for-profit journals to increase APCs at the expense of the American taxpayer. This must stop. NIH funds should cap the allowable APC paid through NIH grant funds and mandate non-profit publishing in order to maximize research dollars and create better incentives for publication, resource sharing, and hiring. In a separate request for comments, the NIH asks for opinions on the postdoc experience--funds payed through APCs could instead be payed out to researchers doing the work, encouraging innovation and talent recruitment. Additionally, current publishers are extremely biased through editors that reach out to particular labs to fast-track papers, particularly when there is perceived competition with Other journals. Create a watchdog system for monitoring and reporting such unethical behavior.

2. Steps for improving equity in access and accessibility of publications.

The NIH could help create searchable databases that ease data parsing. Take for example, this paper: PMC8380731. The screening data are deposited as raw counts data with barcodes, rather than processed gene names and statistics relevant to the figure itself. Clearly, follow-up hits are being obscured, which is unacceptable research practice when funds come from the taxpayer. In addition to data management plans, such case examples should be subject to reporting, and folks at the NIH should insure compliance with data deposition standards.

3. Methods for monitoring evolving costs and impacts on affected communities.

Mandate publishing in nonprofit groups only, particularly ones that register with the NIH. Encourage consistent research release through alternative platforms such as pubpub, and index these alternatives in pubmed.

4. Early input on considerations to increase findability and transparency of research.

Submit date: 2/28/2023

I am responding to this RFI: On behalf of myself

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Because publication in high-quality open access journals is often associated with significant costs, the option to deposit author-accepted manuscripts rather than final published manuscripts in PMC is a critical one. The goal should be to reduce inequalities and barriers to researchers disseminating their work to scholarly communities while also making the results broadly accessible to the public. The plan as written seems workable in these respects.

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

4. Early input on considerations to increase findability and transparency of research.

Submit date: 3/2/2023

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

Name: Julia schaletzky

Name of Organization: Center for emerging and neglected diseases uc berkeley

Type of Organization: University

Role: Bioethicist

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Whatever is decided evaluate administrative impact - very few profs have admin support and it has become very hard to attract funding, publish, hire and motivate students and fulfill ever increasing compliance and training requirements. Nih systems are onerous already. Pushing the most disadvantaged investigators to spend hours on new policy compliance creates undue burden and inequities

2. Steps for improving equity in access and accessibility of publications.

Most important for public is not access to raw data for basic research but clinical trial data ...this is required to be released but isn't and nih complains but does not enforce. This would be transformational for patients and should be prioritized

3. Methods for monitoring evolving costs and impacts on affected communities.

This is a waste of money since it's been well documented that fees are not justified and inherently inequitable. Instead of "documenting" NIH should change the situation and put pressure on publishing houses. This data exists already

4. Early input on considerations to increase findability and transparency of research.

Clinical data needs to be released - enforcement needed

Email: jschaletzky@berkeley.edu

Submit date: 3/2/2023

I am responding to this RFI: On behalf of myself

Name: Sandra Poulson

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

It makes a great deal of sense to install more transparency at the level of review to ensure that competing interests (considering that reviewers often perform research themselves in adjacent areas of expertise) do not prevent the publication of publicly funded research. Although the NIH does not want to disrupt the broad discretion for authors to choose where to publish, it does make sense to have some sort of oversight board to give a rating to journals for how fair the reviews are, for how reasonable the demand for additional evidence is, how frequently feedback targets authors for being female or not from an elite University, and frankly how rude or helpful the feedback is. It might be interesting to anonymize the reviews and rate on a journal level to try to push for accountability at the journal level for managing its reviewer pool.

2. Steps for improving equity in access and accessibility of publications.

I feel that effort to make older articles, e.g. 1950-1995, accessible is worthwhile. These articles may not currently be accessible online without access beyond a paywall, and making them accessible would greatly benefit the public, including students and educators. The older research has valuable information but is often inaccessible.

3. Methods for monitoring evolving costs and impacts on affected communities.

The fact that it costs more to publish with an open access option is ridiculous. It costs researchers more and therefore costs more grant money even though the research was already funded by the public. There should be no additional cost to publish open source, and the publishers should be thankful that the public funded the research that the publishing company now uses in its publications. No company should be charging more for researchers to publish open access. And institutions that house researchers that produce publicly funded research should not be charged exorbitant fees (library fees) to access publisher material. This type of fee increases overhead demanded by the institution on each researcher which takes away from funds that could go toward research. This issue is made more difficult in that the editors of the journals are professors who do not wish to no longer have income from the publisher, but this is public money and it should be going toward buying supplies and funding the postdoctoral and graduate labor that makes research happen.

4. Early input on considerations to increase findability and transparency of research.

After making older articles (e.g. 1960-1995) available, it would be useful to add keywords to help make the research searchable like today's articles are.

It would be a fantastic idea to add searchability of methods used, as opposed to just keyword topics. E.g. "RNAscope" as a searchable term if the article used the RNAscope kit. It would be useful to build a catalog for each articles that used mouse brain tissue, coronal slices, immunohistochemistry. It would be so amazing to search for techniques and find several papers that successfully used the method to

determine whether the method was worthwhile to spend the time and resources to do it. I feel this would eliminate wasted money. It would also be a useful tool to use to review the usefulness of a method.

Email: sandrapoulson@fastmail.com

Submit date: 3/2/2023

I am responding to this RFI: On behalf of myself

Name: Adam Armstrong

Name of Organization: Saint-Gobain

Type of Organization: Biotech pharmaceutical company

Role: Scientific researcher

- 1. How to best ensure equity in publication opportunities for NIH-supported investigators.**
- 2. Steps for improving equity in access and accessibility of publications.**
- 3. Methods for monitoring evolving costs and impacts on affected communities.**
- 4. Early input on considerations to increase findability and transparency of research.**

Transparency of research - communicating critical geometries associated with functions of research.

Lots of the great NIH research I have encountered is based on critical geometries being developed or improved upon to enable specific device functions of research. Having research aligned to a standard 3D file format (maybe stp) and 2D dimensional file format (maybe dxf) would make that communication easier. Further, having those files shared openly would vastly increase research transparency and speed further supporting developments.

Email: adam.armstrong@saint-gobain.com

Submit date: 3/2/2023

I am responding to this RFI: On behalf of myself

Name: Federico Leva

Name of Organization: Dissem.in/CAPSH

Type of Organization: Professional org association

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Expeditious archival on PMC should remain the primary avenue to ensure public access. NIH could invest more in enriching metadata with URLs declaring the copyright status of manuscripts, especially for works not deposited by the publishers.

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

To reduce the costs for researchers and research entities, while increasing compliance, NIH should further invest in reducing the friction involved in getting works deposited in PMC. There's a need for increased participation in preprint deposit and more support for researchers whose employer doesn't have an established institutional repository or open access office to help.

In particular, NIH could expand its cooperation with trusted LinkOut repositories so that they can proactively archive works which are subject to the policy, and if necessary contact authors to facilitate any further required step. Some multidisciplinary repositories may also be able to provide such a service for Other agencies affected by the new OSTP policy, thereby increasing economies of scale and decreasing costs for authors and NIH. NIH could for example contract a repository to develop software and processes to actively solicit, or collect from openly available collections on the web, manuscripts to add to the repository's collection; the NIH could share metadata about grants and authors, as well as HR information for authors of works which may be considered US government works; NIH could further provide a copyright license to the repository, authorising it to host and distribute works which the US federal government has the right to use. This would allow the repository or repositories to preserve millions of works which are already known to be in the public domain, openly licensed or Otherwise licensed to the US federal government, but remain paywalled.

4. Early input on considerations to increase findability and transparency of research.

Email: federicoleva@tiscali.it

Submit date: 3/3/2023

I am responding to this RFI: On behalf of myself

Name: Catherine Christian-Hinman

Name of Organization: University of Illinois Urbana-Champaign

Type of Organization: University

Role: Scientific researcher

- 1. How to best ensure equity in publication opportunities for NIH-supported investigators.**
- 2. Steps for improving equity in access and accessibility of publications.**
- 3. Methods for monitoring evolving costs and impacts on affected communities.**

It would be more equitable for all NIH-funded investigators if open access publication costs for research on NIH grants were directly paid by the NIH, rather than as direct costs on the grants. The grant budgets are already spread very thin (especially for modular R01s or smaller grants), and the costs of OA publishing, now often running into multiple thousands of dollars, can be the equivalent to a month or more of a trainee stipend. In addition, if work is funded by an NIH grant but published after the grant funding period is completed, the grant funds are no longer available to cover these costs.

Create a portal where PIs can input information on the journal, publisher, manuscript, and associated grant(s), and instruct publishers that if a manuscript is citing an NIH grant as support, NIH will pay for the OA fees. This will also further incentivize submission to OA journals, as they will not require an outlay of increased costs on the part of researchers.

- 4. Early input on considerations to increase findability and transparency of research.**

Submit date: 3/8/2023

I am responding to this RFI: On behalf of myself

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The current proposal is resulting in the publishing landscape radically changing. Just this week two of the scientific journals I have traditionally published in have gone to open-access. While they advertise this in the way of 'diversity' and 'equity' it is anything but. Now, those without sufficient funding, will be unable to publish in high quality journals.

In essence, work not supported by the federal government is becoming unpublishable due to these strategies. The federal government should either prevent the use of funding for publications in order to drive down the cost of open-access publishing or consider setting up additional internal publishing opportunities.

As it stands, the federal government, and NIH, are now fully subsidizing the scientific publishing industry.

2. Steps for improving equity in access and accessibility of publications.

NIH should limit the amount of funding they will allow to be used per publication. If they do not, journals will continue to charge fees that are not in line with the reality of the marketplace and scientific advances will be slowed.

I strongly recommend the NIH to develop a journal associated with each of its centers.

3. Methods for monitoring evolving costs and impacts on affected communities.

The NIH should absolutely do this. They should also monitor the new number of journals developed from publishers and the number of journals that go open access as a result of this.

4. Early input on considerations to increase findability and transparency of research.

The NIH should adopt the ORCID as the standard method to report on scholarly activity. It should replace the existing structure and should be used on biosketches.

Submit date: 3/10/2023

I am responding to this RFI: On behalf of myself

Name: Sonal Sathe

Type of Organization: University

- 1. How to best ensure equity in publication opportunities for NIH-supported investigators.**
- 2. Steps for improving equity in access and accessibility of publications.**

Equity in access and accessibility of publications certainly should include the human and machine-readable forms of journal articles. As a person and academic in training with a visual impairment, though, I must say that not all figures and text are easily readable or accessible with use of a screen reader or machines. Nor are searches in NCBI or PubMed easily understandable with speech-to-text functions. Perhaps a priority for the NIH should include an accessibility audit with, and by, disability allies in order to make the rich body of literature available for all to (literally or figuratively) see.

I also strongly feel PI's training PhD students should strive to be inclusive of visual impairments beyond just the letter on an accommodation form. It is one thing to abide by the law (and if you do not, you do not deserve to be a mentor at all.) It is another to be truly supportive.

- 3. Methods for monitoring evolving costs and impacts on affected communities.**
- 4. Early input on considerations to increase findability and transparency of research.**

Submit date: 3/15/2023

I am responding to this RFI: On behalf of myself

Type of Organization: Not applicable

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Researchers may appreciate a description of how NIH plans to monitor compliance of DMS Plans.

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

4. Early input on considerations to increase findability and transparency of research.

Submit date: 3/19/2023

I am responding to this RFI: On behalf of myself

Name: Tiffany Atkins

Name of Organization: Alphastar

Type of Organization: Other

Type of Organization-Other: Working on building business now

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

I would like to be published in public access if it was my work or a part of a team work

2. Steps for improving equity in access and accessibility of publications.

Making sure researchers are accurate and sources as well as letting people involved be involved with publication

3. Methods for monitoring evolving costs and impacts on affected communities.

I think so far NIH has done good in being reasonable

4. Early input on considerations to increase findability and transparency of research.

Submit date: 3/22/2023

I am responding to this RFI: On behalf of myself

Name: Damien Camany

Name of Organization: Self

Type of Organization: Other

Type of Organization-Other: Self motivation

Role: Member of the public

- 1. How to best ensure equity in publication opportunities for NIH-supported investigators.**
- 2. Steps for improving equity in access and accessibility of publications.**
- 3. Methods for monitoring evolving costs and impacts on affected communities.**
- 4. Early input on considerations to increase findability and transparency of research.**

Email: d.camany@yahoo.com

Submit date: 3/23/2023

I am responding to this RFI: On behalf of myself

Name: Peggy Lentz

Name of Organization: Henry Ford Health System

Type of Organization: Nonprofit research organization

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

All Journals/publishers should utilize Method A only for depositing the manuscripts for Public Access Compliance. Having Methods A-D is confusing to PI's - all should be done by the Journal/Publisher.

2. Steps for improving equity in access and accessibility of publications.

I think the publishers are greedy - the 12 month embargo goes against making valuable information available to the public. Do away with the embargo period.

3. Methods for monitoring evolving costs and impacts on affected communities.

The fees are exorbitant - \$3,000 to publish is too much...

4. Early input on considerations to increase findability and transparency of research.

Submit date: 3/23/2023

I am responding to this RFI: On behalf of myself

Name: Rebecca Braddock

Type of Organization: Not applicable

- 1. How to best ensure equity in publication opportunities for NIH-supported investigators.**
- 2. Steps for improving equity in access and accessibility of publications.**

My daughter died of a very rare cancer with an average 11-month survival period after diagnosis. A 12-month embargo on publication of research findings makes the information unreachable and unusable for the patients and caregivers.

I checked, and I could access the studies at the clinic or hospital, or at a University library. However, poor internet connection and time restraints made that impossible.

Since her death, I've been searching the internet and saving many medical journal articles pertaining in some way to her disease. The cause is unknown, and the treatment hasn't changed for 40 years.

She was 24 when diagnosed, and died at 26. Researchers need to be gathering all the information they can from patients and caregivers. If access is denied to very recent research, some of our hope for progress is lost. Clinical trials.gov OFTEN doesn't publish results, even though the trial may be finished. The whole logjam of communication needs to be removed.

- 3. Methods for monitoring evolving costs and impacts on affected communities.**

I wish there were a way to look up data at NIH, NCI, and CCDI to see if information is being shared between researchers in the U.S. about my daughter's very rare extrapulmonary neuroendocrine carcinoma.

- 4. Early input on considerations to increase findability and transparency of research.**

Email: rbraddock_55@yahoo.com

Submit date: 3/23/2023

I am responding to this RFI: On behalf of myself

Name: Thurman McGarian

Name of Organization: Private individual

Type of Organization: Not applicable

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Access through the NIH website and associated publications offer free and extensive amounts of information. A short cut to available printed information would be welcome.

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

Registration or Other identification standards would ensure that equal access to appropriate amounts of data.

4. Early input on considerations to increase findability and transparency of research.

A less cumbersome index of information would shorten time spent navigating the website and getting information on the way to the consumer.

Submit date: 3/25/2023

I am responding to this RFI: On behalf of myself

Name: Stephen J. Kron

Name of Organization: University of Chicago

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

I really don't understand how any of this addresses equity. Bias is baked into the system at lots of levels. Of course, some people think they are being treated unfairly and perhaps they are, but the current system is built around unfair advantages at every level. Clearly, there is some underlying message here, but if you are not from a favored institution, not doing favored style of work, don't up with the favored answer, etc. then you are going to be affected by bias at the level of funding, publication and so on. Is that going to be addressed?

2. Steps for improving equity in access and accessibility of publications.

Sure, NIH paid for it, they get to decide when it becomes public.

3. Methods for monitoring evolving costs and impacts on affected communities.

NIH needs to shift publication costs to the institutions. They should not be allowable costs beyond a standard fee that the publisher may charge at their discretion. That fee could be \$2500, assuming several factors like having provided peer review with at least three reviewers, and Other services that would be valuable to NIH.

4. Early input on considerations to increase findability and transparency of research.

Sure, go ahead. It seems unlikely that this will really help anything, but it might. The burden is not going to be that significant on researchers.

Submit date: 3/28/2023

I am responding to this RFI: On behalf of myself

Name: Peggy Lentz

Name of Organization: Henry Ford Health System

Type of Organization: Health care delivery organization

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

All Journals and Publishers should accommodate Method A for NIH funded research publication. The process is very confusing.

2. Steps for improving equity in access and accessibility of publications.

All Journals/Publishers should take care of making the manuscript available i.e. Method A. The embargo period should be eliminated - they are being greedy.

3. Methods for monitoring evolving costs and impacts on affected communities.

Open access is too much i.e. \$3,000 is significant.

4. Early input on considerations to increase findability and transparency of research.

Description: public access

Submit date: 3/30/2023

I am responding to this RFI: On behalf of myself

Name: Christopher Marcum

Type of Organization: Not applicable

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

One of the easiest ways to support equity in scholarly publication opportunities is to expand the incentive and reward structure by giving credit (i.e. for grant consideration, hiring decisions, etc) to researchers for: participating in peer-review and editorial activities; depositing pre-prints in agency designated repositories; making source code open source and publicly accessible; supporting trainees; publishing datasets in agency designated repositories; and Other activities beyond just publishing.

2. Steps for improving equity in access and accessibility of publications.

I strongly encourage NIH to direct their intramural and extramural funded researchers to use green open access model to submit their author-accepted manuscripts in PMC with no embargo or delay. No Other model is more equitable - its free and easy. I also strongly recommend that NIH clearly articulate this position to the scholarly publishing community

3. Methods for monitoring evolving costs and impacts on affected communities.

4. Early input on considerations to increase findability and transparency of research.

I strongly recommend that NIH require all researchers, intramural and extramural, to acquire ORCIDs, that their home institutions acquire RORs, and that all publicly accessible research products associated with NIH support acquire DOIs. It would be beneficial for NIH to join the DOE-sponsored ORCID Consortium.

Description: Writing in my personal capacity as a scientist and advocate for open science.

Submit date: 3/30/2023

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

Name: Sonya Dumanis

Name of Organization: Aligning Science Across Parkinson's

Type of Organization: Other

Type of Organization-Other: Research Initiative

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Encourage the use of preprints or the posting of author accepted manuscripts in public repositories to allow for early sharing of research. Research without paywalls is a necessary, rather than optional, step in research communication. In our experience, preprints are fast, equitable, and flexible and can be used to describe many types of research outputs and findings including data papers, null results, and incremental progress. Preprints can also be used as a training step to guide researchers on what else needs to be linked in later versions to ensure all outputs are deposited. The cost of open access fees from publishers can be prohibitive for researchers to share these articles Otherwise.

2. Steps for improving equity in access and accessibility of publications.

Require open licensing to ensure ongoing global access to research and embrace CC-BY or an equivalent license as the minimal license required for all research outputs generated by its funding. Only through open licensing can research be truly reusable.

3. Methods for monitoring evolving costs and impacts on affected communities.

Survey costs of publishing and corresponding author demographics for those already utilizing the NIH Manuscript Submission System to deposit author-accepted manuscripts in PubMedCentral (PMC) versus those being deposited in PMC through journals directly during the same time period.

4. Early input on considerations to increase findability and transparency of research.

Require the utilization of persistent identifiers such as ORCIDs for all researchers, DOIs for publications, grants, datasets, and Other research outputs, RORs for institutions to increase reusability and findability of outputs.

Align on how credit for outputs is given such as utilization of the emerging CRediT taxonomy standards to acknowledge the emerging team science approach being utilized for studying complex conditions and changing the current incentive structure towards recognizing collaborations.

Coordinate with all the US Federal Agencies and the open research community to collectively establish best practices and standards so that open access and data sharing, for example, are tracked and reported on in a consistent manner. There are already community-developed best practices such as standards for data/software sharing and FAIR principles. If each funding body counts data sharing in a different way, compliance and meta analysis will be all but meaningless. The US Government could take

on a transformative role by developing a shared agenda in policy implementation, best practices, and by investing in a common set of standards, tools, and centralized support structures.

Coordinate with the global community when developing open science standards. Science is international. Many emerging best practices are coming from around the world and being reported on by UNESCO, the European Commission, and country-specific entities. Any shared agenda developed in the US would be incomplete without attempting to build convergence globally.

Invest in training support and education materials to ensure that the next generation of researchers are aware of best practices, improve the user experience of sharing outputs, and reduce the barriers to complying with emerging requirements.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/2023-03-30-ASAP-Comments-to-NIH-RFI_v2.docx

Description: We have uploaded a more in depth overview of our interest in these policies and point by point considerations to each of the sections of the RFI.

Email: sdumanis@parkinsonsroadmap.org

Submit date: 4/3/2023

I am responding to this RFI: On behalf of myself

Name: Ana Chicas-Mosier

Type of Organization: Not applicable

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Publication is expensive and the price increases with prestige of the journal and to ensure open access. To respond to these sources of inequity, the NIH could require publications fees be included in budgetary requests or as readily available supplemental awards along with the proposed open-access requirements. The NIH has weight that can be used to push journal publishers to reduce the cost of publication so that PIs at smaller institutions or without a formal affiliation can still afford to publish in journals with the highest impact factors. By only forcing open-access requirements, the NIH does not adequately respond to the cost paid by scientists to publish their studies.

2. Steps for improving equity in access and accessibility of publications.

The core of data in manuscripts is often presented in graphical formats. Graphs, even in machine-readable document formats, are not typically accessible to people with vision impairments. To increase equity on this front, the NIH can establish a single format for graph printing that can be deciphered by machine-readers, require detailed text descriptions of the graph, and push journal publishers to use this format.

3. Methods for monitoring evolving costs and impacts on affected communities.

The additional costs that are associated with impact factor disproportionately weed-out smaller institutions and those with smaller endowments. In monitoring these trends, the NIH could investigate the number of published articles from universities/PIs with >\$500 mill in assets vs <\$500 mill and <\$100 mill.

4. Early input on considerations to increase findability and transparency of research.

Submit date: 4/6/2023

I am responding to this RFI: On behalf of myself

Name: Andrea Bertke

Name of Organization: Virginia Tech

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

NIH should consider negotiating with publishers to reduce public access fees. \$8,000-13,000 for public access fees, in addition to regular publication fees, is excessive and limits the ability of researchers to choose where to publish. These fees are also wasteful and would be more appropriately used for the research, rather than the publisher for simply releasing an article to the public immediately upon publishing. Why is \$13,000 needed to release an article?

2. Steps for improving equity in access and accessibility of publications.

Again, negotiate with or regulate the publishers that charge excessive fees for open access and those that charge excessive fees for public access, even if the open access fee is paid by the researcher.

3. Methods for monitoring evolving costs and impacts on affected communities.

I disagree with the statement “ensure that they REMAIN reasonable and equitable.” Fees are not reasonable and equitable now, so they cannot REMAIN so. Many researchers would like to publish in higher impact journals but are unable to do so because of the excessive publishing and open access fees. MDPI has expanded exponentially because they charge lower fees and make research available quickly, even though MDPI was once considered a predatory and questionable publisher. Nature Neuroscience charges a \$13,000 open access fee in addition to publication fees, after a 6-month to 2-year review process, and then charges the public \$35-65 for access to an article. That is not reasonable nor equitable, for either the researchers or the public. These types of fees amplify the perception that higher impact journals are only for the prestigious researchers who have excess funding to pay these fees. Since the modular R01 budget has not increased with increasing costs of research, many researchers must make the choice of using that \$13,000 for research or for excessive open access fees.

4. Early input on considerations to increase findability and transparency of research.

Use a single identifier, instead of multiple identifiers that must be used for different purposes.

Submit date: 4/6/2023

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

Name: Kevin C. Kregel, PhD

Name of Organization: Federation of American Societies for Experimental Biology

Type of Organization: Professional org association

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Researchers interpret NIH's response to the August 2022 Office of Science and Technology Policy Memo as a preference for charging reasonable publishing costs to the direct portion of grants. This misunderstanding could lead grantees down a path that increases overall costs to NIH and slows progress of research activities. Item III.D.1 notes "NIH intends to develop supplemental information that elaborates on and clarifies allowable costs for publication, consistent with these conditions." We encourage that such supplemental information covers all allowable paths for charging publishing costs, including from indirect costs and Other University general or restricted funds.

Reasons many researchers do not want to add publishing costs to the direct portion of their grants include:

- On the University side, publications are primarily supported through the library purchasing subscriptions, and increasingly open access. University general or restricted funds are the source of the support for library purchases, and while varying, include diverse streams: federal and private research and development grants (indirect costs), but also federal and state library funds, state and local tax allocations, direct fundraising by librarians, tuition and fees, and endowments. Without a new injection of funds into the direct portion of grants, or a commitment to move existing general funds now supporting publications to direct, an added cost to the direct portion of grants would result in reduced funds to support postdocs, graduate students, and research support staff; to purchase equipment and supplies; to support travel to conferences and Other career development opportunities.
- The additional administrative burden would further distract researchers from research activities. In today's approach, a team of societies, publishers, librarians, and institutional grant managers work together to arrange payment, support compliance, ensure proper metadata, and deposition to PubMed Central. If the costs are added to the direct portion of grants, the researcher is likely to be expected to handle some of these activities, such as the payment of fees, or deposition of manuscripts, processes which take time.

Researchers at larger institutions are better positioned to adapt, with libraries already implementing new arrangements (e.g., transformative agreements, subscribe to open) that do not impact the direct portion of the grant. Therefore, FASEB encourages NIH to allow flexibility for institutions to use indirect funds for a variety of publishing models, and to encourage institutions to continue to use the diverse revenue streams beyond indirect costs available in the general and restricted funds to support the costs of publication and make the transition to the realities of the new policy easier and more achievable for researchers.

Researchers from underserved populations, including early career researchers, those from historically excluded backgrounds, and those at less research-intensive institutions, do not have assured access to the aforementioned arrangements. Likewise, some societies are too small to handle detailed negotiations to make such accommodations. These disparities are already a reality. Many societies provide waivers, which the author may find an inconvenience and a barrier, with potential required actions such as requesting a waiver, and submitting a manuscript without assurance that a waiver will be provided until the manuscript is accepted. Waivers are provided at societies' expense, and we recognize this as a stop-gap solution that does not fully support equity. NIH could alleviate these issues by dedicating publishing resources for underserved researchers and societies and by providing guidance to program officers on addressing equity in publication opportunities.

2. Steps for improving equity in access and accessibility of publications.

By virtue of their broad membership and core missions, scholarly societies are well-positioned to improve equity in access to publications for many stakeholders. However, financial support for these efforts is lacking. With proper funding, scholarly societies would be ideal partners to improve equity in access and accessibility. Examples of practical steps that could be taken more broadly, and are being experimented with at societies, include plain language summaries, alt text for images, creating more videos, working with media on news stories, and engaging through social media. Societies are also well-situated to develop educational materials and facilitate training to support researchers and the broader diverse community on improving communication around the scientific process and a specific field of science. To facilitate this, resources from NIH could be specifically allocated to address the financial need for domain-specific experts, including scholarly societies.

3. Methods for monitoring evolving costs and impacts on affected communities.

We were unable to identify a comparable approach taken by NIH to monitor fees for Other research services or outputs. FASEB recommends that NIH not monitor publication fees lest the impact result in a system that favors quantity over quality. Any reference to a specific cost or price could have the unintended consequence of driving the system towards a 'one size fits all' pricing structure that negatively affects quality of resulting publications. The building blocks of scientific integrity - best practices and standards, ethical behavior, and the principles of honesty and objectivity - can lead to improved rigor, and reproducibility and must be included with public access approaches. While peer reviewers are not paid, peer review is far from free of cost. Upholding scientific integrity during peer review and publication increases costs through additional human time and adoption of innovative technologies. FASEB appreciates NIH's recognition of the value of peer-reviewed research publications and the services provided by scholarly societies to further scientific understanding and improve human health. Therefore, we encourage continued valuation of scientific integrity.

While there might be an interest in monitoring whether funded researchers are requesting more total resources in the direct versus indirect portion of the grant and resultant changes in awarded amounts over time, this would be challenging to monitor without an effective baseline. Similarly, there are many variables that must be considered; a few examples include the growing costs of ensuring quality against papermills or image manipulation, the number of articles published (output) which may grow if public

access achieves the goals of open science and drives rapid advances in science, and the changing demographics or preferences for services provided by different societies.

Monitoring equity in funded grants will be important, as is understanding where and how the system is developing and evolving. To obtain a snapshot of the current environment and assess impact of policy changes, NIH could compare the total, median, and mean number of publication fees in the direct portion of grants for different stakeholder groups over time and as a percentage of total published articles funded by the agency.

4. Early input on considerations to increase findability and transparency of research.

FASEB is encouraged by NIH's commitment to engage with existing identifier infrastructure and standards already in use across many scholarly societies. Requiring ORCID (Open Researcher and Contributor ID) for the corresponding and/or submitting author has been seamless for integration into societies' manuscript submission, peer review, and publication systems; requiring ORCID for all co-authors has posed more challenging but is improving with time. FASEB supports NIH adoption of a DOI (Digital Object Identifier) overlay on existing grants; this activity could foster a more connected ecosystem of grants, publications, and data.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/FASEB_NIH_RFI_Final_Letter_Submitted_04-06-2023.pdf

Description: The PDF attached is a full letter from the FASEB President that includes answers to the above four specific questions, as well as additional relevant information and some clarification sought from NIH with regards to manuscript types and guidance planned

Email: dhenderson@faseb.org

Submit date: 4/6/2023

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

Name: Heather Patisaul

Name of Organization: NC State University

Type of Organization: University

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

2. Steps for improving equity in access and accessibility of publications.

One of the biggest problems we foresee with NIH's plan is that all the data must be shared before the end of the project. That does not mesh with reality. Lots of publications occur after the project is over, sometimes long after. Researchers are going to need more time to get their data out. Publication is slow, particularly now given the increased demand on reviewer time. Giving people at least a year after the project officially ends would help ensure people have the time they need to be compliant.

3. Methods for monitoring evolving costs and impacts on affected communities.

As both a researcher and an administrator, compliance cost is our biggest concern. It's not just publication fees, which will likely be a big problem since we will now have to become more dependent on open access journals, but lots of Other "invisible" compliance costs that will fall on universities. Storing the data, curating the data, hiring data managers who can put all of this data in repositories or similar are all going to be expensive problems for our University. Data management and sharing isn't logistically simple. The data storage costs alone are easily going to cost us millions of dollars and we do not have the budget for that. And while there are great databases for some kinds of data, such as GWAS and Other genetic data, there are not obvious places for data like animal behavior data, imaging data, or computer code for analyses done in R or similar. Also, getting data into those databases can be very challenging. Some require at least some level of basic coding skills, which a lot of researchers do not have. The administrative burden (both time and cost) this could create for universities is potentially enormous and will disproportionately impact institutions like ours that doesn't have a big NIH portfolio and/or a medical school. Wealthier schools will already have a lot of infrastructure in place for managing patient data and that kind of thing. Others, like ours, will struggle. Researchers are going to need a lot of data management help and hiring those people is expensive. Whole industries will likely arise just to manage all the data NIH now expects we manage and share. It is strongly recommended NIH help shoulder this burden and have people in place to help researchers with data management.

4. Early input on considerations to increase findability and transparency of research.

Not all data is easily put in a database that generates PIDs. So for some kinds of data this is going to be a challenge. It is also unclear how the metadata is supposed to be formatted or what it should include. Ideally it is organized for easy curation and/or systematic review or Other processes but accomplishing that is going to take professional data managers. Most researchers are not going to be able to do this on their own. Who is going to pay for that? If NIH wants things prepared and shared in a specific way, they should have the staff and people in place to help facilitate that. Part of the issue for us is understanding

the intent of NIH's data sharing plan. How is NIH envisioning the data will be used? How is the public supposed to access it? Is that even a reasonable expectation (particularly given the enormous financial and time burden this is going to place on researchers and their institutions)? If there are "higher priority" data sets NIH could start with and pilot to create guidance for Other kinds of data, that would be helpful.

Submit date: 4/9/2023

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

Name: Jessica Moise

Type of Organization: Not applicable

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

An additional 2% should be added to the A component of the F&A specifically restricted to entering into Institution-wide Institutional publishing accounts or to support staff who handle assisting Investigators with the new requirements.

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

4. Early input on considerations to increase findability and transparency of research.

Submit date: 4/10/2023

I am responding to this RFI: On behalf of myself

Name: Luella Allen-Waller

Name of Organization: The University of Pennsylvania

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The NIH should provide funding specifically to subvent the costs to investigators to publish in the open access form of journals, which are often much more expensive than subscriber-access versions. This will reduce disproportionate funding burdens on early-career researchers and researchers in less well-resourced institutions who hope to make their findings publicly available. In addition, the NIH should seek to enter into agreements with all life science publishers to submit final published articles to PMC so that the general public can access quality articles of interest without the undue burden of expensive subscriptions.

2. Steps for improving equity in access and accessibility of publications.

I support removal of the embargo, and believe that all peer-reviewed papers should be made immediately accessible to the general public.

3. Methods for monitoring evolving costs and impacts on affected communities.

I support monitoring publication fees, and reducing them, especially for open-access publications. NIH should create a data analyst position to track costs associated with publication and dissemination of results for all relevant positions, and to liaise with major publishers to understand cost increase trends and where that funding is going.

4. Early input on considerations to increase findability and transparency of research.

I have not had experience with this.

Submit date: 4/10/2023

I am responding to this RFI: On behalf of myself

Name: Elizabeth McNally

Name of Organization: Northwestern University Feinberg School of Medicine, The Journal of Clinical Investigation

Type of Organization: Other

Type of Organization-Other: Medical School and Journal Editor-In-Chief

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Scientific publishing relies on peer review, since peer review provides an independent assessment of scientific discoveries. However, the peer review system is inherently a biased process. The peer review system favors investigators with experience, which has some merit given the role of experience in experimental design and interpretation. Editors should strive for balance when weighing differences of opinions between authors and reviewers, especially because authors typically remain blinded to the reviewers' identity. Opportunities to publish non peer-reviewed work in the form of preprint servers is highly valuable for multiple reasons. Preprint servers allows authors to make information accessible in a timely manner, and authors may cite manuscripts submitted to preprint servers on NIH biosketches and grant proposals. Not all manuscripts posted to a "preprint" server will ultimately appear in a peer-reviewed journal. There is likely value in having a long term archive for non-peer reviewed work since it helps disseminate work, albeit in the absence of peer review.

2. Steps for improving equity in access and accessibility of publications.

With immediate access of published work, journals will lose subscription revenues and the increased cost will be passed on to authors, and hence the NIH. Publication fees have been rising, and it is not evident that all increase in publication fees derive from increasing costs. Larger publishers have economy of scale, while smaller, society-led journals may not have this advantage. In comparison to the large for-profit publishing houses, society-led journals may be nonprofit entities, and society-led journals hold an historically valuable role in the dissemination of science and opinion, which can influence science and science policy in critical ways. While it is tempting to establish flat fee recommendations for publishing, flat fees might endanger the smaller, nonprofit, society-led journals.

3. Methods for monitoring evolving costs and impacts on affected communities.

The NIH should keep in mind the wide range of publishers from the larger, for-profit publishing houses to the nonprofit society-led journals. The financial models supporting these different publishers are strikingly different, and the costs associated with publishing may also differ. Equity in publishing should not favor one financial publishing model. However, equity in publishing might consider opportunities to highlight predatory journals that have inadequate peer review and purely profit-seeking motives since this would be of value to the scientific community and public.

4. Early input on considerations to increase findability and transparency of research.

Persistent identifiers for manuscripts should be an internationally agreed upon format given the international conduct of science. Persistent identifiers for authors should not replace names or identities since knowledge of who and where science was produced is relevant to the role of experience as an investigator.

Email: elizabeth.mcnally@northwestern.edu

Submit date: 4/11/2023

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

Name: Robert Kiley

Name of Organization: cOAlition S

Type of Organization: Nonprofit research organization

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

cOAlition S has long championed the view that their funded researchers should have the freedom to submit their manuscripts to any journal of their choice, irrespective of any open access (or public access) mandate they may be subject to. As such, funded researchers should have the freedom to submit manuscripts to both fully OA journals and subscription/hybrid journals, whilst also being able to honour the conditions of any public access mandate.

Publication costs should not be borne by the author

When a manuscript is accepted for publication in a fully OA journal, any publication costs charged by the publisher - like an APC - should be met by the funder. This is the approach cOAlition S has long endorsed.

Avoiding double payments in hybrid journals

However, when publishing in a subscription journal/hybrid journal, we do not believe a funder should pay an APC (or similar open access publishing fee), as the costs incurred by the publisher in publishing that article have already been met by the journals' subscribers.

Retaining author rights

To ensure that NIH funded researchers can always seek to publish in their journal of choice while at the same time making their papers available in public access via a repository, we strongly support the NIH proposal, outlined in section III. C. 1, to "develop language that NIH-supported investigators may use for submission with their peer-reviewed manuscripts to journals to retain rights to make the peer-reviewed manuscript available post-publication in PMC as soon as processing is complete, without an embargo period".

Many funders within cOAlition S - including the Bill and Melinda Gates Foundation, Howard Hughes Medical Institute, Wellcome and UK Research and Innovation (UKRI) - have adopted a similar approach, providing templated language which researchers must include in the manuscripts they submit to publishers.

By way of example, the Wellcome grant conditions include the following clauses:

7.4. You hereby grant a CC-BY Public Copyright Licence to all future Author Accepted Manuscripts (AAMs). If you allow Others to own copyright in AAMs, you must ensure they grant such a licence.

7.5. All submissions of original research to peer-reviewed journals must contain the following statement:

“This research was funded in whole or in part by the Wellcome Trust [Grant number]. For the purpose of open access, the author has applied a CC-BY public copyright licence to any author accepted manuscript version arising from this submission.”

By requiring researchers to include the language (in clause 7.5) in their submissions, they are giving notice to the publisher of a prior licence. Publishers must either respect this - and allow the author to make the AAM available at the time of publication under the specified licence - or reject the submission.

In the two years or so since this approach was introduced by many cOAlition S funders, we are only aware of one example where a publisher rejected a manuscript due to the existence of a prior licence. In contrast there are many examples where an AAM has been made freely available at the time of publication (with a CC BY licence), but where the publisher version (the so-called Version of Record (VoR)), is paywalled.

See below three examples of articles published in 2023 where the AAM is freely available and licensed CC BY, but the VoR is paywalled with a more restrictive licence.

1. Article published in Nature Cell Biology, January 2023.

AAM, published under CC BY licence, freely available at:

<https://europepmc.org/article/MED/36650381#free-full-text>;

VoR, paywalled and published under an exclusive licence to Springer Nature Limited, available at:

<https://dx.doi.org/10.1038%2Fs41556-022-01053-0>

2. Article published in Journal of Virology, February 2023

AAM, published under a CC BY licence available at: <https://europepmc.org/article/MED/36749077#free-full-text>;

VoR, paywalled, copyright of the American Society for Microbiology, All Rights Reserved, available at:

<https://dx.doi.org/10.1128%2Fjvi.00039-23>

3. Article published in Journal of Immunology, March 2023

AAM, published under a CC BY licence, available at:

<https://europepmc.org/article/MED/36695776#free-full-text>;

VoR, paywalled, copyright of the The American Association of Immunologists, available at:

<https://dx.doi.org/10.4049%2Fjimmunol.2200211>

2. Steps for improving equity in access and accessibility of publications.

We are delighted that the NIH will remove the 12-month embargo period for NIH-supported publications.

Using licenses that allow sharing and reuse

However, to ensure that this research can be used by a large and diverse community of users, it is imperative that this work is properly licensed in ways which facilitate this.

For example, it may be desirable to translate an article from English to another language, such that it can be read by communities where English is not their first language. Equally, there may be value in creating a lay-person summary of a research article, such that it could be made accessible to non-experts. In both examples cited here, this would only be possible if third parties had the right to create derivative works, which is only possible under specific licences.

Beyond the need to create derivatives, some third parties may wish to re-use NIH-funded work which could have commercial implications, such as re-using a figure from an article for inclusion in a commercially published textbook. To ensure this is possible, the ability to re-use NIH funded research for commercial purposes must be made explicit in the licence which accompanies the research article.

It is also worth stressing that re-using images/figures from an article to create or enhance a page on a resource like Wikipedia, is only possible if the images are free of copyright or in the public domain. See: https://en.wikipedia.org/wiki/Wikipedia:Image_use_policy

All the use cases described here can be enabled if the NIH makes it a requirement that research findings which arise from its funding are made available under a Creative Commons Attribution licence (CC BY) or similar licence.

3. Methods for monitoring evolving costs and impacts on affected communities.

We agree with the NIH that it is important to monitor trends in publication fees, to ensure they are reasonable and equitable.

Price and services transparency.

One way cOAlition S is seeking to do this is through the free, online Journal Comparison Service (JCS), which we have developed.

The primary purpose of the JCS is to provide those who procure publishing services (typically libraries, library consortia, and funders) with the ability to quickly compare journal publishing services and fees. As of March 2023, 28 publishers have shared their data through this service.

Although the JCS holds data on journal APCs and subscriptions - and will retain such data to enable longitudinal analyses to be conducted over time - the service also provides information on the services publishers provide (copy editing, managing peer review, marketing etc) and the proportion of the total price which is allocated to each service. As such we believe it will be possible for users to determine whether the fees levied are commensurate with the services provided.

Consequently, one way the NIH could operationalise its ambition to monitor trends in publication fees is by strongly encouraging publishers who publish NIH-funded research to make their price and service data available through the JCS.

4. Early input on considerations to increase findability and transparency of research.

The widespread adoption of PIDs will both reduce the burden on researchers (as information required for publisher and funder systems can be pre-populated) and provide all users with richer and more accurate data. For example, a funder reporting system, which requires grantees to disclose a list of publications arising from their grant, will get more accurate metadata if the publication data is pulled from services like Crossref or SCOPUS, using the researchers ORCID id as its match point.

Regarding specific actions NIH could consider to further encourage the adoption of PIDs, we would make two recommendations:

1. Require researchers to have an ORCID iD .

Although NIH already makes good use of ORCID - for example by allowing researchers to populate their SciENcv and eRA Commons records using their ORCID iD - having an ORCID iD is not yet a requirement for NIH applicants and grant holders.

However, we would like to suggest that, as part of the grant application process, all applicants are required to have an ORCID iD, and for that PID to be validated as part of the application process. A number of funders - such as Wellcome and HHMI - already require their researchers to have an ORCID iD.

By implementing this change, NIH can be assured that every funded researcher has a valid ORCID iD, which will make downstream reporting far simpler, as all published papers carrying the ORCID iD can be automatically added to the researcher's ORCID record.

Although some may argue that mandating the use of ORCID will discourage Other researcher identification systems to be developed, there is no need for multiple systems in this space, especially given the fact that ORCID is run as a community initiative, governed by a Board of Directors representative of its membership with wide stakeholder representation.

2. Assign a DOI to every grant awarded by the NIH

A number of funders within cOAlition S - including Wellcome and the Austrian Science Fund (FWF) - mint a DOI for every grant they award.

This approach has two distinct benefits.

Firstly, it enables the funder to make a trusted assertion in the researchers' ORCID record that they are in receipt of a Wellcome (or FWF) grant. Consequently, when anyone else looks at this ORCID record - maybe a funder considering a new award, or an institution determining a promotion or tenure decision - they can be assured that the applicant does hold the award they claim.

Secondly, it enables third party systems - such as publisher submission systems - to query Other sources (such as the Crossref registry) to prepopulate the submission system with the correct name of the funder and the specific grant ID. And, if the article is eventually published, then the Grant DOI will become part of its public metadata, enabling the funder (or the researcher) to unambiguously identify all the articles which have arisen from that grant.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/Response-to-NIH_cOAlition_S.pdf

Description: Formatted version of responses provided via the form.

Submit date: 4/11/2023

I am responding to this RFI: On behalf of myself

Name: Robert Weinberg

Name of Organization: Whitehead Institute for Biomedical Research/MIT

Type of Organization: Nonprofit research organization

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

This continues the trend to complicate receiving and maintaining administratively an NIH grant, making it even more cumbersome and bureaucratic in order to secure and preserve grant funding. Those of you who applaud all these new steps continue to make it less and less attractive to apply for and maintain an NIH grant, making it more and more laborious administratively to keep the grant and administer it properly. (The amount of time spent by PIs and AAs in negotiating the labyrinthine rules grows progressively with each year.) I suppose it's the job of administrators to add more and more layers of detailed regulations. These new requirements continue the onward march of oppressive bureaucratization of NIH grant applications and reporting of awarded grants at a time when NIH grants are increasingly unable to support many of the experiments that are being proposed. I suppose you will only be happy when you totally smOther the program with more and more layers of bureaucratic regulation. You will have secured a pyrrhic victory, having proudly added all of these new bells and whistles to grant programs that increasingly no one is interested in applying for any more. . Robert Weinberg, Whitehead Institute/MIT

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

4. Early input on considerations to increase findability and transparency of research.

Submit date: 4/11/2023

I am responding to this RFI: On behalf of myself

Name: Nils Walter

Name of Organization: University of Michigan

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Europe has found an equitable solution in the form of Plan S (<https://www.coalition-s.org/>) that supports open-access publication without burdening shrinking (in terms of inflation-corrected dollars) grant budgets. Such a program will a) remove open-access inequities among both researchers/authors and the public; b) reduce the extra work and cost involved in the duplication publication on the NIH MS system; c) make a single, consistent, peer-reviewed version of a publication available immediately upon publication (and often at time of acceptance) that publishers already offer; and d) allow the NIH/government to negotiate discounted open-access pricing from all publishers, rather than the current “Wild West” where highly reputed journals can charge large sums biased toward improving the publisher’s bottom line.

2. Steps for improving equity in access and accessibility of publications.

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3. Methods for monitoring evolving costs and impacts on affected communities.

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4. Early input on considerations to increase findability and transparency of research.

On top of a “Plan S-like” solution, publishers could be encouraged to work with NIHMS to develop faster, more versatile access options, most likely through AI tools.

Submit date: 4/11/2023

I am responding to this RFI: On behalf of myself

Name: Clifford B. Saper, MD, PhD

Name of Organization: Beth Israel Deaconess Medical Center, Harvard Medical School

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The costs of publication must be borne by someone. In the subscription model this was largely users, and most of the burden fell on University libraries and industry. While non-academic members of the public would have had to pay high fees for access, in fact very few private individuals read the primary scientific literature, and under the current system this is available within one year anyway. In the open access model, the costs fall on the scientists and clinicians who publish. University libraries are happy about this because it takes pressure off their budget, but industry is ecstatic because they get a free ride. Scientists have to pay these fees out of their grant budgets, if they have grants, but there has been no increase in funds available for this purpose, so they come out of the scientific budget. Worse, many clinical research studies are done without benefit of NIH grants, and there is often no way to pay for the publication fees in the open access model. This problem falls disproportionately on individuals who work at institutions that do not have large discretionary budgets, i.e., clinicians and scientists who serve underprivileged segments of society. A fair and equitable system would be similar to countries in Europe where there is a single fee shared by government and universities and industry and paid to publishers, which gives their scientists the ability to publish in open access journals without additional fees, and gives the entire country access to publications.

2. Steps for improving equity in access and accessibility of publications.

Mandating immediate access essentially will undermine and destroy the subscription model, without coming up with an adequate replacement. As noted above, this will unfairly punish investigators who do not have NIH grants, investigators who work at institutions that have low budgets because they serve poor people, and will unfairly benefit rich universities and industry (who hire the staff to promote this model).

3. Methods for monitoring evolving costs and impacts on affected communities.

The way to do this fairly is for the US to establish a consortium of industry, universities, and the federal government, to provide funds, proportionate to their use of published scientific material, to publishers, who would then eliminate both manuscript processing and access fees. This is similar to what has evolved, for example, in Germany.

4. Early input on considerations to increase findability and transparency of research.

While it is laudable to have work done by NIH-funded investigators available to Other investigators and the public, realistically it costs about 10% of the cost of the actual research to establish and maintain such databases. This is a very time-consuming and expensive proposition. Investigators cannot do it in

a few minutes of their spare time. To provide a robust and searchable archive will, realistically, require the NIH to devote about \$4B a year of its budget just to do this. It would also help if there were a national infrastructure in place that investigators could use to deposit data. We are now relying upon institutional databases, with no funds provide for establishing them, putting the data into a searchable format, monitoring the deposits to make sure that they actually occur, and providing public access to those databases. It is extremely unlikely that the NIH will be able to succeed in its goals with the current plans. More likely than not, we will have a system like the ClinicalTrials.gov database, where more than half of those who should be contributing are scofflaws.

The moral is: without adequate funding and infrastructure, these plans are burdensome, reduce research efficiency, and are likely to provide nothing of value in the long run.

Email: csaper@bidmc.harvard.edu

Submit date: 4/11/2023

I am responding to this RFI: On behalf of myself

Name: Amy Wright

Type of Organization: Not applicable

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

I come from a University with limited resources but which is not a PUI. I am a chemist and would typically publish in ACS published journals. The ACS open access costs are very high (in excess of \$4000 for an ACS member). ACS is selling reduced cost open access to large Universities/University systems (Transformative program) and provides free open access publication to PUIs. Almost all of the ACS journals are moving to full open access because of the removal of the currently allowed 12 month embargo. Since I work at a low resource, high research (but not R1) University I am caught with having to pay the full open access fee to publish. I can publish in MDPI journals for a reduced cost, but I think overall I will be publishing less under these new rules rather than more - so in the long term my program will suffer (fewer pubs=fewer grants). Eventually I will simply not be able to continue in my field. I envision that the day when research conducted at smaller Universities simply stops (and our students will not have access to that experience reducing workforce readiness overall). Just the top Universities will get most of the grants and diversity will be greatly reduced.

I have had a number of R21 grants which have had the same cap in total direct costs (\$275k over 2 years) for probably 25 years. Colleagues with R15s are equally stuck with budget caps from the dark ages. These types of projects (and even some continuing RO1s) don't have a lot of extra \$\$ for publishing OA. Perhaps it is time for these budget caps to be changed.

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

See my comments above- there are a lot of us stuck in the worst category for publishing OA and our Universities don't have the resources to buy reduced cost OA publishing.

4. Early input on considerations to increase findability and transparency of research.

Submit date: 4/11/2023

I am responding to this RFI: On behalf of myself

Type of Organization: Not applicable

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

You have created the problem that you seek the solution to! Publication via subscription journals, whether published by professional societies or commercial publishers, had no bias or barrier Other than quality. Now, by requiring open access, you put a financial burden on people with low levels of funding. Already, I ask my students, do you want anOther paper published or do you want a month of your stipend. This is the tradeoff that we now face due to the belief that there was a problem with lack of access to research results.

2. Steps for improving equity in access and accessibility of publications.

There are very few people who will read and use the results of research who do not have ready access to a library. Libraries routinely use interlibrary loan to get access to the journals they do not have subscription for. The access problem existed only in the minds of political activists.

Now that the problem has been created, the best solution would be for NIH to pay directly for publication, in addition to, not part of, the awarded funding in the grant. This is a little like the American Chemical Society (ACS) Petroleum Research Fund did (I do not know the current policy). They would pay the so-called "page charges" if you published in an ACS journal. Page charges went way when commercial publishers began competing with professional society publishers.

3. Methods for monitoring evolving costs and impacts on affected communities.

NIH can ask for accounting of publication costs in annual reports. NIH can also ask if people combined results into conglomerate papers to avoid paying for multiple papers.

4. Early input on considerations to increase findability and transparency of research.

I have no idea what problem this attempts to solve. Each area of science has abstracting and search tools. Chemical Abstracts Service is the oldest and best in the US. Scientists are already asked to use numerical identifiers (ORCID) to overcome problems of inconsistent use of names or changes in names. An ORCID could be required to get a grant or to publish a paper.

Submit date: 4/11/2023

I am responding to this RFI: On behalf of myself

Name: Lynn Brielmaier

Name of Organization: ALS Problem Solvers

Type of Organization: Patient advocacy organization

Role: Patient advocate

- 1. How to best ensure equity in publication opportunities for NIH-supported investigators.**
- 2. Steps for improving equity in access and accessibility of publications.**

Open up the NIH lecture series to the public. It is a simple matter to mirror the video seminars onto a cyber secure website outside of NIH or HHS.

eg. For this Nirenberg Lecture, Patapoutian will speak on his latest research on the structure-function relationships of Piezo proteins and their roles in somatosensation and interoception.

Note: This is a special Monday, Monday, Monday WALS.

* Join and you will learn such fascinating trivia as this: Ardem Patapoutian is the only WALS speaker to be featured on an Armenian postage stamp. And Marshall Nirenberg is the only NIH scientist to be featured on a Palau Islands postage stamp.

Most of these science seminars ARE NOT available to the public.

- 3. Methods for monitoring evolving costs and impacts on affected communities.**

<https://www.manuscriptedit.com/scholar-hangout/market-trends-open-access-publishing/>

<https://authorservices.taylorandfrancis.com/choose-open/publishing-open-access/open-access-cost-finder/>

<https://theplosblog.plos.org/2023/04/open-science-indicators/> (datasets published every six months)

- 4. Early input on considerations to increase findability and transparency of research.**

Make data compatible with OMAP.

Please contact Danielle Boyce at dboyce3@jhu.edu, ok to say I sent you.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/NIH-Seminar-series-fail_Screenshot-2023.jpg

Description: NIH seminar list access denial.

Email: lynnbr2@att.net

Submit date: 4/12/2023

I am responding to this RFI: On behalf of myself

Name: Gail A. Bishop

Name of Organization: The University of Iowa

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The major challenge of all plans that mandate early or immediate Open Access for all scientific publications from NIH-supported researchers is that there are significant costs associated with scientific publishing. If publishers can no longer use subscription revenues to support such costs, they will continue and accelerate the trend already underway of passing on more and more costs to authors. The costs of publishing a paper have risen considerably over the past 10-15 years, but the NIH modular budget has gone unchanged. At the same time, costs of research personnel, particularly the cost of benefits, have also increased substantially. Thus, mandating more and more open access without providing any cost relief steadily decreases the funds available to NIH-funded PIs to spend on the actual research project. Additionally, scientists who receive funding from major foundations, such as Howard Hughes or Wellcome Trust, receive funds from these entities for open access publishing, but not the majority of researchers, further increasing the advantages that scientists with additional resources such as these, or large endowments from some institutions, have, and risks narrowing the field of those who can contribute to scientific discovery.

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

HOW will NIH 'ensure that publication fees remain reasonable and equitable'. What will NIH do if, as seems likely in a mandated 'immediate open access for all publications', such fees for its grantee authors rise substantially?

4. Early input on considerations to increase findability and transparency of research.

Submit date: 4/12/2023

I am responding to this RFI: On behalf of myself

Name: Mr. Stephen P. Panossian

Name of Organization: Unemployed

Type of Organization: Not applicable

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Allowing the submission of final, published articles to PMC satisfies the centralized distribution aspect of published scientific research. However, many reputable journals are becoming open access, which may diminish the need for PMC. Furthermore, it does not address the initial hurdle of publishing research results in a reputable scientific journal, that of the publishing fees. These fees can range from several hundred to several thousand of US dollars, which can be a sizable obstacle for researchers from developing nations and small colleges in the Western world. These publishing fees siphon away valuable funding that principal investigators could use for resources and/or temporary labor (who would gain valuable experience during the research process). Ensuring equity in publication opportunities requires financing the publication fees and monitoring the expenditures. This is an additional responsibility that the PI will need to undertake to prove responsible spending of research funds. Thank you for considering my perspective on this topic.

2. Steps for improving equity in access and accessibility of publications.

Ensuring Internet access to researchers in developing nations improves their ability to submit research articles in human and machine-readable forms for publication. It also improves download access for the diverse communities of users, who can then read research results online and/or print them as they need. Furthermore, it will increase the accessibility of publications via assistive-technology, such as language translation and text-to-speech applications. While NIH cannot endorse any specific software or hardware, it could initiate the development of those applications and/or devices. Thank you for considering my perspective on this topic.

3. Methods for monitoring evolving costs and impacts on affected communities.

NIH's proposal to monitor trends in publication fees and policies to ensure that they remain reasonable and equitable is welcome. One challenge will be defining the landscape of reputable US and foreign scientific journals. NIH needs to consider whether the journals they monitor actively or passively constitutes an endorsement of those publications. Thank you for considering my perspective on this topic.

4. Early input on considerations to increase findability and transparency of research.

One aspect NIH may consider regarding the effort to increase findability and transparency of research is leading the release of standards for metadata governing content and format, and for datasets, the standards for datasheet contents. Another aspect to consider is, should PMC provide an easy user interface for researchers to document their publications with additional PIDs and metadata?

Furthermore, would NIH support financially the efforts to “retrofit” older publications with the latest metadata and PIDs? This would incentivize the standardization process. Thank you for considering my perspective on this topic.

Email: stephenpanossian@gmail.com

Submit date: 4/12/2023

I am responding to this RFI: On behalf of myself

Name: Phil Hurvitz

Name of Organization: University of Washington

Type of Organization: University

Role: Scientific researcher

- 1. How to best ensure equity in publication opportunities for NIH-supported investigators.**
- 2. Steps for improving equity in access and accessibility of publications.**
- 3. Methods for monitoring evolving costs and impacts on affected communities.**
- 4. Early input on considerations to increase findability and transparency of research.**

It would be great to develop a standard for PDF metadata so that publications brought in to reference managers would populate fields correctly. I have had to spend considerable effort editing records in EndNote and Mendeley because fields are not populated correctly. At the same time, it would be good to encourage publishers to enter metadata correctly--I have had to edit many records because the PDF metadata are simply incorrect (wrong journal or author names, page numbers, etc.). Thanks for your consideration.

Submit date: 4/12/2023

I am responding to this RFI: On behalf of myself

Name: Andriy Fedorov

Name of Organization: Brigham And Women's Hospital

Type of Organization: Not applicable

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The lack of consideration in this RFI survey for the requirements and strategies aimed to support sharing of research data - in addition to sharing of the publications - is unfortunate.

This is particularly important in consideration of ensuring equity in publication opportunities. Researchers have highly uneven access to the data needed both to conduct innovative research and to validate findings that have already been published. As a result, investigators from large institutions that have access to data have exceedingly stronger opportunities to receive even more funding. At the same time, at NIH, there appears to be lack of clear strategy and infrastructure investment to encourage and enable data sharing, and discourage and (as much as possible) mitigate hoarding of the data in the individual NIH-funded labs and institutions. Infrastructure currently being established by NIH to support collection and sharing of data does not appear to have plans or commitments in place to ensure continuing funding of the repository and guarantee longevity of the deposited data for ****any**** period of time, which is in direct contradiction of the principles set forth by the National Science and Technology Council! The new data sharing policy introduced by NIH does not affect the existing peer review process, which means what is shared and how will be decided by administrators and lawyers - not scientists! It is very likely that the outcome of the new policy will be datasets of limited utility, due to lack of scientific oversight of the approaches used to share those datasets.

To sum up, there is urgent need to 1) develop strategy for sharing datasets produced by NIH-funded projects, 2) establish plans for the development of the technology to enable such strategy; 3) establish framework and policies to support longevity of the repositories. It is very important that items 1 and 2 in the above are developed with participation of the domain experts representing research community, and that the process is transparent.

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

4. Early input on considerations to increase findability and transparency of research.

Email: andrey.fedorov@gmail.com

Submit date: 4/12/2023

Name: Robin Ely MD

Name of Organization: Integrative and Regenerative Medicine

Type of Organization: Health care delivery organization

Role: Medical provider

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Totally agree!

2. Steps for improving equity in access and accessibility of publications.

Totally agree- motivated “ patients” are often more informed than their doctors-

3. Methods for monitoring evolving costs and impacts on affected communities.

Can't speak to this

4. Early input on considerations to increase findability and transparency of research.

Recommend an immediate update process to clinicaltrials.gov and pubmed-

No embargoes, no blocks-

Information that can save or improve a life should be FREE-

This obviously is not a capitalistic view which puts a price on information sharing- but there should be a way around it -

Submit date: 4/13/2023

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

Name: Ashley Farley

Name of Organization: Bill & Melinda Gates Foundation

Type of Organization: Nonprofit research organization

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

This response to the “NIH Plan to Enhance Public Access to the Results of NIH-Supported Research” request for public input is submitted on behalf of the Bill & Melinda Gates Foundation. Guided by the belief that every life has equal value, the Bill & Melinda Gates Foundation works to help all people lead healthy, productive lives. In developing countries, it focuses on improving people’s health and giving them the chance to lift themselves out of hunger and extreme poverty. In the United States, it seeks to ensure that all people—especially those with the fewest resources—have access to the opportunities they need to succeed in school and life. Based in Seattle, Washington, the foundation is led by CEO Mark Suzman, under the direction of co-chairs Bill Gates and Melinda French Gates and the board of trustees. In 2022, the foundation’s annual giving exceeded \$7 billion USD and continues to grow.

Since 2015, the Bill & Melinda Gates Foundation has had a strong Open Access (OA) Policy that is included in all grant agreements with no exemption. The scope of the OA policy enables the unrestricted access and reuse of all peer-reviewed published research funded, in whole or in part, by the foundation, including any underlying data sets. The policy implementation changed beginning January 1st 2021 to align with Plan S as the foundation joined cOAlition S in 2018. The OSTP Nelson Memo is a welcomed and much needed policy change to further advance OA publishing and establish it as the norm for research communication. However, implementation specifics will be important for adoption to ensure that OA publishing becomes more equitable and a real option for any researcher anywhere. With seven years of policy implementation, the foundation shares its learnings below.

- Opportunity to expand publishing equity beyond NIH-supported investigators. While most funders focus primarily on equitable options for its own grantee author community - it is equally important that funders understand the influence their policies have on the wider community. We have learned this at the foundation: while we may be able to afford a range of OA fees on the behalf of our grantee authors - this promotes a business model that impedes equity for non-funded authors. Recognizing outputs that do not require the publisher’s version of record (VoR) - such as preprints, author accepted manuscripts, archived versions - is critical for equity within the entire publication ecosystem. Along with providing multiple routes to compliance, authors must retain their rights at the point of submission - safeguarding author choice from being stripped away by publisher policies and practices. As much as possible, the NIH should use its voice and influence to push back on publisher bad practices and decouple research dissemination from business models. Publishing will become more equitable as the academic career incentives shift from focusing on faulty metrics stymied in prestige publications. Strong signaling of the validity of open sharing of funded research by the NIH is a vital step.

2. Steps for improving equity in access and accessibility of publications.

Open licenses improve equity in access and accessibility of publications. Open and flexible licensing (particularly CC-BY) allow for increased innovation through discoverability and curation of published research. As more and more research is accessed for translation and further research, there will be less reliance on standard article formats and publisher versions of record. Funders and institutions should value different forms of outputs, such as plain language summaries, preprints, micropublications, protocols, case studies, and data notes. Supporting such a variety will expand the burgeoning AI and ML technologies to parse, summarize, and further disseminate research information. Foreign language translations of language in the author's native language will further expand reach and accessibility. Support and prioritize knowledge translation for the general public to be able to read, understand, and implement knowledge into their communities.

3. Methods for monitoring evolving costs and impacts on affected communities.

Trends in costs and community impact through robust compliance tracking. With improved tracking of data through the foundation's partnership with OA.Works the trend appears that the foundation policy is resulting in an increase of OA publications yearly, however the foundation is paying more year on year for fewer publications. In Other words, APC pricing continues to rise year over year for major publishers without notice, topping out in some cases at over \$12,000. Recent research projects show that funders are ineffectual in affecting APC pricing and it has been near impossible to define a "reasonable fee". While we presume that it does not cost \$12k to publish an article in a highly-selective journal, we do recognize that costs are incurred to support the publishing process. Funders have been advocating for more cost and price transparency but these initiatives have been slow to achieve impact with little publisher participation. The APC model is not sustainable or equitable and Other models have been slow to be tested or implemented. Readers and authors currently pay for cumbersome and antiquated publisher technology, various revenue streams (paywalled content, subscriptions, etc), and print-based legacy processes. Understanding actual publication costs and system improvements will help us realize a sustainable publishing model that is free to both readers and authors. More exploration and financial support for alternative models, such as Diamond and S2O is needed.

4. Early input on considerations to increase findability and transparency of research.

Consistent metadata increases findability and transparency of research. Steps must be taken to increase funder metadata in the publication record to allow for proper attribution and discovery of funded research across multiple platforms and indexing services. Ideally consistent metadata travels with the research from inception to early sharing to data management to publication. There are various Persistent Identifiers (PIDs) projects to help improve this issue, however uptake is slow and requires adoption from a lot of actors. .

The Bill & Melinda Gates Foundation wishes to again express our gratitude and support for the work of the NIH, the OSTP, and Other federal agencies to advance a more open, equitable, and inclusive research ecosystem. We appreciate the opportunity to comment on this draft plan, and we are eager to assist in its rollout.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/NIH_PublicAccessRFI_Gates.docx

Email: ashley.farley@gatesfoundation.org

Submit date: 4/14/2023

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

Name of Organization: American Academy of Neurology

Type of Organization: Professional org association

Role: Medical provider

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Dear Dr. Tabak,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 40,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as multiple sclerosis (MS), Alzheimer's disease (AD), Parkinson's disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

The AAN greatly appreciates the opportunity to provide feedback in response to the "Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research" from the National Institutes of Health (NIH). 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 NIH Public Access Plan as described in NOT-OD-23-091 will be highly disruptive to the ongoing operations and article quality of *Neurology*[®] and *Neurology Clinical Practice*[®].

The AAN is deeply concerned that the NIH Public Access Plan 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 NIH Public Access Plan will likely necessitate a shift of financial responsibility from subscribers to the researchers seeking to have their research published, creating substantial additional barriers for those seeking publication. The rapid implementation of the NIH plan, 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 for the NIH Public Access Plan to create substantial inequity in those able to contribute to the body of peer-reviewed published scientific 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.

AAN Publications Impacted by the NIH Public Access Plan

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.

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The request for information (RFI) states that the “NIH seeks information on additional steps it might consider taking to ensure that proposed changes to implementation of the NIH Public Access Plan do not create new inequities in publishing opportunities or reinforce existing ones.” As stated previously, the AAN is deeply concerned that the NIH Public Access Plan is likely to contribute to substantial inequity in relation to who has the resources to contribute to the body of peer-reviewed, published research. The AAN believes that the NIH Public Access Plan is predicated on a belief that implementation is unlikely to have a substantial impact on journal sustainability under the existing business model. The AAN believes that the current subscription model used for Neurology® and Neurology Clinical Practice® is equitably accessible to researchers submitting their work as there are no fees for submitting a paper to either publication. Upon submission, authors are able to receive valuable feedback on the paper, prior to the paper being published in a journal within the AAN’s family of journals.

The AAN is concerned that the NIH Public Access Plan will result in changes to the underlying publication business model resulting in AAN journals at least partially needing to be funded through article processing charges (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 NIH Public Access Plan.

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 policy refrain from requiring reuse rights under licenses that restrict 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.

While the NIH Public Access Plan states that “NIH currently allows funding to be used to cover costs of publication, consistent with the NIH Grants Policy Statement, 7.9 Allowability of Costs/Activities. Under the NIH Public Access Policy, NIH has clarified that publication costs, including article processing charges often associated with open access publishing, may be charged to NIH grants and contracts” provided

that certain conditions are met. The AAN is concerned regarding the lack of clarity surrounding the amount of funding that will be available and the length of time for which it may be available. Additionally, it would be helpful for the NIH to precisely define the conditions under which a submitted paper may claim NIH funding and/or under which conditions the public access mandate will apply. It is currently unclear how the NIH Public Access Plan applies to a number of potential cases that a journal may encounter. The AAN requests clarification on each of the scenarios below:

- NIH-supported researchers submit for publication after grant funding has elapsed and they no longer have funding to cover APCs or Other fees.
- Cases in which researchers are not funded by the NIH but cite long-running NIH studies or analyses that use data from NIH-studies.
- Instances in which an author is receiving NIH-funding for a subject Other than the topic of the work that is seeking publication.

The AAN also notes that one of the conditions is that “costs are charged consistently regardless of the source of support.” The AAN requests clarification regarding whether the same fees must be charged to all researchers, even those without adequate funding to cover APCs or Other fees that may be covered under an NIH grant or contract. Additionally, the AAN requests clarification regarding the impact of the NIH Public Access Plan on researchers that publish research using data from NIH-funded studies after the relevant study has been concluded and as such do not have NIH support to compensate for APCs and Other necessary fees. Does this requirement preclude journals from accounting for a lack of author resources in determining an appropriate fee? The AAN is concerned that in both of these cases, there will be inequitable access for researchers to access the AAN’s robust peer-review and publication process.

Furthermore, the AAN is concerned that access to funding to account for APCs and Other necessary fees may systematically bias the types of research able to receive peer-review and publication within *Neurology*[®] and *Neurology Clinical Practice*[®]. This is in part due to variability in funding levels for long-standing NIH priorities and is also attributable to long-standing biases, that the NIH is currently working to address, relating to the link between funding gaps and the identities of researchers, as well as the topics chosen by those researchers. Additionally, a recent study found that publishing open access drops significantly for researchers from middle-income countries whose waivers for fees are either smaller discounts or non-existent. The AAN is concerned that the NIH Public Access Plan will exacerbate inequities for the global scientific community by forcing a large-scale shift to open access models that will price underfunded researchers out of the market.

To avoid these adverse consequences, the NIH could consider financial agreements with journals and publishers to directly cover the fees that will be required to support the NIH Public Access Plan, including compensating for changes to the underlying business model. Such agreements could then allow all authors, regardless of funding source, to continue to publish in the publication venue of their choice without directly incurring fees. Alternatively, the NIH could consider including a minimum threshold of funding on which to apply this proposed mandate.

While it may appear that the NIH Public Access Plan is the most equitable for readers, the NIH should be aware that institutional subscribers have tools to assess metrics relating to the value of a subscription,

including the relative volume of journal content that is freely available to the public. Institutions then use this information to determine whether to continue subscribing to a particular journal. The AAN is concerned, absent substantial modification and clarification, that many institutions may decide not to renew existing subscriptions once this plan is implemented, necessitating a substantial modification of the existing business model for *Neurology*[®] and *Neurology Clinical Practice*[®]. Historically the value of subscribing to individual journals has been evaluated by subscribers at the point of purchase. Journals were therefore required to demonstrate their value to the end user or institution who purchased the subscription. To do so, the AAN provides metrics to illustrate the value of *Neurology*[®] and *Neurology Clinical Practice*[®], including both usage data and impact factors. By removing the need to demonstrate quality to the end user or institutional subscriber, and instead shifting towards a business model that is at least partially predicated on fees generated based on the volume of submissions, publications will be incentivized to maximize revenues by accepting as many manuscripts as necessary without regard for quality of science or impact.

In addition to supporting the dissemination of the highest-quality and most impactful research in neurology and neuroscience, the AAN's current subscription-based publishing model supports author equity by providing equal opportunity for all authors to submit for review and publication by the journal, and 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 costs borne by the journal to engage in these activities may not be able to be recouped under the NIH Public Access Plan. As such, the AAN is concerned that our ability to continue to develop supplemental content and provide timely and robust peer-review at the same scale will be negatively impacted by this policy. Editorial operations that produce credible, validated, accessible and timely scientific papers may be weakened under the NIH Public Access Plan, due to budget shortfalls. This may result in slower peer review and/or a less rigorous review overall. Editorial offices and publishers are also addressing numerous Other issues, including equity, diversity, and inclusion, scientific and editorial misconduct such as plagiarism, data and image manipulation, conflict of interests, author impersonation or fabrication, papermill output and ethical violations, all of which may be hindered under this plan.

The AAN takes its role in preserving the scientific integrity of research published in our journals very seriously. The reputations of the AAN's journals and the AAN itself relies on being a provider of trusted content. 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. Diligent peer review, management and public disclosures of conflicts, and data and figure integrity checks are vital parts of the process. These services are critical to production of a final product our members can rely upon as they conduct vital research and deliver evidence-based care, but they also require direct and substantial expense. Significant staff training and resources could be endangered if the AAN loses revenue in the form of cancelled subscriptions, insufficient total APC income, and lost licensing fees for

approved reuse of content. The AAN believes it is critical that NIH account for the impact of decreased revenues on our ability to continue to offer the full range of services now protecting the scientific integrity of research published in our journals.

The AAN requests additional clarification regarding author self-deposit of the accepted manuscript on PMC as an acceptable method of compliance with the NIH Public Access Plan. While the NIH requirement is for authors to deposit, many publishers facilitate this submission to ensure the version published by the journal is the one deposited. The AAN is concerned that this policy may necessitate that journals charge additional fees to researchers for deposit to PMC to ensure compliance and consistency in cases in which the author fails to submit directly.

The AAN also requests clarification regarding NIH's statement that it will limit "inappropriate uses" of NIH-supported articles, "such as redistribution of PMC content for sale." Would this include a publisher's reuse of material from their own publications for a derivative commercial product, if that material is also hosted in PMC?

2. Steps for improving equity in access and accessibility of publications.

The RFI notes "removal of the currently allowable 12-month embargo period for NIH-supported publications will improve access to these research products for all. As noted in the NIH Public Access Plan, NIH also plans to continue making articles available in human and machine-readable forms to support automated text processing. NIH will also seek ways to improve the accessibility of publications via assistive devices. NIH welcomes input on Other steps that could be taken to improve equity in access to publications by diverse communities of users, including researchers, clinicians and public health officials, students and educators, and Other members of the public."

Although the NIH is not promoting one specific publishing business model, the AAN believes that the NIH Public Access Plan will likely result in a substantial weakening of the current subscription-based model for the AAN's journals, which may require a substantial modification of the existing model to more closely resemble a Gold OA model. The existing Green OA model with a 12-month embargo is currently underwritten by subscription, licensing, and advertising revenue. Removal of the 12-month embargo undermines the AAN's ability to recoup investment in content-related and infrastructure costs including, stipends for editors, validation of publication research integrity, content recruitment, development and enrichment through production of ancillary material, submission and peer review systems, editorial tools such as plagiarism detection, digital platforms, and dissemination. The AAN also invests in the development of capabilities for ensuring that content is tagged and presented in a way that is useful to adaptive devices needed by users with visual and auditory disabilities.

With regard to improving access for individuals outside of the typical subscriber or society, the AAN routinely produces and/or publishes infographics, short form article summaries, and patient pages. All of the AAN's guidelines are also published for free public consumption. Absent a direct link to the hosted page on the Neurology.org website, users on PMC have no chance to discover this content. With zero-embargo, it is possible that usage and visits to Neurology.org will fall substantially and along with it, usage of this added value content. This will discourage the AAN from continuing to invest in this content. Additionally, advertising revenue is a substantial component of the business model supporting Neurology® and Neurology Clinical Practice®. By demanding that all papers that report on NIH funded

research appear in PMC with zero embargo, the NIH is restricting usage of content on the publisher sites and thereby significantly threatening advertising revenue.

As noted above, all of these activities add substantial value for researchers and readers and are reflected in the subscription cost. The AAN is concerned that we will need to investigate new means of supporting content and infrastructure costs by directly charging authors APCs and Other necessary service-based charges. Furthermore, the NIH Public Access Plan erodes the longer-term value of subscriptions for journals with significant amounts of federally funded content, creating a perverse incentive related to publishing NIH-supported research in AAN journals.

In addition to clinical practice guidelines which are immediately made free to the public, the AAN routinely makes Other content that is less than 12 months old freely available to any reader. With a zero-embargo policy, the AAN will be forced to decide whether they can continue to make this content available for free. This will be true regardless of whether the AAN ultimately decides to maintain a subscription model under the NIH Public Access Plan or if the AAN shifts to a Gold OA model.

The work of converting Word files into machine readable, highly tagged extensible markup language (XML) is important, particularly for readers in need of assistive devices. Doing so also aids in search and discovery. The AAN believes there is a duplication in effort in creating XML and metadata for content reporting on NIH funded projects. To support equity in access to publications and to support automated text processing, the NIH could compensate journals or publishers for depositing high quality XML machine readable content instead of processing XML a second time via a licensing agreement. Only 11% of publishers depositing content to PMC have agreements with the National Library of Medicine (NLM) whereby they deposit already parsed and tagged XML. Whether these agreements will continue without an embargo remains to be seen. A licensing arrangement would boost compliance of deposits into PMC. While not every journal or publisher will have the ability to enter into such an arrangement, the majority, including the AAN, are already investing in XML processing.

3. Methods for monitoring evolving costs and impacts on affected communities.

The RFI notes that “NIH proposes to actively monitor trends in publication fees and policies to ensure that they remain reasonable and equitable. NIH seeks information on effective approaches for monitoring trends in publication fees and equity in publication opportunities.”

If the NIH moves forward with implementing the Public Access Plan, the AAN recommends that the NIH monitor each publication separately and avoid using average calculations. Costs involved in publishing vary across the industry and are highly dependent on specialty, as well as the nature of the publication. Even within the field of medicine, clinical journal costs vary across practitioner type and specialty. Furthermore, the costs involved in publishing in a highly selective journal, like *Neurology*[®] and *Neurology Clinical Practice*[®], both of which receive a high volume of submissions, are vastly different from the costs of publishing in less selective journals or those with lower volumes of submissions. Costs and revenue streams vary drastically depending on many factors such as audience, circulation, ranking, article quality, supplemental materials, number of articles published, field/specialty, and distribution method.

The AAN requests clarification regarding how NIH will operationalize its approach to monitoring costs and impacts on affected communities. Specifically, the AAN requests clarification regarding how the NIH

will determine the affected communities and whether it will include the entire medical publishing ecosystem and the broader neuroscience and neurologic community. The AAN also requests clarification regarding how the NIH will determine whether publication fees and policies are “reasonable and equitable.” We note that reasonable and equitable fees may vary greatly across the industry and that there is no one-size-fits-all approach. The AAN also believes that this determination may vary under different models including read and publish models and multi-payer models. Further, services rendered to authors vary by journal, which can affect the overall fee structure. The AAN firmly believes that authors need to be given the freedom to choose the journal most appropriate for their research.

The AAN is concerned that the NIH Public Access Plan may impose substantial additional reporting burden on publishers and urges the NIH to engage in a transparent process to determine and evaluate the most appropriate monitoring method(s). There are several complications in tracking publication fees for the NIH in this scenario. We ask that any method the NIH chooses to take the following into consideration:

- It is not uncommon for authors to report NIH funding on manuscripts related to funded projects many years after the grant is officially closed. These papers will be subject to the mandate and yet no further reports (or direct grant expenses) will be accrued. However, these are direct expenses and therefore should be tracked to fully assess the impact of the proposed plan.
- Open access fees should be specifically tracked as separate from any Other publication fees to truly assess the cost of the mandate. In Other words, non-OA fees (such as page fees, submission fees, and color charges) that may already exist should not be included in the tracking associated with this mandate.
- Discounts given (whether by author request or as a result of society membership) and waivers should be noted in the expense tracking so as to avoid skewing the averages. The NIH should account for whether societies and journals are subsidizing author fees to understand the full impact of the mandate.
- The mandate will likely force institutions and industry to pay for publication fees on papers that report on NIH funded research. If an NIH funded author is on a paper but does not have any grant money left to pay publication fees, anOther author on the paper or the author’s institution will have to pay. To truly understand the impact that this proposed policy is having, the NIH should be tracking exactly who is paying the fees.
- Many NIH funded authors will be able to take advantage of Read and Publish agreements that their institutions have made with publishers. As such, the grant money may not be used to pay publication fees. Still, this is an expense to the authors that ties directly to their grant funding and should be tracked by the NIH to gather a complete picture of the impact of the policy.

4. Early input on considerations to increase findability and transparency of research.

The NIH is requesting “suggestions on any specific issues that should be considered in efforts to improve use of PIDs and metadata, including information about experiences institutions and researchers have had with adoption of different identifiers.”

The AAN believes it would be beneficial for PMC 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. The NIH Public Access Plan states that “NIH will continue to enable broad reuse of NIH-supported articles through services that allow for automated retrieval and downloading of full text and metadata, consistent with available license terms. NIH-supported peer-reviewed manuscripts, Other article files as license terms allow, and article metadata are made available by PMC in formats and through channels that enable text mining, large-scale machine-analysis, and computation. These machine-readable article datasets also include retractions, corrections, and expressions of concern.” Although the AAN appreciates this commitment, the AAN believes that our recommendation could achieve several important outcomes including:

- Elimination of the administrative burden on authors to make deposits in PMC. NLM could use the already existing CrossRef metadata APIs to fuel PMC as a metadata repository. Compliance would be promoted as publishers would have an incentive to invest in the metadata deposits to CrossRef as the NLM would be a strong driver of traffic to journal sites.
- Elimination of the NLM expense of “processing” content for display in PMC.
- Serving the users by aiding in discoverability of value-add related content on the publisher site, ensuring that addenda are displayed, and mitigating some of the financial damage the NIH Public Access Plan will have on societies and society journals.

If the NIH declines to implement the above recommendation, to minimize implementation burden, the AAN believes that NIH should utilize existing infrastructure already widely adopted across the industry to support findability and transparency of research. The current persistent identifier and metadata structure is supported by publishers through sponsorship and membership in organizations such as CrossRef and ORCID. Publishers also work with National Information Standards Organization to ensure metadata remains current, accessible, and included in the cost to prepare for content dissemination. By adopting persistent identifiers already in use in scholarly publishing, journals can include persistent links to critical pieces of research for the users to access.

Publishers are very interested in and have been early adopters of persistent identifiers in the scholarly communication life cycle. Digital Object Identifiers (DOIs) have been the backbone of online journal publishing since the 1990s. Much like the NIH requirement for grantees to have ORCIDs, many journals, including those within the AAN’s family of journals, require or encourage authors to use ORCID to assist in author disambiguation. The AAN’s family of journals recently updated our tracking system and authors are now required to use ORCID and FUNDREF as persistent IDs to disambiguate authors and credit funders. Further, publishers make use of FunderID and ROAR identification to again disambiguate human input data received by authors. We encourage the NIH to engage with the AAN, publishers, and the PID community of partners to use or adapt what has already been created. We highly encourage the NIH to employ DOIs for grants as well as require DOIs for datasets published.

Lastly, a commitment from the NIH to adopt persistent identifiers already in use should end the NLM practice of replacing publisher DOIs in the references of papers in PubMed. The NLM does not have permission from publishers or authors to make material changes to the deposited manuscripts. By stripping DOIs from reference links or choosing to include links to the PMC versions instead of the Version of Record, the NLM is unnecessarily restricting the user’s access to associated editorials, letters to the editor, podcasts, infographics, and Other added value content hosted by Neurology® and/or Neurology Clinical Practice®.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/Final-AAN-Comments-on-NIH-Public-Access-Plan.pdf>

Description: Please see the attached for the full comments from the AAN

Email: mkerschner@aan.com

Submit date: 4/14/2023

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

Name: Susan Galandiuk, MD

Name of Organization: American Society of Colon & Rectal Surgeons/ Journal Diseases of the Colon & Rectum

Type of Organization: Professional org association

Role: Scientific researcher

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/Galandiuk-DCR-Letter-NIH-Request-for-Comments-4.13.23-.pdf>

Description: American Society of Colon & Rectal Surgeons' Journal "Diseases of the Colon & Rectum" Editor-In-Chief" response to request for comments

Email: s0gala01@louisville.edu

Submit date: 4/14/2023

I am responding to this RFI: On behalf of myself

Name: Sonal Sathe

Name of Organization: Virginia Tech

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Increasing visibility and engagement of those with documented disabilities as defined under the Americans with Disabilities Act is one critical part of advancing research---especially because visibility of NIH-supported investigators with ADA-documented disabilities is often ignored.

2. Steps for improving equity in access and accessibility of publications.

a) Assistive devices are one part of the equation, but examining and determining the user experience of these devices is also critical to advance the NIH agenda for both improving access to publications and as an actual specific aim for research itself. A person with a vision impairment, for instance, needs accessible websites to complete their literature review in order to set up the dissertation---and so much more.

b) In addition, removal of paywalls for certain articles would be most helpful to support open-access initiatives and to remove cost as a barrier. Not all institutions cover all databases or articles, and sometimes those articles are needed to form the basis for new and innovative research.

3. Methods for monitoring evolving costs and impacts on affected communities.

As mentioned above, removal of paywall is critical, but also monitoring the actual incidence and prevalence of said paywalls might be helpful when surveying NIH-supported investigators' efforts in a literature search.

Tracking and monitoring publication fees for journals for open access will be critical for this purpose. PLoS journals (One, Digital Health, Water, etc.) and Frontiers (Public Health, Nutrition, Digital Health) are two examples of journals that tend to have steep fees to publish; a challenge when a student is seeking to get an article published in those venues.

4. Early input on considerations to increase findability and transparency of research.

Clear and specific verbiage associated with metadata, and guides for visual and hearing impaired users, are most welcome.

Email: sss20a@vt.edu

Submit date: 4/16/2023

I am responding to this RFI: On behalf of myself

Name: Steve Pieper

Name of Organization: Isomics, Inc.

Type of Organization: Other

Type of Organization-Other: Technology consulting and independent research small business.

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The scientific publication process has become a primarily yardstick for determining academic promotions and this should be recognized and separated from the purely scientific role. NIH should encourage academic leaders to recognize contributions like tool development and data curation as critical scientific output. The current system generates too many junk publications that only exist to puff up resumes. The NIH itself is also stuck with this paper-counting bias, and even the Public Access Plan is guilty of assuming that more papers means more progress.

This focus on papers also makes it hard for investigators to invest money in supporting their peers by developing open source software and training people to use it. I believe that as a general rule resources invested to support an open source softwares tools maintained by communities of skilled users and developers result in a much better value to science than the corresponding investment in scholarly publications.

2. Steps for improving equity in access and accessibility of publications.

This is all great. Definitely requiring the data and articles to be freely available is a really good thing.

The NIH should also consider how to ensure the quality of the articles, since there is already a lot of dubious literature and machines are learning to generate even more of it.

3. Methods for monitoring evolving costs and impacts on affected communities.

NIH should really fully support alternatives to the current for-profit scientific publication model. Researchers provide free labor to these companies in the form of publications and reviews and then they are charged for the publications and blocked by paywalls from reading Others.

4. Early input on considerations to increase findability and transparency of research.

No particular suggestions.

Submit date: 4/17/2023

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

Name: Thomas Guillemaud

Name of Organization: Peer Community In

Type of Organization: Other

Type of Organization-Other: Nonprofit publisher and preprint peer-review service

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The NIH should index preprints that have been peer-reviewed, and in particular those that have been validated by academic preprint peer-review and validation services such as Peer Community In (<https://peercommunityin.org>), regardless of the source of funding for the studies that form the basis of these publications.

The NIH should publicly state, as Other international research institutions have done (e.g. Coalition S, <https://www.coalition-s.org/statement-on-peer-reviewed-publications/>), that peer-reviewed and validated articles, including preprints, are considered by the NIH in all its evaluation works to have the same a priori value as articles published in journals after peer-review.

A public statement such as that of Coalition S (“‘peer reviewed publications’ - defined here as scholarly papers that have been subject to a journal-independent standard peer review process with an implicit or explicit validation- are considered to be of equivalent merit and status as peer-reviewed publications that are published in a recognized journal or on a platform.”) would be useful.

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

4. Early input on considerations to increase findability and transparency of research.

Email: contact@peercommunityin.org

Submit date: 4/17/2023

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

Name: Libraries and Sponsored Projects Administration

Name of Organization: University of Minnesota

Type of Organization: University

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

We support this intention to remove existing burdens and avoid creating new ones for NIH funded researchers. However, we urge NIH to consider the potential for these policies to ripple and cause inequities for non-funded projects and researchers. Submitting to PMC has been a requirement for NIH-funded research for over a decade, and removing the allowed embargo period will not introduce a compliance burden. However, NIH must be aware of the limitations on institutional capacity to help authors comply with this requirement. Currently, this responsibility falls on the PI or the journal, and care should be taken to not move that responsibility to the institution, which would create inequities for authors at less resourced institutions. The current policy requires only that the text of the accepted (final, peer-reviewed) version of the manuscript be shared. Continuing this will avoid authors being required to pay an article processing charge (APC) for each article that results from their grant. We have been carefully monitoring the development and implementation of Plan S in Europe, which has focused much of its efforts on read-and-publish agreements and transformative journals, which are based on the APC model of open access (OA). We are not alone in our concerns that publishers are taking advantage of the requirements for immediate open access for research funded by cOAlition S members, as we have seen a large increase in the number of publishers who are focusing their efforts on APC-based OA. One path Plan S supports is transformative journals, in which journals avow that they will achieve annual growth of OA content and “flip” to full OA when they reach a certain percentage of OA content published per year. cOAlition S and publishers who have registered their journals as “transformative” have not adequately defined what model the fully OA journals will use. If they all move to APC-based models, significant portions of the world will be prohibited from sharing their research. This will introduce new inequities for all researchers. Those who do not have funding, or do not have sufficient funding, will be unable to share their work. Researchers from the Global South may be affected more dramatically, but in the United States, many researchers do not have grant funding, and many institutions would be unable to pay for all articles from their institution to be made OA. The University of Minnesota publishes more than 8,000 journal articles per year. APCs vary widely in price, but at \$2500 per article, the University would need to find an additional \$20 million to fund publishing—an amount that is insurmountable. Currently, many publishers have aligned their policies with this and allow for sharing of the author-accepted manuscript (AAM) in any non-profit repository after 12 months. It is possible that publishers may be unwilling to alter their policies to allow for immediate deposit of articles to PMC (although if they were to decide not to accept articles from NIH-funded researchers, they would miss out on significant high quality research). To help ensure authors are able to publish in the journals that are most appropriate for their audience, NIH could increase support for alternative methods. Plan S includes a path for compliance that is based on “green” OA, in which the AAM is deposited into a repository and no APC is required (provided the journal is not fully OA). This path affirms longstanding strategies for green open access that predate widespread adoption of APCs, such

as institutional open access policies - while also providing new tools to researchers and Other advocates. The “Rights Retention Strategy” approach has the potential to address the inequities that will arise from continuing or increased reliance on APC-based publishing models. In addition to the members of cOAlition S, the Ligue des Bibliothèques Européennes de Recherche - Association of European Research Libraries (LIBER) support the rights retention strategy for enabling access to publicly funded research. (<https://libereurope.eu/article/liber-supports-coalitions-rights-retention-strategy-to-ensure-open-access-to-publicly-funded-research/>). If authors will need to negotiate rights to share their articles to comply with NIH’s policy, we would like for NIH to provide very specific guidance and templates for authors to use. Many publishers use “click-through” copyright transfer systems that are opaque to the researchers, so there needs to be very clear instructions for how to ensure they do not accidentally agree to something that is counter to NIH policy. COAlition S provided an analysis of an example publishing agreement from Taylor and Francis (T&F copyright advice. Author, beware. February 9, 2023. <https://www.coalition-s.org/blog/tf-copyright-advice-author-beware/>), which outlines the many ways publishers can use obscure language to conceal from authors what they are committing to when agreeing to publish in a particular journal. The burden of understanding and negotiating this legal agreement should not be solely on the researcher. It should also not be a new burden that is placed on their institution to manage on behalf of their researcher. One solution would be to require publishers accepting NIH-funded manuscripts to indicate clearly in their copyright assignment materials either whether the journal is or is not compliant with NIH publishing requirements, or a statement embedded in their copyright assignment processes that in the event of a conflict between the NIH requirements and that of the journal, the NIH requirements will take precedence. Although NIH will allow for publication fees to make their work publicly accessible to be paid from grant funding, an APC-based publishing system would prevent the many researchers who do not have funding from sharing their research. This would have negative effects on all researchers, including those funded by the NIH. A common theme at the 2023 United Nations Open Science Conference (<https://www.un.org/en/library/OS23>) was that open science, and open sharing of publications, is necessary for the world to achieve the United Nations’ Sustainable Development Goals. For example, researchers from the Global South conduct important research on climate change, which is essential for all, including those in the Global North. NIH should establish policies that proactively avoids predictable adverse outcomes. NIH should also consider increasing support for more equitable publishing models. “Diamond” open access publishing is free for all readers and free for all authors to publish. Support for diamond OA is growing, as demonstrated by investments from Science Europe and statements from Deans at some of the most prestigious universities in the US (<https://libraries.mit.edu/news/libraries-support-3/34036/>) and researchers in the United Kingdom (<https://docs.google.com/document/d/1ZAIPDvECb5Zm1pqAf0I1f0sjcBqPbkPGMvGIhaCz6IM/edit#>). Science Europe, cOAlition S, OPERAS, and the French National Research Agency also jointly developed an Action Plan for Diamond Open Access with steps that NIH could consider undertaking to support this open access model (<https://zenodo.org/record/6282403#.ZDhEvXbMI2w>). Examples of options for NIH support in this space could include direct grants to Diamond OA publishers, support for meetings among these publishers, and educating NIH-funded researchers about Diamond OA journal options. Additionally, because of pressures to optimize “impact” of publications, researchers often prefer “big name” journals over less well known ones—NIH could support Diamond OA by promoting specific Diamond OA journals relevant to NIH areas of focus or by building processes into future grant application assessments that reward diamond OA publication in ways that adjust for lower “impact”.

2. Steps for improving equity in access and accessibility of publications.

We support NIH's goals of making full text articles and related metadata available and accessible to the public. We strongly encourage continuing to make the full text and metadata of articles available via API, which enables text-based and text-mining research that is not possible with many closed-access and restrictively licensed articles. We also strongly support NIH's goals of making articles accessible via screen reader and encourage guidance for researchers to make tables and figures more accessible, including providing alternative text as well as descriptive captions. We applaud NIH's desires to make public articles more understandable to a broader audience. NSF already requires PIs to submit brief project outcome reports written for a public audience. We would encourage NIH to adapt a similar policy to increase accessibility of the research to a broader audience. Additionally, we want to encourage as much clarity as possible in the scientific articles to encourage interdisciplinary collaboration; for example, including less jargon, using active voice, and clearly defining abbreviations.

3. Methods for monitoring evolving costs and impacts on affected communities.

We appreciate NIH's commitment to ensure that publication fees do not increase due to the new public access policy. However, publication fees for many journals are already unreasonable and inequitable. Based on data from Web of Science, the average APC for the top 10 journals in which NIH-funded articles were published had an average APC of \$3,434, and APCs can reach as high as \$11,690 per article. These costs are already consuming significant portions of NIH grants, reducing the amount of funding available for conducting research. It is important to monitor publisher fees, but NIH must be willing and able to act if publishers increase fees to ensure researchers do not face ever-increasing burdens for publication. NIH must define what they consider to be unreasonable, and must take into account that, based on past experience, publishers will continually increase article processing charges (APCs) and are likely to set APCs at the maximum that NIH allows. The current public access policies and ones that will result from the 2022 OSTP memo are based on providing access to federally funded research for taxpayers. These policies are motivated by ensuring the public has timely access to the results of federally funded research. It remains important to find the proper balance between ready access to results and ensuring that federal research dollars are primarily devoted to conducting the actual research, rather than paying publishers.

4. Early input on considerations to increase findability and transparency of research.

In order for all aspects of NIH funded research to be available and findable, we strongly encourage NIH to urge researchers to adopt a standard data citation method to link the articles with the associated datasets. We would also like to see guidance from NIH and Other scientific communities on how best to apply PIDs to various parts of a larger study in order to make sure the components are clearly linked, identified, and findable. For example, some repositories assign DOIs for each file within a study, while Others assign a global DOI for the set of files within the project. Unregulated proliferation of PIDs likely will make findability MORE difficult as individual datasets or articles may be associated with multiple identifiers and cited inconsistently. Linkages between components and PIDS associated with the research study should be both human readable and machine actionable, and ideally in a central metadata aggregator. AnOther consideration for PIDs is the cost associated with minting them - DOIs are costly for repositories or entities who are creating them. However, less costly PIDs (such as ARKs and handles) lack the central metadata infrastructure for discoverability that DOI agencies like DataCite and CrossRef provide.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/RFI-NIH-public-access-response_UMN_UL-SPA_2023.pdf

Description: PDF of comments

Email: hunt0081@umn.edu

Submit date: 4/17/2023

I am responding to this RFI: On behalf of myself

Name: Carl Tuttle

Type of Organization: Not applicable

Role: Patient advocate

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

STOP propagating the false Lyme disease narrative on NIH funded research through omission of the truth, facts, and opposing scientific references. End the debate and find a cure for persistent/chronic infection.

The Lyme disease debacle stems from the NIH funded “Klempner Antibiotic Trials” which set the stage for treatment denial leaving hundreds of thousands (if not millions worldwide) in a debilitated state. Patient testimony across America is describing a disease that is destroying lives, ending careers while leaving its victim in financial ruin.

These “antibiotic trials” in the early 2000’s were stopped short at 90 days whereas there are many known infections requiring months to years of antibiotics to clear the infection.

Leprosy for example (Now known as Hansen’s disease) is curable with long term antibiotics. In some cases, it may take two years to clear the infection.

CDC: Hansen’s Disease (Leprosy)

<http://www.cdc.gov/leprosy/treatment/index.html>

On a personal note, it took two years to clear a chronic prostatitis in my early twenties and when symptoms returned no one questioned the need to prescribe additional antibiotics or a different combination. It was the advent of Bactrim that finally cleared the infection.

These so-called “antibiotic trials” were stopped at 90 days and prove nothing. In 2017 scientists at the Tulane National Primate Research Center reported evidence of persistent and metabolically active *B. burgdorferi* after antibiotic treatment in rhesus macaques as mentioned in the NIAID webpage below:

National Institute of Allergy and Infectious Diseases “Chronic Lyme Disease”

<https://www.niaid.nih.gov/diseases-conditions/chronic-lyme-disease>

Other researchers are finding the same results in humans; current antimicrobials are not working as described in the letter below addressed to Dr. Mark Klempner.

700 articles LYME Evidence of Persistence (Personal Dropbox storage area)

<https://www.dropbox.com/s/n09sk90eo6xz7ua/700%20articles%20LYME%20EvidenceofPersistence-V2.pdf?dl=0>

This pathogen requires an all-out Manhattan project to find a cure! Time to step up the efforts here and STOP propagating the false Lyme disease narrative through omission of the truth, facts, and opposing scientific references. End the debate and find a cure for persistent/chronic infection.

Letter to Dr. Mark Klempner: (For the record, there was no response)

It should be noted that Klempner is presently looking for his piece of the Lyme vaccine pie.

<https://theconversation.com/a-lyme-disease-vaccine-doesnt-exist-can-a-seasonal-shot-help-slow-the-epidemic-spread-by-ticks-138230>

----- Original Message -----

From: Carl Tuttle

To: mark.klempner@umassmed.edu

Cc: michael.collins@umassmed.edu, ddotko@hanszenlaporte.com, ryan.kantor@usdoj.gov, michelle.seltzer@usdoj.gov, william.rinner@usdoj.gov, makan.delrahim@usdoj.gov, tickbornedisease@hhs.gov, "Elias, John" , officeofthechancellor@umassmed.edu

Date: 04/27/2018 7:53 AM

Subject: Persistent Borrelia Infection in Patients with Ongoing Symptoms of Lyme Disease

April 27, 2018

University of Massachusetts Medical School

55 Lake Avenue North

Worcester, Massachusetts 01655

Attn: Mark S. Klempner, MD, Executive Vice Chancellor, MassBiologics

Dr. Klempner,

I would like to call attention to the attached study recently identifying chronic Lyme disease in twelve patients from Canada.

Persistent Borrelia Infection in Patients with Ongoing Symptoms of Lyme Disease

<http://www.mdpi.com/2227-9032/6/2/33>

All of these patients were culture positive for infection (genital secretions, skin "Morgellons" and blood) even after multiple years on antibiotics so there was no relief from current antimicrobials. Some of these patients had taken as many as eleven different types of antibiotics.

In contrast, your 2001 antibiotic treatment study found; "no evidence of B. burgdorferi in a total of more than 700 different blood and cerebrospinal fluid samples from the 129 patients in these studies."

Two Controlled Trials of Antibiotic Treatment in Patients with Persistent Symptoms and a History of Lyme Disease

http://www.nejm.org/doi/full/10.1056/NEJM200107123450202#article_references#t=references

Not a single positive Dr. Klempner? Doesn't this statistically prove that your methodology was fatally flawed?

Did you culture skin and genital secretions as the Middelveen paper reports? It would appear that you conveniently stopped looking after your results supported the existing thirty year dogma; chronic Lyme does not exist.

Persistent Lyme disease is not new and has been intentionally/deceitfully suppressed for decades as described in the Vicki Logan case identified in the following letter to past CDC Director Barbara Fitzgerald:

<https://www.dropbox.com/s/xaul84dqmgbre0/Brenda%20Fitzgerald%20MD%20Director%20CDC.docx?dl=0>

In 1991 *B. burgdorferi* had been isolated in culture from Vicki Logan's CSF (CDC's laboratory in Fort Collins CO.) despite prior treatment with 21 days of IV cefotaxime and 4 months of oral minocycline.

The dishonest science here in the U.S. has denied chronic Lyme which stifled research to find a curative approach. Now the rest of the world is suffering.

We have lost nearly four decades to this 21st century plague due to the racketeering scheme identified in the RICO lawsuit filed by SHRADER & ASSOCIATES, LLP against the Infectious Disease Society of America, seven IDSA Panelists and eight insurance companies. The U.S. Centers for Disease Control has aligned itself with the seven IDSA Panelists identified in this lawsuit.

Court Document:

<https://www.courthousenews.com/wp-content/uploads/2017/11/LymeDisease.pdf>

Lyme is an incurable disease when not treated immediately which is spreading across North America and deceitfully misclassified as a low-risk and non-urgent health issue. Patient experience is describing a disease that is destroying lives, ending careers, causing death and disability while leaving victims in financial ruin. Current antimicrobials are ineffective for eradicating all forms of the *Borrelia* spirochete.

Public outcry has been ignored for decades while the Centers for Disease Control sat on evidence that this infection was not easily treated with a one size fits all treatment approach as dictated by the Infectious Diseases Society of America.

Once again your studies were fatally flawed while supporting the controlling dogma leaving hundreds of thousands if not millions worldwide with a persistent infection and absolutely no relief. We have another AIDS on our hands.

Carl Tuttle

Independent Researcher

Lyme Endemic Hudson, NH

Cc: -Michael F. Collins, Chancellor

-The Tick Borne Disease Working Group

-US Department of Justice

-Daniel R. Dutko, HANSZEN LAPORTE

- 2. Steps for improving equity in access and accessibility of publications.**
- 3. Methods for monitoring evolving costs and impacts on affected communities.**
- 4. Early input on considerations to increase findability and transparency of research.**

Email: runagain@comcast.net

Submit date: 4/17/2023

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

Name: Greg Tananbaum

Name of Organization: Open Research Funders Group

Type of Organization: Other

Type of Organization-Other: Philanthropic Network

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The proposed NIH guidance promotes compliance via the archiving of articles in agency-designated repositories (PubMed Central, in the case of NIH). This guidance wisely balances the broad freedom that funded researchers enjoy in deciding where to publish their results with the taxpayers' interest in ensuring federal funds don't inadvertently exacerbate research ecosystem inequities. Paywalls limit access to knowledge, limit replication and reproducibility, and stifle civic engagement in science. Replacing paywalls with exorbitant open access article processing charges (APCs) would potentially trade one set of inequities for another, creating a two-tiered system in which authors outside of well-funded R1 institutions lack the financial wherewithal to publish in some prestigious, brand-name journals. A repository-mediated ("green") route to federal policy compliance, as NIH allows/supports through manuscript deposit in PubMed Central, is an effective way to reduce the impact on younger researchers, women, scholars at minority-serving institutions, and others who are more likely to be disadvantaged by an APC-dominant publishing system (see, for example, the AAAS survey "Exploring the Hidden Impacts of Open Access Financing Mechanisms"). Note that this input is also intended to address the "Monitoring Evolving Costs & Impacts" request for information proffered by NIH. We also encourage the NIH to explore strategies to support preprints as a mechanism for ensuring equitable, low-cost, and timely access to federally funded research.

Additionally, the NIH should consider providing funded researchers clear guidance on rights retention, building on guidance developed by other funder groups (e.g., COALITION S) and the larger academic community. Expecting scientists to be experts not only in biomedicine, but also in the labyrinthine world of copyright law, presents an undue burden. The NIH should make it as easy as possible for grantees to retain sufficient rights to make copies of their papers available and reusable in PubMed Central. We appreciate NIH's inclusion of rights retention considerations in this RFI as a signal of this issue's centrality to a comprehensive public access strategy.

2. Steps for improving equity in access and accessibility of publications.

One area of potential improvement for the NIH's draft plan is with respect to reuse rights for shared research, which the OSTP guidance includes as an important consideration. While the draft plan does say, "NIH will continue to promote the broadest possible reuse of its supported articles", it does not include an open licensing requirement that would codify and maximize reuse rights. This lack of specificity means researchers could potentially deposit both articles (and data) under a variety of licenses or conditions that could significantly restrict how these materials can be built upon by

researchers and the broader community. A CC BY license or functional equivalent is the best way to enable text and data mining computational uses, and educational reuse. Importantly, from an inclusivity standpoint, this form of licensing is the best way to ensure content accessibility via assistive devices. The ORFG also appreciates the NIH's expansive definition of "accessibility" to emphasize that a range of individuals and communities - including those needing assistive devices and community members not well-versed in scientific jargon - are not presently able to fully engage with federally funded research. We would be pleased to engage with the NIH to identify practical solutions to these limitations.

3. Methods for monitoring evolving costs and impacts on affected communities.

Please see "How to best ensure equity in publication opportunities for NIH-supported investigators" response.

4. Early input on considerations to increase findability and transparency of research.

The NIH should include specific, actionable guidance on persistent identifiers (PIDs) and metadata to its funded researchers. The ORFG encourages the NIH and Other federal agencies to embrace de facto community standards where they exist. These include digital object identifiers (DOIs) for articles, datasets and data management plans, ORCIDiDs for authors, and RORs for institutions. In the interest of making policy compliance as easy as possible for individual researchers, the NIH should coordinate with Other agencies and the National Science and Technology Council's (NSTC) Subcommittee on Open Science, to align on PID and metadata best practices. The ORFG would welcome the engagement of the NIH and Other federal agencies in the community we have nurtured since fall 2022 to improve research output tracking. This group is uniquely positioned - with its cross-sector expertise drawing from funders, higher education, technology providers, publishers, standards bodies, and international organizations - to provide such guidance on best practices.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/ORFG-NIH-2023-Public-Access-RFI-response.pdf>

Description: Full response to the "NIH Plan to Enhance Public Access to the Results of NIH-Supported Research" request for public input submitted on behalf of the Open Research Funders Group

Email: greg@orfg.org

Submit date: 4/17/2023

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

Name: John Willinsky

Name of Organization: Public Knowledge Project

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

I have attached a letter, signed by a publisher, legal scholars, librarian, program manager, and two researchers, outlining why I believe that the NIH can better serve its mission and the progress of science, capitalize on its public access experience, and build on its leadership in this area by moving beyond an enhancement of its current policies to engage in discussions aimed at sustainable, universal public access on a global scale.

2. Steps for improving equity in access and accessibility of publications.

The letter addresses equity in access.

3. Methods for monitoring evolving costs and impacts on affected communities.

The letter addresses cost management.

4. Early input on considerations to increase findability and transparency of research.

The letter addresses transparency of research.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/Willinsky-Response.pdf>

Description: An Open Letter on NIH's Request for Information on Public Access

Email: willinsk@stanford.edu

Submit date: 4/18/2023

I am responding to this RFI: On behalf of myself

Name: Steven D. Smith

Name of Organization: Frontiers

Type of Organization: Other

Type of Organization-Other: Publisher

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

NIH public access plan is welcome. Universities and institutes can continue to be encouraged to strike institutional agreements with publishers to ensure cost-neutral access, with relevant discounts etc. Right now, there are surprisingly few institutional partnerships, although a few well-publicized so-called transformative agreements have been signed, such as Wiley's with California (CDL?) in recent days. There is a potential inequity here with the so-called 'free rider' effect: that research universities pay for the publication of open access research through APCs (gold OA), but universities and colleges that do not produce research effectively get 'free access' to the research. So costs are spread unevenly.

Publishers should be encouraged to offer discounts and waivers, which are typically country-specific, but could in theory vary based on Other factors.

2. Steps for improving equity in access and accessibility of publications.

It may be publicly available, but needs CC-BY license. Clarification seem, rights are important.

3. Methods for monitoring evolving costs and impacts on affected communities.

There should be better clarity around the APCs so that people understand the reason for investment, sustainability and transparency; such as the journal-checker tool / database with Plan S.

4. Early input on considerations to increase findability and transparency of research.

Use of ORCID should be encouraged.

Grant ID numbers and PIDs for grants.

But much is not currently interoperable or universal.

Making and collecting meta-data and making sure open review is captured.

Data citations, links to resources.

In 2017 Cross-Ref does offer Fund Ref and global PIDs for grants and facilities. Interoperable identifiers are necessary!

Email: steve.smith@frontiersin.org

Submit date: 4/18/2023

I am responding to this RFI: On behalf of myself

Name: Mark Peifer

Name of Organization: University of North Carolina

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

If you simply mandate posting of the author version of the PMC article with NO embargo, that would be awesome. We all already produce author versions for review and you have forced journals to accept the posting of PMC versions--removing the embargo will be a simple solution for researchers and will also undercut some of the outrageous fees some for-profit journals are charging for "Gold Open Access"

2. Steps for improving equity in access and accessibility of publications.

I think this is a good investment, but the burden needs to be on NIH, not the researcher.

3. Methods for monitoring evolving costs and impacts on affected communities.

I love the fact that you are stepping in here. The outrageous fees charged by some for profit journals (the Nature family has gotten the most attention) are creating inequities. fees at most non-profit society journals are much lower. I would speak with those smaller publishers to get their input.

4. Early input on considerations to increase findability and transparency of research.

This is outside my expertise

Submit date: 4/18/2023

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

Name: Hilary Davis

Name of Organization: NC State University Libraries

Type of Organization: University

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

We applaud the NIH's recent efforts to engage with stakeholders on topics such as current policy on public access to the results of federally funded research, the evolution of scholarly communications, and access to data and code. We thank the NIH for the opportunity to provide feedback and recommendations. These comments are provided on behalf of NC State University.

Many publishers are actively promoting that the primary path to open access (and public access) is via the payment of an Article Processing Charge, or APC. We are concerned that many grantees will assume that the publishers are correct and will not feel confident in choosing Other options available to them, including green open access. We strongly encourage the NIH to be explicit early and often about the no-cost options for compliance when working with grantees (at grant submission stage, at grant award stage, during progress reports, etc.).

Feedback from some authors is that the author-initiated process of submitting articles to PMC is confusing and creates additional burden. Ideally, the NIH will establish a role/unit that will streamline publisher-initiated deposits or NIH-mediated deposits of articles into PMC and make researcher/author involvement in the PMC deposit process optional. This would alleviate a burden that authors/grantees currently bear.

Some NIH-funded researchers have and will publish their articles as Open Access (e.g., via payment of an Article Processing Charge, or APC). In these cases, the researchers may not realize that they still must comply with the requirement to submit articles to PubMed Central (PMC).

Therefore, we recommend that the NIH make it clear via the FAQs and on the public access policy website that even though an article may have been published as Open Access (e.g., via payment of an Article Processing Charge, or APC), authors must also submit the article to PubMed Central (PMC).

Many publishers who used to submit articles on behalf of authors to PubMed Central (PMC) do not follow that practice anymore. Some publishers will only submit articles to PMC if an APC is paid by the author, creating further confusion and placing more burden on the researcher/author. We encourage the NIH to provide clear guidance on a situation that we expect to be common: if a publisher refuses to deposit an article into a repository (PMC) without a paid APC, the "final peer-reviewed manuscript" should still qualify as eligible for deposit in PMC, and this action will not be in violation of copyright.

2. Steps for improving equity in access and accessibility of publications.

We hope the NIH will encourage and explain to grantees the need to provide alternative text for images, figures, and tables written by subject matter experts rather than editors or publishers. In an effort to

make any visual content in a publication accessible to readers who use assistive technology, descriptive alternative text is key and is best created by the subject matter experts who understand not only the visual content but also its relationship to the surrounding textual content.

We are glad to see the use of the most recent American National Standards Institute (ANSI) NISO Journal Article Tag Suite (JATS) XML format to create accessible documents in PubMed Central (PMC). It would be useful to continue to encourage authors to consider accessibility in manuscript creation by using word processing programs' headings, formatting, and tagging features. Using NIH's influence to encourage authors to make born-accessible manuscripts can improve the accessibility of not only NIH-funded manuscripts but also manuscripts in general, particularly when it comes to preprints and Other manuscripts without formal editing or curation.

Actively encouraging the use of accessible markup languages for formulas, such as MathML, may save time for PMC's JATS markup by ensuring that manuscripts are coming in with accessible formulas.

We hope the NIH will consider extended engagement with or investment in the infrastructure needed to support the PID (or DPI) ecosystem that currently makes research outputs discoverable and accessible (see Section 4 below).

3. Methods for monitoring evolving costs and impacts on affected communities.

We encourage the NIH to think expansively about costs and fees associated with publication, taking into consideration the costs associated with publishing data, including data curation and long-term storage of research data. We acknowledge that these costs can be highly variable, particularly among disciplines, but we hope that the NIH can develop some general guidance for estimating these costs and exhibit some flexibility when awarding funds.

We additionally encourage the NIH to consider further investment in the cyberinfrastructure required to publish and preserve research outputs, including data. Recommending specific disciplinary repositories for researchers seeking to make available NIH-funded research is an excellent step. Acknowledging the cost and ongoing effort required to maintain these systems will help to further the discussion around support.

We are glad to see that the NIH does not propose requiring authors to publish in journals with any specific type of business model, e.g., publishing their articles Open Access in gold or hybrid journals which requires the payment of an Article Processing Charge (APC).

We are concerned that publishers may introduce new fees for publishing NIH-funded research or require NIH-funded researchers to publish their articles as Open Access. We recommend that the NIH keep a close watch on fees or APC charges that are being levied specifically against NIH-funded authors.

Another concern is whether publishers will begin flipping hybrid journals to Gold OA in response to the NIH's and Other federal agencies' updated public access policies and/or raise APC costs. To monitor costs and provide transparency, It may be helpful for the NIH to ask publishers who have Participation Agreements with PMC to make available up-to-date pricing models. Alternatively, the NIH or a collaborator organization can track APCs paid out of research funding to see if these costs increase over time.

4. Early input on considerations to increase findability and transparency of research.

We are glad to see the emphasis placed on persistent identifiers and robust metadata, as these play a key role in making research FAIR. Common standards, such as DOIs, ORCiDs, and RORs, have gained traction and are well regarded. We recommend that the NIH endorse the usage of these PIDs to the community, and, to the extent possible, require the use of ORCiDs. We also recommend that the NIH discourage the proliferation of new PIDs, ensure any new systems where necessary are interoperable with existing systems, and consider supporting efforts to sustain existing and well-established PIDs.

We additionally encourage the NIH to continue to expand the use of existing identifiers into new contexts, like machine-actionable DMSPs, to facilitate better metrics and tracking of research outputs.

There is an opportunity to sustain, grow, or improve efforts around Other PIDs (e.g., instrumentation), and we recommend that the NIH remain aware and supportive of these efforts.

Email: hmdavis4@ncsu.edu

Submit date: 4/18/2023

I am responding to this RFI: On behalf of myself

Name: john vaughen

Name of Organization: stanford University

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

I 100% approve of making NIH-funded work available on PMC immediately without paywall/embargo!!
Could we retroactively make currently paywalled articles done w/ research historically funded by NIH available on PMC as well?

2. Steps for improving equity in access and accessibility of publications.

Consult with smaller journals and users not affiliated with large R1 institutes. Is there a mechanism for ensuring authors comply with PMC upload?

3. Methods for monitoring evolving costs and impacts on affected communities.

4. Early input on considerations to increase findability and transparency of research.

Submit date: 4/20/2023

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

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

As NIH has already indicated, certain publishing models (such as those that charge fees to authors to publish their research) shift barriers to access from readers (and their proxies) to authors (and their proxies), and are likely to create inequity for researchers who lack funds to cover article processing charges (APCs) or Other publishing fees. NIH should endeavor to make very clear to researchers that they are not required to pay APCs to publishers in order to be in compliance with the public access requirement, and should make clear to publishers and organizations that they should not try to convince authors that paying an APC is the only way (or the best way) to comply with the requirements, publisher behavior that we already see happening. It is not in the interest of NIH, taxpayers, researchers, and research organizations for APC-based publishing to become the dominant model, so NIH should ensure that its public access policies do not inadvertently help establish paying APCs as a norm.

To the extent possible, public access deposit and compliance processes should be integrated into existing researcher workflows, so that public access compliance does not become an additional burden that may create further inequity and potential resistance to the policy and its intentions. The complexity of the current process for depositing publications requires significant infrastructure, training, and time that often falls on lower paid administrative staff at major research institutions, especially administrative assistants, grant coordinators, and librarians. Many smaller institutions, including those that serve primarily rural populations and communities of color, may not have support staff available to assist with policy compliance. This is harmful to the research landscape as these constraints make it even harder to perform research that reflects the needs of vulnerable populations. It is in the best interest of the scientific community to limit the complexity of compliance processes that fall to investigators and their support staff, and instead leverage or mandate the resources of publishers. For example, publishers could make final versions of manuscripts available to PubMed Central when sending records to PubMed for indexing. Managing this complexity should be of primary concern when executing Section III.A.3.b.

2. Steps for improving equity in access and accessibility of publications.

NIH can improve equity in access and accessibility of publications by requiring that NIH-funded research be openly licensed for re-use, through a license such as CC-BY (Creative Commons Attribution), which unambiguously enables a variety of re-use possibilities while still allowing authors to retain those associated rights and the rewards. This would concretely clarify concerns raised in section III.C.1. As noted above, NIH should monitor whether publishers are attempting to charge authors for public access or use of open licenses, and push back by asserting a pre-existing open license for NIH-funded research -

in Other terms, a rights-retention policy such as that being used by “Plan S” funding agencies in Europe. Duke University has had an open access policy since 2010 that retains for Duke and Duke Faculty authors a non-exclusive license to make their scholarly articles open access via Duke’s repository. This has enabled Duke research to be made open access, while allowing authors to continue to publish in the venues of their choosing - even if publishers pressure them to sign over Other rights in order to be published, a pre-existing non-exclusive license remains in place to enable them to make their work available through open access, at no cost to them.

While senior researchers who are already established in their careers may feel confident about negotiating with publishers to retain their rights, early career researchers and researchers from historically disadvantaged communities may fear a punitive reaction, and as a result may be reluctant to advocate on their own behalf. When funders like NIH and institutions like Duke establish a baseline of rights retention for their researchers, this levels the playing field and provides a more equitable benefit to all researchers, enabling them to retain control over their own research outputs, make them widely available, improve the reach and impact of their research, and support maximum benefit to the public and their own careers.

NIH has already established expectations for machine-readable publications with high quality metadata, and Duke supports these efforts, as they should enable research to be findable and accessible to people using assistive technologies, researchers who wish to do “distant reading” analysis via software, or Other potential uses that may emerge in the future.

3. Methods for monitoring evolving costs and impacts on affected communities.

NIH can monitor which journals grantees are publishing in, whether they charge fees to authors, and what these fees are. Neither authors nor NIH should be expected to pay high fees simply to publish. As Harvard scholar Peter Suber has noted, high publication fees are essentially a “prestige tax” that are set at the level of what researchers might be willing to pay for the benefit of being associated with a particular journal’s brand, and have no connection to the actual costs of publication. As noted above, high publication fees are a barrier to entry for any authors, and especially early career researchers or those from smaller institutions or historically disadvantaged communities.

NIH can use its influence as a major funder of research to lead efforts to transition journals away from charging either authors or readers, by partnering with Other research funding agencies in the US and abroad and with research organizations like universities and libraries to expand initiatives like SCOAP3 to journals in more disciplines. Such initiatives allow costs to be controlled and sponsors to have greater influence in scholarly publishing processes and outputs, while removing barriers for researchers and readers.

NIH should invest in open and community owned infrastructure to help develop and sustain research infrastructure that is aligned with the research mission of funders and universities rather than primarily with a profit motive. Organizations such as Invest in Open Infrastructure, Lyrasis, CrossRef, ORCID, and Dryad are non-profit member organizations that develop and manage essential research infrastructure, and are more transparent about their costs and the value they provide to the community, as well as having a more direct connection to the research community and a clearly defined mission to serve its needs rather than primarily to extract value.

4. Early input on considerations to increase findability and transparency of research.

High quality metadata and standard persistent identifiers for both research outputs and researchers and their organizations will significantly assist findability and transparency of research, as well as accurately providing credit to researchers for their contributions and funders for their sponsorship.

Wherever possible, NIH should require use of existing identifiers such as DOI, ORCID, ROR, and existing taxonomies such as CRediT (Contributor Roles Taxonomy), and work in conjunction with NISO and Other standards bodies to ensure integration of NIH processes with identifiers and infrastructure already widely used by the research community.

Additionally, Duke encourages the NIH to pursue a more open and accessible API for the MeSH Database and materials categorized using this metadata to further increase the findability and bibliometric analysis of medical information. More standardized metadata for NIH funding can assist institutions in developing and maintaining compliance reports, enable better discovery of published manuscripts based on funding information, and may help in crosswalking with Other PIDs, such as NCT numbers. Enhanced metadata for data availability will also assist with connecting published manuscripts with data.

It's important to recognize that full implementation and integration of these standards, identifiers, and functionality involves significant technical challenges, as well as commitment of staff and resources. NIH should aim to support research institutions and smaller organizations in implementing the necessary functionality in their own systems, to avoid potential inequities where systems supported by large publishers and corporations are more easily equipped to develop and support this functionality, leaving less resourced institutions and smaller organizations at a disadvantage.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/Duke-University-response-to-NIH-Public-Access-RFI-April-2023.pdf>

Description: PDF attachment includes an introductory paragraph about why Duke supports this effort, some links in the text body, and information about leaders of multiple Duke University organizations that are signatories in support of these comments.

Email: paolo.mangiafico@duke.edu

Submit date: 4/20/2023

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

Name: Katherine B. McGuire and Jasper Simons

Name of Organization: American Psychological Association

Type of Organization: Professional org association

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/Letter-in-Reponse-to-NIH-RFI-on-Enhancing-Access-April-18-2023.pdf>

Email: ahill@apa.org

Submit date: 4/20/2023

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 Heart Association, American Diabetes Association, American Society of Anesthesiologists, American Urological Association, American Thoracic Society, American Gastr

Type of Organization: Professional org association

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The medical societies represented in this response to the National Institutes of Health (NIH) Request for Information (RFI) on the NIH Plan to Enhance Public Access to the Results of NIH Supported Research thank the NIH for the opportunity to comment on the proposed public access plan.

As the NIH works to incorporate feedback and refine a draft policy, we recognize that the NIH proposed plan has a path for compliance whether a funded author chooses to publish in journals with an open access model, a subscription model, or Other publishing model. It would be extraordinary and detrimental to non-profit organizations for a US agency to develop policies that force one business model over another with no consideration for the economic harm and/or impact to societies and science communication overall.

In recognition of our continued support in aiding researcher compliance with NIH requirements and to make peer-reviewed content accessible without an embargo, and we ask that the NIH policy refrain from requiring reuse rights under licenses that restrict our ability to establish copyright and preserve the downstream revenue associated with the final version of record.

Beyond whether a journal is subscription access, open access, or hybrid, there are supplementary revenue streams that society journals use to remain sustainable including licensing, commercial reprints, permissions, and advertising. Broad reuse licenses that do not respect publisher copyright rights jeopardize those revenue streams and the sustainability of society publishers. The value we provide to our research communities is at risk. Under copyright provisions, we guard against misuse of author content by requiring third parties to follow our policies regarding appropriate use of published content.

Maintaining scientific integrity is paramount.

The societies represented in these comments take seriously the scientific integrity of research published in our journals. The reputations of our societies and journals rely on being a provider of trusted content.

Our clinical journals focus on expedient but thorough review and publication of research that affects patient care—not in a matter of years, but sometimes hours. Our societies use our journals to disseminate clinical practice guidelines that impact research practice or clinical decisions, rules of hospitals and clinics, spending by government and insurers, and ultimately public health. The guidelines are developed at great expense and with significant resource burden. Utmost care is taken that they are current on the research, provide appropriate guidance based on proper methods and analysis of evidence, and bar any industry influence.

Maintaining this trusted role in society, at a time when disinformation is rampant, requires a significant investment. Vigilance in publication research integrity and conflict of interest management not only aligns with our missions but, more importantly, gives confidence to clinicians and researchers that information we publish has been verified and is reliable.

Diligent peer review, management and public disclosures of conflicts, and data and figure integrity checks are vital parts of the process. Threats such as plagiarism, “paper mills,” and fraudulent data are increasingly present and require steady attention.

These services are critical to production of a final product researchers and clinicians can rely upon as they conduct vital research and deliver evidence-based care—but they also require direct and substantial expense. Significant staff training and resources could be endangered if publishers lose revenue in the form of cancelled subscriptions, insufficient total article processing charge (APC) income, and lost licensing fees for approved reuse of content, among Others. Each publisher will have their own budgetary tipping point when decreased revenues impact our ability to provide services that now protect the integrity of research published in our journals.

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The subscription model is largely accessible to researchers submitting their work and thus the most financially equitable for authors. Free to read (via gold or green OA) is most equitable to the readers.

The NIH proposed plan to mandate zero-embargo and allow green access appears equitable for both authors and readers. However, that assumption does not consider that many subscription and hybrid journals will have a large quantity of content that they invested in freely accessible. Under this zero-embargo proposal continuing subscription revenue may be implausible for some journals. Libraries have begun and will continue to cancel subscriptions to journals with large amounts of content that are free to access.

In such an environment, journals with high numbers of papers reporting on NIH funded research may need to convert to an author-pays open access (gold OA) model. While the NIH portends that NIH funded authors will have the ability to pay Article Processing Charges (APCs) to these now newly flipped journals, this creates an equity issue for NIH authors who have minimal funding or their funding is expended on necessary research expenses.

This proposed plan will be mandated for all NIH funded authors regardless of how much funding they received or how small a role any given individual plays in a research project or manuscript. The NIH should apply a minimum threshold of funding and/or level of participation by authors and researchers before subjecting the papers to the proposed mandate. Also, minimal contributions to studies (or use of funded shared resources) made by NIH-funded authors should not qualify a paper for the proposed mandate.

It is commonly understood that there is significant overreporting of federal support on submitted manuscripts as a component of research grants. We are aware that grantees, or Others working on their behalf at their institutions, have deposited articles in PubMed Central in error. In light of this—and the impact of proposed changes—we urge NIH to publish clear guidance, both on circumstances that qualify submitted papers to claim NIH funding, and the conditions that invoke a requirement to comply with the

public access mandate. More and better communication to grantees and Other stakeholders regarding the administration of compliance is essential with the planned zero embargo policy.

Regardless of whether NIH funded authors intend to pursue a green OA option and reserve their funds for Other research purposes, a concerning number of scientific journals will be vulnerable to library subscription cancelations given the amount of content that will be accessible without embargo on PubMed Central and Other government repositories. Not all journals will be able to offer a green route. We do not believe OSTP or federal funding agencies fully appreciate the extent to which zero-embargo public access policies will disrupt the entire ecosystem of the research enterprise.

2. Steps for improving equity in access and accessibility of publications.

The work of converting Word files into machine readable, highly tagged extensible markup language (XML) is important, particularly for readers in need of assistive devices. It also aids in search and discovery. One efficiency and savings of taxpayer dollars we can do today is to remove the redundancy of this being done twice—once by the publisher and once by the National Library of Medicine (NLM). This is not a good use of taxpayer money.

The NIH could reduce their expenses in performing duplicate tasks. We call on the NIH to engage publishers in possible private-public partnerships to avoid duplication of work and excess spending.

Our organizations invest in development of journal hosting platforms with capabilities for ensuring that content is tagged and optimized for adaptive devices needed by users with visual and auditory disabilities. We are concerned that by taking users off our platforms to read our content on PubMed Central, the value of this investment will be diminished.

Medical societies routinely produce infographics, visual abstracts, context summaries, plain-language summaries, and patient pages for individuals outside the typical subscriber or society member. Currently the NLM refuses to link references to the publisher site, and users on PMC have little chance to discover this content. A zero-embargo policy is likely to further diminish existing usage.

3. Methods for monitoring evolving costs and impacts on affected communities.

The NIH must engage the researcher community to understand their concerns about public access policy changes. While the NIH asserts authors can use grant money to pay publication fees, our members overwhelmingly tell us that they do not have enough money in their grants to cover publication fees for multiple papers likely to arise from a single grant. Further, researchers tell us their proposals for funding are typically cut in review.

The likelihood of large increases in government funding of agencies is low and researchers are concerned that publication fees will not be adequately covered by their research grants.

4. Early input on considerations to increase findability and transparency of research.

Publishers are very interested in and have been early adopters of persistent identifiers (PIDs) in the scholarly communication life cycle. We encourage the NIH to engage with publishers and the PID community of partners to use or adapt what has already been created. We strongly recommend the NIH both employ digital object identifiers (DOIs) for grants and require them for datasets published. By

adopting persistent identifiers already in use in scholarly publishing, journals can include persistent links to critical pieces of research for users to access.

Lastly, a commitment from the NIH to adopt PIDs already in use should end the current NLM practice of replacing publisher DOIs in the references of papers in PubMed. The NLM does not have permission from publishers or authors to make material changes to the deposited manuscripts. By stripping the DOIs from reference links or choosing to include links to the PMC version instead of the version of record (VOR), the NLM is depriving the user of access to associated editorials, letters to the editor, podcasts, infographics, etc. The NIH has shown strong interest in understanding how journals make content more accessible to non-subscribers and non-specialists; it makes no sense for the NLM to refuse to link to the VOR for the discovery of this content via references.

We urge the NIH, OSTP, and OMB to carefully consider the points raised and we thank you for the opportunity to comment.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/Medical-Societies-RFI-Response.pdf>

Description: Full letter in PDF form included.

Email: angela.cochran@asco.org

Submit date: 4/21/2023

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

Name: Joanna L. Groden, PhD

Name of Organization: University of Illinois Chicago

Type of Organization: University

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

We appreciate the NIH's leadership in areas of open science and open data sharing and are delighted to see the move towards coordinating with the requirements of the Office of Science Technology Policy memo. We support the continued move towards open research which will benefit researchers, the general public, and communities around the world to improve their health and knowledge. As we actively support sharing all forms of scholarship equitably and responsibly, we are pleased to have the opportunity to provide feedback and raise a few ongoing concerns about sharing both publications and the underlying research data.

In order to ensure equity in publication opportunities for NIH researchers, there are significant challenges related to misunderstandings related to fee expectations and across different publishing models. We encourage the NIH to state explicitly that the researcher needs to pay no charge to comply with NIH's policy. It should be possible for a researcher to deposit the final peer-reviewed manuscript of any work funded by the NIH in PubMedCentral free of any payment to a publisher as a way to ensure that the researcher is in full compliance.

Journal business models requiring authors to pay a fee for journal publication (APC) present significant publication barriers for many researchers. Any open access fees charged by a publisher should only be for the standard APC for publications in verified fully open access journals. No additional fees should be required for compliance with NIH's Public Access Policy, either to make the article open or to submit it to PubMedCentral on the authors' behalf.

In addition to concerns about fees, creating a standard template for copyright agreements would improve equitable change for authors across disciplines. NIH should also offer clear language and processes that investigators can use upon submission to publishers to retain rights to make their peer-reviewed manuscript freely available and fully reusable post-publication in PMC without an embargo period. Specific instructions for doing this effectively would help authors comply with the policies, make federally funded research reusable, and further support NIH's goal to ensure equity in publishing.

Institutional repositories run by libraries and Other research institutions generally do not charge authors to deposit articles or manuscripts, and NIH should work with the U. S. Repository Network to encourage investigators to utilize options that are interoperable and free to use for deposit. For example, it would be great if researchers could deposit in one repository such as PMC through the NIHMS and have a way to also deposit the same material in the repository of their home institution. This allows universities to highlight and provide access to their organization and communities and allows researchers to display

their impact more effectively. Adding this secondary path for discovery also improves opportunities for access both by researchers and members of the public.

Finally, equitable publishing considerations will require that the NIH work with the higher education community to align research assessment and career advancement incentives to support scientific channels that actively promote equity in publication opportunities.

2. Steps for improving equity in access and accessibility of publications.

To fulfill the reusability requirement, all publications resulting from NIH-funded research should carry open licenses, and NIH or authors should explicitly retain the rights needed to authorize those open licenses. As part of this, NIH should offer clear language that investigators can use to specifically retain rights to make their final peer-reviewed manuscript freely available and fully reusable post-publication in PMC without an embargo period. Placing a creative commons attribution-only license or its functional equivalent on a publication is the best way to ensure that publications can be freely accessed and fully reused.

As part of the grant development process, NIH should provide guidance for researchers on budgeting for publication costs, though we recognize that this will be highly variable across disciplines and programs. It is also advised that NIH have a cap on the amount that can be paid towards APC funds. Publishers' APC costs are increasing without added value to the services they provide. They will continue to increase their costs unless a cap is put on how much can be charged per article.

3. Methods for monitoring evolving costs and impacts on affected communities.

Models requiring authors to pay an Article Processing Charge (APC) fee for journal publication present significant publication barriers for most researchers. There is a significant risk that scholarly publishers will attempt to use the embargo removal to attempt to further extract increased funding from researchers seeking to comply. Publishers should be required to be transparent when charging hybrid OA fees that the researcher has the option to pay no fee in order to comply with the NIH Public Access Policy by submitting to PubMedCentral.

Additionally, the rising cost of APCs has already proven prohibitive to individuals and their institutions, resulting in fewer opportunities for publications and increasing disparities. Even this week colleagues such as the entire board of NeuroImage (an Elsevier journal) resigned over the high new publication fee. As research is already funded primarily by federal agencies and the majority of scholarly publishing labor including editing and peer review work is done on an unpaid volunteer basis or with modest stipends, the current practice of article processing fees on top of page fees and Other charges can only be seen as exploitative by the scholarly publishers.

Studies, such as Exploring the Hidden Impacts of Open Access Financing Mechanisms by AAAS, have documented that APC costs disproportionately affect younger researchers, female researchers, and those at less well-funded institutions. APCs also require a diversion of funds away from the research process; investigators often must use money originally intended for materials and equipment, supporting trainees, and professional development opportunities including presenting research results at conferences. This is in addition to the hundreds of millions of dollars annually spent by academic libraries attempting to provide and maintain access to subscription-based journals.

We recommend that the NIH monitor costs associated with APCs to ensure that federal research dollars are being spent as intended on research and that the costs of publishing are not creating arbitrary barriers to entry for researchers, and the ultimate availability of publishing opportunities for researchers at traditionally underrepresented institutions and in less-well-resourced disciplines. The NIH should monitor the cost of APCs levied on its investigators. Data collection on the amount spent to publish NIH-funded research regardless of the source would increase transparency and insight into how these fees affect various communities - including the potential impacts of publishing opportunities - on traditionally underrepresented institutions and in less-well-resourced disciplines.

4. Early input on considerations to increase findability and transparency of research.

The NIH should ensure that the results of NIH-funded research along with metadata containing information about who conducted the research, where it was done, and with what resources. This requires NIH to articulate clear expectations about the use of Persistent Identifiers (PIDs) throughout the research process. Where possible, NIH should explicitly name and require the use of existing external identifiers (DOIs for data sets, DMPs, and publications, ORCIDs for authors, RORs for institutions, etc.) along with continued requirements for internal identifiers (PMIDs, GeneBank Accession numbers, etc.).

Similar identifiers are required to be used by all federal agencies as a result of the OSTP Memorandum. The NIH should coordinate its efforts with Other participants in interagency working groups, including the National Science and Technology Council's (NSTC) Subcommittee on Open Science, to identify best practices and potential standards and announce these as soon as possible to allow institutions to advise researchers. NIH should also consider collaboration with a standards body, such as the National Information Standards Organization (NISO), to help to begin to develop a set of standards and framework for a national PIDs strategy to facilitate smooth implementation. NIH should consider mechanisms for increasing the findability and transparency of research, including exploring the use of the DOI system to overlay NIH's current unique identifiers for awards, and current best practices for assigning PIDs and collecting metadata for articles, clinical trials, and genetic sequences.

We appreciate that the NIH has recently implemented the new Data Management and Sharing Policy, however, we have remaining concerns about its impact on researchers and whether it will be sufficient guidance for researchers to be able to meet the goals stated in the OSTP memo.

There are several areas where the NIH and the DMSP implementation team have failed to provide requested guidance including providing a recommended minimum duration for data retention, have not yet addressed the challenges of the need for controlled data repositories, and have not yet made a public statement about managing intellectual property rights alongside meeting data sharing goals.

In regards to the duration of data preservation, the policy guides researchers to keep data as long as is appropriate or necessary. However, this does not provide a preservation baseline. As a result, it is difficult for researchers and institutions to appropriately budget for retaining and managing data, which may further compound inequities for smaller grants or institutions that are unable to provide local repositories. We recommend that the NIH establish a standard minimum timeline for preservation and collaborate with professional associations to identify best practices for data retention standards that address the complexity of data captured across the institutes and centers.

The DMSP implementation team has repeatedly touted the availability of NIH repositories and generalist repositories as mechanisms for researchers to use when planning to share their data. While these are a solution for very specific grant proposals, these resources cannot meet the general broad need for data sharing as required by the data policy. This can be seen when reviewing the NIH repositories in that many of them are not currently accepting new data. Further, the reliance on generalist repositories does not address the significant challenge of providing access to sensitive and controlled data. Instead, it has the potential to create a two-tier system for researchers whose institutions do not have a data repository and who must therefore use vendor-controlled generalist repositories and runs the risk of researchers inadvertently exposing sensitive data in order to meet data sharing expectations. We encourage the NIH to invest in and support the development of non-profit databases and repositories that will not only meet the generalist repository initiative but also engage further with the challenges related to controlled data access and preserving the privacy of sensitive data that we get from research participants.

We wish to ensure that data can be shared in a controlled fashion that does not inadvertently create further situations of harm where minority groups' data sets are mined and Otherwise used against their wishes in order to pursue research interests. As a minority-serving institution, we have encountered frequently challenges with interest in extracting data and the value of it from the individuals we serve without mechanisms that allow those communities to actively participate in the work that is being done and without returning specific value to those communities either in the forms of knowledge, education, job force training, or Other active development. This additionally runs the risk of becoming a target for vendors who seek to gatekeep data or charge exorbitant fees to manage access, further exacerbating data-sharing inequities.

The storage and preservation issues in particular must be addressed in order to ensure equitable participation in open sharing opportunities that do not further replicate historical inequities in what data can be retained and shared. This is of critical importance to fund funding for women and minority health programs and we encourage the reevaluation and the reallocation of funding to these programs to ensure access.

Email: pearsong@uic.edu

Submit date: 4/21/2023

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

Name: Matthew Thakur

Name of Organization: European Bioinformatics Institute EMBL-EBI

Type of Organization: Nonprofit research organization

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

On Section III.D.1. NIH 'will continue to allow reasonable publication costs for all NIH-supported or authored scholarly publications consistent with current policy and guidance' - this section of the policy should state a more explicit intent to learn from, and in some areas align with, similar open access mandates of funders elsewhere, as in the case of the EU's Plan S.

2. Steps for improving equity in access and accessibility of publications.

On Section III.B.1. - this gives NIH's intent to 'continue the current practice of making manuscript files and Other article files submitted with permissive licenses available...'. To maximise the utility of manuscript files, can the use of permissive licenses also be mandated such that all of these files become machine readable? Guidance on licenses that reach the required level of permissiveness should be specified or even mandated (similarly to how explicit guidance is suggested below for preferred repositories)

3. Methods for monitoring evolving costs and impacts on affected communities.

On Section III.D.2. 'monitoring trends in publication fees', as all funders with open access mandates are likely to require or indeed already be carrying out similar monitoring, the policy should state a more explicit intent to coordinate with Other funders eg EU Plan S. Beyond monitoring, early indication of how NIH plans to ensure that publication costs remain reasonable would be helpful.

4. Early input on considerations to increase findability and transparency of research.

The decision to remove embargos is a welcome one, and consistent with broader trends in scientific publishing which have accelerated in recent years eg the exponentially growing popularity of preprints.

On the requirement for DMS Plans - is the aim simply to cue researchers to spend more time planning their data management - or is the intent for DMS plans to become useful digital objects in their own right? Making these openly accessible, machine readable and, if possible, linked to a subsequent review of their implementation and any outputs would provide greater transparency and a means of monitoring how the realisation of data sharing measures up to intent at the award stage.

A big step forward would be the requirement to submit, at project end, together with the financial report, a DMS Report, which provides a point-by-point report on the intentions stated in the DMS Plan.

On 'Maximising Sharing' - is the intent to maximise the likely utility of the shared data to Other researchers, or to maximise its findability - or both? If the intent is that data should be both findable and

of greatest utility, this would place a greater obligation on investigators, but also align more with the desired impact of data sharing.

On Section IIA (Scientific data) the current proposals use 'use of PIDs and metadata' as a catch all for many types of research outputs which funders may need to make more findable. The policy is explicit about which outputs are exempt from the expectation for open sharing. Among these exemptions, laboratory specimens stand out as a data type which does currently have mechanisms in operation for findability/PIDs (eg through the BioSamples database), which suggests that an exemption may be unnecessary. Following the exemptions, similarly explicit expectations should be stated about the outputs which are to be shared - for example, whether making data alone findable/accessible is sufficient, or whether Other outputs such as software and beyond-preliminary analysis should also be made findable. Some of these output types have relatively well developed systems for persistent identifiers eg accessions and DOIs for datasets. Others are further behind eg software. The roadmap and lessons learned from institutions' experiences with making each findable are likely to be very different.

On Section II.D - guidance of repositories used - the policy should take account of already existing systems for recognising databases of greatest value to the research community - such as the Core Trust Seal, Global Core Biodata Resource and ELIXIR Core Data Resource systems - rather than attempting to invent any new accreditation system.

On Section IV.A - metadata associated with data - in addition to the minimum metadata fields listed, the point on 'referencing digital persistent identifiers' should be developed further to highlight opportunities to build on existing PIDs such as ORCID for researchers, ROR IDs for research organizations, Accessions and Data DOIs for research data.

On Section IV.B. "Instruct federally funded researchers to obtain a digital persistent identifier..." While a requirement for individuals receiving NIH support to have Open Researcher and Contributor Identifiers (ORCID iDs) is laudable, additional policies may be required to ensure these are then used and linked to subsequent outputs, in order for the benefits of the PID to be realised.

The FAQ notes state that preprints are excluded from the public access policy - yet the data preprints refer to is included as per Section II.C. This seems rather inconsistent - does this not imply that the preprint based on the data should also be within scope for public access?

Email: mthakur@ebi.ac.uk

Submit date: 4/21/2023

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

Name: Kevin Wilson

Name of Organization: The American Society for Cell Biology

Type of Organization: Professional org association

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/ASCB-letter-to-Larry-Tabek-re-Open-Access-Policy.pdf>

Description: ASCB position on NIH Open Access policy

Email: kwilson@ascb.org

Submit date: 4/21/2023

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

Name: Casey Rojas

Name of Organization: Massachusetts Medical Society - New England Journal of Medicine (NEJM)

Type of Organization: Not applicable

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The New England Journal of Medicine (NEJM) is the most widely read, cited, and influential general medical journal and website in the world and the oldest continuously published medical periodical. Widely recognized as the gold standard for current research and best practices in medicine, NEJM publishes peer-reviewed research and interactive clinical content for physicians, educators, and the global medical community. Our mission is to bring health care professionals the most reliable biomedical research and clinical information to inform their practice and improve outcomes for patients. NEJM is a publication of NEJM Group, a division of the Massachusetts Medical Society, a non-profit corporation.

Thank you for the opportunity to respond.

We are writing to express our concern over the NIH implementation of policies in response to the 2022 Office of Science and Technology Policy (OSTP) Public Access Memorandum. We call on the NIH to remain neutral with respect to publishing business models, honor copyright, and not place additional burdens on researchers and small society publishers by mandating license requirements with overly broad reuse rights.

Patient-care professionals and the patients they serve rely on medical journal content that is vetted by medical experts, peer reviewed, revised, edited, and enhanced through the editorial process to provide them with results that are appropriately measured for making evidence-based clinical decisions. Each year, our editors filter through over 5,000 research manuscripts submitted and select only the best. Our editors are experts in their fields, most of whom are practicing clinicians, who work to ensure that conclusions are not overstated or misleading and that results are put into the proper context for treating patients. We strive to uphold standards around rigor and reproducibility, and we are investing in programs to improve equity not only in research but also in patient care and outcomes. Considering the medical misinformation that has spread over the last several years, the need for top quality and highly credible medical information has become even more apparent.

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 becomes a published article. Our reader-pays subscription model 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 NEJM meets the need of physicians and health care professionals for trusted, rigorously peer-reviewed research and review articles.

We fully believe the reader-pays business model is the best approach to serve our readers and their patients and to sustain our publication. The reader pays model maintains editorial independence and

protects against bias. Furthermore, this model also spreads the costs of publishing across many institutions and large number of readers rather than smaller number of authors.

We caution the NIH against requiring a CC-BY license, which by permitting derivative works allows for the misrepresentation and misuse of research results, increasing the risk for patient harm and leading to greater mistrust in science. In addition, forcing a specific CC-BY or similar requirement will severely diminish our ability to recover the substantial investments made in ensuring that NEJM articles meet our exacting quality standards and can be trusted by medical professionals to bring them the most impactful advancements in clinical care. We ask that the NIH policy refrain from requiring one size fits all licenses that permit broad commercial and derivative reuse rights.

Our reader-pays subscription model is the most equitable approach for ensuring that all authors have the opportunity to publish in our pages regardless of their financial means. And we firmly believe that authors should be able to choose where to publish.

We acknowledge that Other business models may work for Other publishers. However, we remain committed to a subscription-based publishing model, as that best fits the standards that we have set for ourselves and that our readers expect of NEJM. Further, for the reasons mentioned above, we believe that mandating a single approach to publishing — particularly one that favors high volume, rapid publication of medical research with less rigorous or no peer-review — will not result in a more equitable publishing ecosystem or better care for patients.

Thank you for this opportunity to provide information relevant to this important issue. NEJM looks forward to staying engaged and stands ready to assist in any way that we may be of assistance. Please feel free to reach out to Casey Rojas, Federal Relations and Health Equity Manager at crojas@mms.org with any questions or to continue this discussion.

- 2. Steps for improving equity in access and accessibility of publications.**
- 3. Methods for monitoring evolving costs and impacts on affected communities.**
- 4. Early input on considerations to increase findability and transparency of research.**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/NIH-RFI-submission-21Apr2023_.pdf

Email: crojas@mms.org

Submit date: 4/21/2023

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

Name: Shawna Sadler

Name of Organization: ORCID

Type of Organization: Nonprofit research organization

Role: Institutional official

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/ORCID_Response_to_NIH-Signed.pdf

Email: s.sadler@orcid.org

Submit date: 4/21/2023

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

Name of Organization: Association of American Medical Colleges

Type of Organization: Professional org association

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

As NIH is well aware, the existence of multiple publishing models as well as varied journal policies create inherent difficulties for researchers as they seek publication opportunities, navigate the processes for making articles publicly available, and access scholarly publications. The current system of publication and its increasing use of article processing charges can disparately impact early-career scientists and researchers in lower-resourced institutions or underfunded disciplines.

We appreciate the intent of NIH to implement an approach to public access which “maintains the flexibility of NIH-supported researchers to publish in the journal of their choice and submit the peer-reviewed manuscript, regardless of whether or not the journal uses an open access model, a subscription model of publishing, or Other publication model.” In order to achieve this goal, we request that NIH state clearly in the public access plan that researchers will be in full compliance with the requirement to make publications freely available and publicly accessible by depositing the peer-reviewed manuscript into PubMed Central (PMC) and emphasize that this is an option which is available to researchers at no charge. Communicating this detail is an essential element so that researchers understand that NIH is not requiring that grantees publish in a journal that requires authors to pay a fee to enable access to their work, which may exacerbate disparities in publication opportunities. This point is particularly important given the diversity of language and statements used in publisher policies for open access and public access. While NIH does not set publisher policies, we believe there is value to the agency identifying and publicly noting those publishers and journals, such as JAMA and Science, with clear policies that support the NIH public access plan by allowing immediate deposition of the author-accepted manuscript into a public repository. Finally, we also request that information on PMC submission methods, as well as the Public Access Compliance Monitor, be clearly linked in the plan to assist institutions and researchers with this requirement.

AAMC appreciates the clear assertion that “NIH reinforces that NIH-supported authors should retain rights to the final peer-reviewed manuscript, regardless of the pathway to publication.” We ask that proposed language for rights retention be included in the draft plan and released for public comment. We also refer NIH to the language developed by many funders within cOAlition S for researchers to submit to publishers along with their manuscript. The suggested language from NIH will not only be critical for researchers to be able to submit their manuscript to PMC, but also for use and re-use of information contained in and across publications, an essential component to maximize the benefit of the growing number of publications available on PMC.

2. Steps for improving equity in access and accessibility of publications.

AAMC believes that access to publications by diverse communities of users, including researchers, clinicians and public health officials, students and educators, and patients and Other members of the public, should be the driving goal of the public access plan, and considered in any decisions the NIH

makes. We recognize the historical inequity in access to publications, especially for individuals not associated with a well-resourced institution.

We appreciate the current practice of making scholarly publications available in accessible and machine-readable formats through PMC. We encourage NIH to continue to work with the broader community on improving article accessibility as well as the PMC interface, particularly to ensure that standards adapt to the latest technology, and also that the agency consider the many factors and broad definition of disability which may impact accessibility, to include physical, sensory, learning, psychological, and chronic health conditions.

AAMC notes the NIH assertion it will “provide additional educational materials and resources to assist the investigator community in improving the accessibility of articles.” We request that any resources and educational materials regarding accessibility be directly linked in the final policy and easily findable by NIH grantees.

3. Methods for monitoring evolving costs and impacts on affected communities.

We believe that NIH is uniquely positioned to understand the nature and amounts of publications costs for NIH-funded researchers. We encourage NIH to develop a systematic effort to collect this information and to understand how these costs impact grant budgets and may differentially affect under resourced investigators and institutions. Given the different mechanisms for funding publication costs (grant-based, departmental, library funds, etc.), we suggest that NIH look beyond the grant budget line item for publications to capture publication expenses more fully. Potential methods for capturing this information include surveying researchers at closeout for additional information on publication costs or through a commissioned study. We also ask that NIH commit to sharing the findings of this research back out to the research community.

As stated in the plan, NIH “proposes to continue to monitor trends in publication fees and policies to ensure that they remain reasonable and do not serve as an impediment to publishing by researchers from limited-resourced institutions or under-represented groups.” While AAMC supports the efforts to understand publication costs, this statement does not adequately assure the research community that the NIH will be in a position to address the fees and policies that may prevent some researchers from publishing in certain journals. There is a substantial gap between monitoring costs and ensuring that they remain reasonable. This cannot be accomplished without collaborating and reaching consensus across a wide range of publishers, an undertaking which has proved challenging. We urge NIH to provide additional information regarding the actions that NIH is able to take and would pursue in the case that publication costs are found to serve as an impediment to publishing.

Although NIH has made efforts to uncouple compliance with the public access plan from any particular publication model, we note that the plan, along with many similar changes and requirements from Other funders, will have an upstream impact on journals, whether owned by major publishers or small societies. Changes to how articles are accessed will feed into an ongoing and important conversation about the sustainability of current models of publication and how journals are funded, that will have broader consequences than what is discussed in this RFI. Academic researchers are impacted by the publishing process at multiple steps, not only by their ability to submit to certain journals and access articles, but also the entrenched role that publications in high-impact journals, long held as the gold standard in quality, have in determining tenure and promotion.

Finally, we appreciate NIH's intent to develop supplemental information that elaborates on and clarifies allowable costs for publication and believe this would be most useful for the grantee community if developed and released along with the draft plan to allow time for feedback. We also note the longstanding issue that current publication timelines often do not fit within the closeout period for an NIH grant and urge the agency to take this into consideration.

4. Early input on considerations to increase findability and transparency of research.

The AAMC strongly supports the use of persistent identifiers (PIDs) and metadata, not only to increase the findability of research, but also to link researchers to their research outputs, whether this be publications, data, code, or any Other products. AAMC supports a requirement for NIH grantees to have an ORCID ID, as well as DOIs for publications and data resulting from NIH-funded research. As the agency develops these policies, we refer NIH to the considerations for PID adoption from our fellow higher education organizations. Additionally, as AAMC has long been invested in tracking trainee career outcomes, we support the requirement for individuals receiving research training, fellowship, research education, and career development awards to also have an ORCID ID.

As NIH notes, PIDs are most useful when they can be linked in standardized ways, and we encourage NIH to look not only to Other federal agencies, but also to community organizations, institutions, and societies. Cross-stakeholder groups such as the Research Data Alliance and FORCE11 have spent years developing suggested protocols and standards for both PIDs and metadata that align with the FAIR and TRUST principles. We also emphasize that being able to find and use the shared data resulting from the NIH Data Management and Sharing Policy will require significant investment in infrastructure and agency guidance on metadata standards. AAMC recommends that PIDs for research outputs can be easily linked and found when searching grants on NIH RePORTER.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/AAMC-Comments-on-NIH-NOT-OD-23-091.pdf>

Email: adev@aamc.org

Submit date: 4/21/2023

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

Name: Caroline Trupp Gil

Name of Organization: American Chemical Society

Type of Organization: Professional org association

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The American Chemical Society (ACS) is a congressionally chartered non-for-profit organization and the world's largest scientific society with more than 173,000 individuals in our global membership community across 140 countries. ACS advances knowledge and research through scholarly publishing, scientific conferences, information resources for education and business, and professional development efforts.

As a socially responsible organization deeply rooted in the scholarly community, we share NIH's goal to ensure equity in publication opportunities. The best way to achieve this goal is to ensure that all stakeholders in the process of transitioning to immediate open access, e.g., researchers, funders, and institutions, understand that every method of open access publication has a cost that must be funded and budgeted - and that competition and diversity in publication outlets is the best way to maximize the efficiency, and therefore the cost, of those outlets.

Researchers need specific guidance on planning for and budgeting any new requirements: including budgeting during the grant application process to account for anticipated publications costs. We suggest that NIH work with organizations like ACS to help develop budgeting guidance. Encouragement and education should be provided at the start of the grant process to make sure that appropriate planning takes place. For recent open science examples, the NIH Data Guidance (which explicitly directs grantees to budget for data sharing and curation costs) and NASA SPD-41a (which encourages researchers to fund open access articles) could be used as models.

Of the different methods that can ensure equity at scale in publication opportunities, direct funder support for publishing, i.e., Gold Open Access (Gold OA), is the most financially sustainable. This is because researchers can be secure in the knowledge that they have the funds needed to support publication in the outlet of their choice and the outlets themselves have a reliable source of funding with which to continue their operations and ensure the integrity of the content published. Gold OA at the ACS, as with many Other society publishers, is a dynamic and customizable option for researchers to enable immediate OA. We have a robust waiver and discount program that helps researchers from low- and middle-income countries to publish at highly discounted rates; currently a minimum of 75% discount, rising to a complete waiver for low-income countries.

Immediate access to an accepted manuscript version of an article, i.e., immediate Green OA, has not proven to work at scale, even if it may work for a very small number of publishers or disciplines. It often appears cost free to researchers and Others, but in fact it is reliant on subscriptions to cover the cost of peer review and publication. A widespread use of this method, in conjunction with tools such as

Unsub.org that explicitly encourages institutions to cancel subscriptions where alternative free versions of articles are accessible, threatens the viability of the subscription funding on which Green OA methods of providing public access rely. The loss of subscription funding in this context, means depleted resources available for publications to ensure the quality and integrity of the scientific record. This will directly result in erosion of public trust in science and a dampening effect on innovation, job growth, and scientific progress. It will also increase the likelihood that important publication outlets will cease operations due to lack of funds, creating new barriers to access and equity in publication opportunities. Smaller and not-for-profit publishers, including those associated with learned societies, are most likely to be at risk from this practice that could easily result in increased market consolidation. This, in turn, is likely to reduce author choice and market competition, stifling innovation and undermining equity in publication opportunities.

We recommend that NIH avoid creating these barriers, especially for scientists from traditionally marginalized communities, as well as early career researchers, by ensuring that all its grantees have the funding support necessary to enable their research and choose the publishing option that best suits their needs.

We encourage NIH to read and reference the position statements (<https://www.stm-assoc.org/stm-oa-position/>) by STM on this subject, representing much of the publishing industry.

2. Steps for improving equity in access and accessibility of publications.

NIH can improve equity in access and accessibility of publications by helping to educate researchers that the publication cost of immediate open access is as much a part of the dissemination of research reports as attendance at scientific conferences and gatherings. They can achieve this by ensuring that adequate funds are available to researchers to enable them to support immediate open access and by advocating for the long-term funding support from Congress needed to enable equity in access and accessibility. NIH is also encouraged to initiate public-private partnerships with organizations like ACS that provide discovery tools widely used by scientists globally to seamlessly identify research reports, data, and analyses that fuel innovation, economic prosperity, and scientific progress.

Of the different methods designed to achieve equity at scale in access, Gold OA has the greatest chance of success and NIH initiatives such as the Cancer Moonshot and Helping to End Addiction Long-term (HEAL) Initiative are both examples of programs that provide financial support to achieve their OA goals. Gold Open Access at the ACS, as with many Other society publishers, is a dynamic and customizable option for researchers to enable immediate OA. We have a robust waiver and discount program that helps researchers from low- and middle-income countries to publish at highly discounted rates; currently a minimum of 75% discount, rising to a complete waiver for low-income countries. Gold OA is a powerful model for enabling universal access to the most authoritative publications reporting on the results of scientific research, the Version of Record (VoR). The VoR is the authoritative version for researchers and the public, and is more cited and used, and garners more attention and trust than Other versions. It can link bi-directionally to research objects like data and code, is continually updated, and is hosted on the publisher's platform where it can be integrated with Other relevant content and analytical tools.

We are aware of NIH's desire to be business model agnostic and therefore caution against the promotion of immediate access to accepted manuscript versions of an article, i.e., immediate Green OA,

especially through the so-called “rights retention strategy” (RRS) that some have observed in the NIH plan, e.g., at section III.C.1. Immediate Green OA has not proven to work at scale, even if it may work for a very small number of publishers or disciplines. It often appears cost free to researchers and Others, but in fact it is reliant on subscriptions to cover the cost of peer review and publication. A widespread use of this method, in conjunction with tools such as Unsub.org that explicitly encourages institutions to cancel subscriptions where alternative free versions of articles are accessible, threatens the viability of the subscription funding on which Green OA methods of providing public access rely. The loss of subscription funding in this context, means depleted resources available for publications to ensure the quality and integrity of the scientific record. This will directly result in erosion of public trust in science and a dampening effect on innovation, job growth, and scientific progress. It will also increase the likelihood that important publication outlets will cease operations due to lack of funds, creating new barriers to access and equity in publication opportunities. Smaller and not-for-profit publishers, including those associated with learned societies, are most likely to be at risk from this practice that could easily result in increased market consolidation. This, in turn, is likely to reduce author choice and market competition, stifling innovation and undermining equity in publication opportunities.

We recommend that NIH avoid creating these barriers, especially for scientists from traditionally marginalized communities, as well as early career researchers, by ensuring that all its grantees have the funding support necessary to enable their research and choose the publishing option that best suits their needs. We encourage NIH to read and reference the position statements (<https://www.stm-assoc.org/stm-oa-position/>) by STM on this subject, representing much of the publishing industry.

Immediate Green OA also contributes to version-control issues and potential confusion because, although there can be important and even critical differences in the text, an accepted manuscript and a VoR can look the same in their raw versions - implying trust when this could be misplaced. It risks slowing the move towards full open access because it is not a publishing model in itself but is primarily supported via subscriptions which leave the most valuable version of an article, the VoR, subject to access controls. Finally, the “rights retention strategy” approach to immediate Green OA restricts rather than expands a scientist’s ability to choose how best to maximize the benefits of their work. For these reasons, immediate Green OA cannot deliver on the promise of an easily accessible, navigable, and interconnected Open Research ecosystem.

ACS instead recommends that researchers be allowed to publish under rights consistent with their vision and needs, including non-commercial, non-derivative licenses. We support access methods that are most consistent with academic freedom of expression globally based upon the responsible exercise of independent editorial control.

3. Methods for monitoring evolving costs and impacts on affected communities.

In our answer to question one, we addressed how NIH can best ensure equity in publication opportunities. Here we will respond to the question of monitoring publication fees. The simplest and most effective way for NIH to keep itself informed about publication fees is to partner with publishers and organizations like ACS whose fees are publicly posted on their websites. This practice would not only ensure transparency around costs, but also enable NIH to confirm that grantees are paying a fair market price for the services and value provided. We note that cost structures are very different for different organizations - medicine, physical sciences, social sciences, and humanities - and for different types of journals based on selectivity, services, technology, and Other features. A diverse, financially

sustainable, and robust publishing system which provides authors with broad choice is the most effective way to control cost. We caution against inflexible cost caps which will likely drive existing industry trends toward publisher consolidation and volume-based models which compromise integrity, quality, and author choice.

One constant, regardless of the field of research endeavor, is that rigorous publications are essential to support scientific communication and public trust in science. Researchers and policy makers must be able to rely on the integrity of the scientific publications that inform their decisions. The public, in turn, must be able to feel confident that practitioners' and policymakers' scientific and technical decisions are grounded in accurate information. Organizations like ACS are deeply committed to supporting this integrity and trust in science by building and maintaining infrastructure that enables the widespread production and communication of validated and reliable reports on scientific research. Among Other things, this involves creating scientific journals and staffing their editorial boards with experts that read and evaluate thousands of submitted manuscripts for quality and relevance. ACS also spends significant resources to ensure the integrity of journal articles by verifying author and content integrity, assessing articles for ethical considerations, managing and underscoring authors' potential conflicts of interest, and conducting plagiarism, ghost and gift authorship checks to combat paper mills, image manipulation, and the use of artificial intelligence tools like ChatGPT in inappropriate ways.

Our investments in support of scientific communication do not end when a peer reviewed article is published. We update articles for correction and addenda, update links, and conduct ongoing plagiarism and copyright protection to safeguard the integrity of the work and ensure articles are not modified or pirated in misleading and harmful ways. Upholding the version of record and providing the clarity necessary to easily distinguish between the version of record and earlier, less reliable versions of an article, is a key principle of scientific integrity. In order to build trust in science, readers must be able to easily identify and discover trusted peer reviewed content. To facilitate this process, we assign digital identifiers, provide metadata, conduct search engine optimization, track citations and Other important metrics, and submit articles to abstracting, indexing, and discovery services. These valuable services support scientific integrity by pointing readers to the highest quality scientific publications and data.

At a time when concerns around misinformation — including on critical issues of science and medicine — have become a national priority, there is an urgent need for stakeholders that support scientific integrity to work together and uphold the role of objective, trusted information in a democratic society. Therefore, it is essential that federal policies related to publications ensure that scientists and publishers can continue producing and disseminating the trusted, peer reviewed, VoR of scientific articles by providing sufficient funding for researchers who choose to publish OA to support investments in publishing their works in high-quality journals that uphold scientific integrity.

4. Early input on considerations to increase findability and transparency of research.

ACS is a participant in the Open Research Funders Group's persistent identifiers (PIDs) discussions. We regularly engage with developments around new PIDs and support best practice in ensuring the accurate and enduring tracking of all relevant aspects of the research cycle. It may be helpful to NIH to know how we are taking steps to increase the findability and transparency of research data, perhaps the most challenging object of PID activity. We have data policies and guidelines, consistent with principles of open science, to ensure results reported in ACS journals are verifiable, reproducible, and easily accessible to researchers. The ACS Research Data Policy (https://publish.acs.org/publish/data_policy)

provides best practice recommendations for data citation, data availability statements, and the use of appropriate data repositories. An evolving set of Data Guidelines by sub-field and data-type provides authors with specific instructions on how to make data available and comply with discipline-specific standards.

We are members of the Research Data Alliance (<https://rd-alliance.org/>), a community-driven initiative by the European Commission, the National Science Foundation and National Institute of Standards and Technology, and Australia's Department of Innovation to build the social and technical infrastructure to enable open sharing and re-use of data. We have endorsed the Joint Declaration of the Data Citation Principles (<https://force11.org/info/joint-declaration-of-data-citation-principles-final/>) that provides a set of guiding principles for data within scholarly literature, another dataset, or any other research object. ACS Publications has also signed the Declaration on Research Assessment (DORA - <https://sfedora.org/>) and made citation data for all ACS journals openly available.

Finally, we have created the ACS Research Data Center (<https://acsopscience.org/open-science/acs-research-data-center/>) as part of ACS Publications evolution, experimentation, and innovation with new models of OA. It is designed to help researchers forge new partnerships, improve the visibility of their research findings, and facilitate the means by which they can disseminate their work to a wider audience.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/ACS-Supplemental-comments-2023-04-20-NIH.pdf>

Description: Additional comments not included in the answers to the four questions posed in the RFI.

Email: c_truppgil@acs.org

Submit date: 4/21/2023

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

Name: Josh Caplan

Name of Organization: AcademyHealth

Type of Organization: Nonprofit research organization

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/AcademyHealth-response-to-NIH-on-Public-Access-Plan.pdf>

Email: josh.caplan@academyhealth.org

Submit date: 4/21/2023

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

Name: Michael Boock

Name of Organization: Oregon State University Libraries and Press

Type of Organization: University

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Oregon State University Libraries and Press (OSU) is writing to provide our input on the Plan to Enhance Public Access to the Results of NIH-Supported Research. OSU had more than \$471 million in competitive research grants and contracts in 2022 and has an R1 Carnegie Classification. It is one of only two universities in the U.S. with Land-, Sea-, Space- and Sun-Grant designations and is one of a select group of 28 universities in the United States and its territories to earn the community engagement classification in 2020 and also hold a “very high research activity” classification from the Carnegie Foundation for the Advancement of Teaching. As such, the institution and its libraries place a high value on the importance of open access to research: through a faculty-led University Open Access Policy passed in 2013, providing open access to the University’s corpus of extension and experiment station publications, and open access to every thesis and dissertation ever produced by OSU students. We commend the NIH for taking important steps toward ensuring equitable access to the research it funds in the form of research articles and datasets as well as equity in publication opportunities.

The OSTP memo is deliberately “neutral” on the topic of business models for scholarly publishing. But, of course, we know that neutrality favors those who benefit from existing systems. We believe that federal agencies need to make a clear and unambiguous statement in their implementation plans that there is a pathway for researchers to comply with these mandates without paying Article Processing Charges (APCs). It is important that the NIH does not inadvertently entrench the APC system by remaining neutral on it.

We strongly support the proven, most-equitable, manuscript deposit method of policy conformance that permits authors to publish articles in whatever journals they choose so long as they deposit author-accepted manuscript versions to PubMed Central (PMC) or a trusted institutional repository that is able to share requisite metadata with PMC. Our library agrees wholeheartedly with the IVY Plus Libraries letter sent to the White House Office of Science & Technology Policy (<https://libraries.mit.edu/news/libraries-support-3/34036/>) in their rejection of an article processing charge model that requires direct payment of APCs from authors, libraries, and universities to ensure open access. This model goes against the OSTP goal of providing an equitable system of publication by disadvantaging those who are not fortunate enough to be associated with institutions of higher education that can afford to pay such fees. The model also disadvantages those who do not receive adequate funding to pay such fees.

If the NIH does endorse or choose a gold OA model, we encourage the NIH, or the NIH in collaboration with Other federal agencies, to conduct an independent analysis to determine what a transparent price, based on actual value delivered, would be for an APC. This cannot be left to the publishers to determine.

Their behavior to date shows that they will prioritize neither transparency nor equity in their price-setting. Is a reasonable price \$995 (PeerJ), \$2100-6500 (PLOS), or \$11,000 (Springer Nature)? What does the research tell us? Why does it vary by discipline/publisher/journal? If an APC-based model is endorsed, it must be made clear that it is not an end goal, but a transitional step towards a more sustainable journal publishing system.

2. Steps for improving equity in access and accessibility of publications.

It appears that the current NIH Public Access Plan (III.C.2) argues for the equivalent of CC-BY-NC rather than the equivalent of CC-BY. We do not understand the restriction on commercial reuse. Such a restriction may have the effect of restricting access to publications (and research data) by not allowing commercial and Other interests to create and make available value-added discovery and access tools that include ads.

We also encourage the NIH to require authors to provide a structured abstract for all research articles that can be understood by citizens with less education in the field of study. At a minimum, this might consist of context/background, objectives, design, setting, participants, interventions, main outcome measures, results, and conclusions.

3. Methods for monitoring evolving costs and impacts on affected communities.

4. Early input on considerations to increase findability and transparency of research.

Consider the adoption of the Library of Congress Classification (LCC) system as a means of collocating funded research by subject. The LCC system is a widely used classification scheme in academic and research libraries in the United States and many Other countries that assigns a unique call number to an item based on the subject matter of the item. The assignment of a LCC to research outputs helps users easily locate items on particular topics and browse related materials on the topic. Classification systems can be an important component of artificial intelligence and machine learning algorithms that categorize or group data into specific classes or categories based on their attributes, characteristics, or features.

Email: michael.boock@oregonstate.edu

Submit date: 4/21/2023

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

Name: Meagan Phelan

Name of Organization: American Association for the Advancement of Science

Type of Organization: Nonprofit research organization

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

AAAS applauds the NIH for the leadership it has assumed in emphasizing equity as a key consideration in public access policy development. Through experimentation and analysis, AAAS has found that vast differences exist in how different open access models impact the ability and equity of opportunity for scientists aiming to publish their work for wide dissemination. Some models of open access lock in place and exacerbate existing inequities in the scientific enterprise. Finding the right balance between enabling access to published work and publishing opportunity will be crucial as NIH and Other federal agencies move forward with revision of their public access policies. AAAS further wishes to express support for NIH's plan to allow for submission of "the final peer-reviewed manuscript to the NIHMS System at the time of acceptance for publication in a journal" as a means of complying with the Public Access Policy. Allowing for submission of this version of the manuscript is critical to mitigate issues associated with author- and institution-borne costs for publishing open access, including article processing charges (APCs).

To strengthen its policy as relates to equity, AAAS recommends that NIH explicitly define and recognize the "author accepted manuscript" as the version that should be submitted to the NIHMS system, to create public access. This would directly address growing challenges that alternative public access models - for which authors pay to make their work open - create for early-career scientists, scientists at smaller schools, and scientists in underfunded disciplines, among Others. It would help to ensure a diverse universe of scientists can publish important work, regardless of their economic circumstances.

This step would also require the agency to more directly consider the role of business models - some of which do not foster inclusivity - in its efforts around public access. While NIH's Plan for Scholarly Publications does not address business models Other than to state that "NIH does not propose requiring authors to publish in any particular type of journal or journal with any specific type of business model (e.g., subscription model, open access model)," it is essential to recognize that if journal policies do not allow for deposition of the author-accepted manuscript in the NIHMS system at the time of publication, this policy will limit authors' publishing options - driving scientists to publish in open access journals to which they must pay an APC (fees for which only stand to increase as the publishing market consolidates) or in journals with which their institution has a transformative agreement. This may temporarily work well for senior scientists who are (routinely) well-funded, tenured, and overwhelmingly male and white, but it will freeze in place and exacerbate inequities for many Others, including a new generation of scientists. By channeling researchers to a limited number of commercial publishers, it will also drive further consolidation in a market that is already heavily concentrated, and where APC fees will only increase with time. The resultant heavy cost burden will be borne not only by

researchers and their institutions, including at a time when institutional research budgets are increasingly challenged, but by funders of research (including taxpayers). We urge the agency to proactively communicate with publishers about their policies to ensure they allow authors to deposit the AAM in the NIHMS system. 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, as addressed in the response to the third question within this RFI, AAAS also believes that monitoring implementation of changes to the public access policy and publishing costs paid by researchers and institutions will be critical to ensuring that these changes do not create new inequities or reinforce existing ones. It may be valuable for NIH to conduct a survey, as AAAS did on a smaller scale in 2022 (<https://www.aaas.org/news/aaas-survey-many-researchers-face-difficulties-paying-open-access-fees>), and/or develop a public reporting scheme about scientist-borne publishing-associated costs and related tradeoffs.

2. Steps for improving equity in access and accessibility of publications.

AAAS supports open-research initiatives, including text and data mining, that use technology to meet the needs of researchers. However, appropriate limitations are important to ensure such offerings remain sustainable; we have seen some initiatives lead to unintended consequences when the necessary rights have not been secured to enable their sustainability. Given the fast pace of artificial intelligence development, it is critically important to monitor the creation and adoption of guidelines for tools that can be trained on full text journal articles, including for the purposes of replicating scholarly journal content, to ensure a focus on responsible and ethical development.

Science journal articles, and specifically the author accepted manuscript (AAM) versions of such articles, may be used for text and data mining by individuals and by nonprofit, noncommercial subscribing institutions. Sustainably increasing accessibility to publications via this route requires that publisher reuse policies are followed by federally funded researchers. AAAS encourages NIH to consider how adherence to related policies will be monitored and what administrative burdens this might create for researchers, institutions, and the agency. NIH should also endeavor to monitor how changes resulting from the open access policy, including a breadth of open license types, might facilitate and incentivize reuse that adversely impacts the integrity and accuracy of the downstream communication of research published by federally funded researchers.

Regarding Other avenues by which to improve accessibility to publications, including for people with disabilities, NIH may wish to consider implementing guidelines around adherence to the Web Content Accessibility Guidelines, with a concerted focus on making text and data available.

3. Methods for monitoring evolving costs and impacts on affected communities.

Careful and continued study of publication fees and policies will be essential for understanding the near- and long-term effects of changes in public access policies. Study of costs effects at the researcher, institution, and enterprise levels is needed. Adaptation of federal grant agreements to require reporting on the payment of publication fees and reliance on transformative agreements (in instances where authors avoid payment of a fee because their institution has a transformative agreement with their journal of choice) represents one logical approach to monitoring fees. AAAS also encourages NIH to

consider a study or studies that engage institutional leadership to estimate and report on publishing costs across institutions.

In addition to developing methods for monitoring costs, AAAS encourages NIH to develop and adopt a public reporting scheme to ensure visibility and transparency into publishing costs borne by scientists, their institutions, and ultimately the NIH. This will allow for future course correction.

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. Analysis and reporting should assess if and how changes in the Public Access Policy may affect the volume of research publications authored by scientists who are early career or are from smaller, lesser-funded, and historically underrepresented institutions, including Historically Black Colleges and Universities; Hispanic-Serving Institutions, EPSCoR, and Other Minority-Serving institutions; where researchers choose to publish; and potential variability in effects across different research disciplines including, but not limited to, the life sciences, physical sciences, social sciences, humanities, mathematics, and engineering.

4. Early input on considerations to increase findability and transparency of research.

Access and transparency are foremost considerations at AAAS, where our mission includes communicating science accurately, broadly, and in such a way to ensure the scientific community can reanalyze and reproduce new works. In recognition, AAAS supports the final peer-reviewed author-accepted version of a paper being broadly and immediately shared and the flexibility afforded by NIH's intention to accept the final peer-reviewed version of the article as a means of complying with its updated public access policy. At AAAS, however, we believe that publisher oversight of a final version (the version of record, or VOR) is essential not only to maintaining the quality and accuracy of scientific research but also to advancing the subsequent work from which new research stems. Only the final version of a manuscript overseen by a publisher committed to maintaining the accuracy of the scientific record can be counted on to be corrected, retracted or Otherwise updated with clear notation for the global scientific research community. Ensuring that publication repositories clearly distinguish between multiple versions of articles (i.e., ensuring that singular publication records point to the VoR, where the AAM is deposited first) will be critical, as NIH moves forward. The NIH may wish to implement guidelines requiring that authors depositing their AAMs provide a DOI (digital object identifier) pointing to the VOR. Indeed, at AAAS, our instructions for authors depositing AAMs require them to include a link to the VOR.

With respect to metadata, linkages between publishers and organizations such as the Research Organization Registry (ROR), Open Researcher and Contributor ID (ORCID), Crossref, and data repositories are aimed at increasing robustness of metadata by providing persistent identifiers and connecting them to research outputs. As a publisher, AAAS monitors and implements best practices for both metadata collection (e.g., on institutions and funders) and metadata propagation in the VOR and associated research objects.

All Science journal papers include details about funding, author contributions, competing interests, data and materials availability, and license information. The publisher oversees accuracy of important associated metadata after publication, including in cases where authors request to change their names in previously published papers, as one example. As a criterion to publish, AAAS requires authors to make

their data publicly accessible. AAAS has also piloted a partnership with Dryad, an international open-access data repository; we encourage such partnerships because they help ensure that publishers and repositories share the same metadata, thus providing better linkage between the data and the research paper. NIH may wish to consider implementing guidelines for data availability in publications. These guidelines could include a clear set of criteria for data deposition and ease of linking to that data, which publishers could help enforce. As a best practice, NIH could also encourage connections between publishers and data repositories of various kinds (general or field-specific, or both).

Uploaded File: [https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/AAAS-NIH-RFI-Response- - April-2023.pdf](https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/AAAS-NIH-RFI-Response--April-2023.pdf)

Description: Attached, please find the full AAAS response to the NIH RFI on OA. This includes information outside of responses to the four questions listed above.

Email: mphelelan@aaas.org

Submit date: 4/21/2023

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

Name: Lindsay Morton, Senior Manager, Open Science Community Engagement

Name of Organization: Public Library of Science (PLOS)

Type of Organization: Other

Type of Organization-Other: Scholarly Publisher

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

As a nonprofit Open Science publisher, PLOS aims to ensure that Open Science is practicable for the entire scholarly community, and that the reward system of science appropriately acknowledges and honors Open Science practices as contributing to a common good. We wish to express our enthusiastic support for the vision articulated in the OSTP memo of August 25 2022 and our appreciation of the NIH's thoughtful steps toward realizing that vision. We appreciate the opportunity to share our perspective on the NIH's plan to enhance access to the results of research, and improve equity in scholarly publishing for authors and readers alike.

The rapid dissemination and widespread availability of research and underlying data through Open Science is key to meeting major challenges—from the Sars-CoV-2 pandemic to the climate crisis—with effective, evidence-based solutions grounded in rigorous reproducible science. We see Openness as more than the ability to read research articles. Openness includes unrestricted access to the tools and information necessary to understand research results in context, to verify and reproduce results, and to reuse data and methods. True Openness also means equitable opportunities for publication and participation in the peer review process.

How to best ensure equity in publication opportunities for NIH-supported investigators.

We believe that equitable access to Open publishing opportunities requires a shift away from a volumetric 'pay per publication' model reliant on Article Processing Charges (APCs). APCs have demonstrated that Open Access is viable—but they are exclusionary and they create incentives for publishers to increase volume or price. Waivers, while a useful stop-gap, are not a sustainable solution.

Instead, we should work together to evolve new models based on partnership, collaboration, and community. Already, publishers, including PLOS, are experimenting with new ways to finance Open Access, including Community Action Publishing, Subscribe to Open programs, and more.

In the short term, and in parallel with developing and honing new solutions, we can implement simple changes to better meet author and stakeholder needs.

1. Establish funding mechanisms specifically for research dissemination. Researchers shouldn't have to choose between using their grant to pay a publication fee, or to conduct more experiments.
2. Aggregate funding for publication services fees through a University library or similar body, rather than allocating small amounts through individual research grants. Centralizing administrative functions

increases efficiency, reduces the administrative burden on individual researchers and the administrative costs to publishers, and makes it possible to more fairly distribute the cost of publication, putting Open Access within reach for more of the research community.

In the US, libraries and consortia have shown that they are open to testing new methods, and that these types of partnership can be effective both in increasing transparency, and addressing cost inflation.

2. Steps for improving equity in access and accessibility of publications.

PLOS supports the NIH's efforts to increase and accelerate access to publicly funded research. Eliminating the embargo will meaningfully benefit researchers, practitioners, and patients alike, and is reasonable and feasible for publishers as well. PLOS has always deposited research with indexing and archiving services as soon as possible following publications.

We also appreciate the emphasis placed on machine readability, which is essential to discoverability, reuse, and reanalysis. However, because the NIH policy provides for access alone, without the legal right to reuse that true Open Access licensing provides, its utility is limited—especially in this era of big data and rich text data mining. Reuse and redistribution are key to maximizing the reach and impact of research.

Equally vital to reproducibility is ensuring access to research outputs Other than articles, such as data and methods documentation, including study designs, code, and protocols. The NIH can help to drive change in this area by encouraging, reinforcing, and rewarding the sharing of a broader range of research outputs in line with best practices for reproducibility, transparency, and inclusivity, in the grant application process.

3. Methods for monitoring evolving costs and impacts on affected communities.

The expectation of transparency in pricing policy will encourage continued experimentation with more equitable scholarly communications business models, helping to drive positive change.

In the short term, we recommend that the NIH take advantage of the considerable public information on pricing already available, by aligning with established systems (like those of Coalition S). Gathering similar information independently in a new system will create additional administrative tasks and unnecessary expense.

In developing any new monitoring or measurement frameworks, it's crucial to recognize that individual article fees are not an essential part of an Open system. Future monitoring efforts must be structured in a way that allows for the evolution of business models, which is key to increasing equity in publication opportunities. In order to be successfully adopted, any new monitoring framework must also be broadly applicable beyond the NIH, or the US context alone.

4. Early input on considerations to increase findability and transparency of research.

The development and consistent application of shared metadata standards is key to discoverability and credibility. We encourage the NIH to invest and participate in community-based metadata initiatives in order to build systems that work for all, and to prioritize systems with the broadest potential impact, focusing on utility and reuse with the aim of increasing system-wide efficiency and accelerating scientific advancement.

To be effective, metadata and persistent identifiers (PIDs) must be interoperable and follow some level of standardization. Therefore the NIH should recognize the benefits of making specific recommendations in this area, to accelerate harmonization around emerging standards adopted by the scientific community. In developing guidelines for grantees and publishers, the NIH should:

- Specify clear and detailed metadata standards and provide recommendations about which PIDs to use to describe diverse research artifacts and the links between them, both in a machine-readable way at scale, and as human readers accessing individual research elements.
- Set expectations for PIDs and metadata to understand the individual contributions of authors, editors, and peer reviewers, and provide a digital infrastructure to support credit for all contributions.

Conclusion

Although Open Access has made great strides over the past two decades, the majority of research outputs are still not accessible, either because they are behind a paywall (according to a recent analysis of Web of Science and Dimensions data, 53-56% of published research remains closed), or because they have not been shared at all (e.g. datasets, protocols, negative and null results).

In order to actively move away from paywalled research, we need to change the reward system of science, ensuring that researchers receive meaningful credit and recognition for all kinds of contributions. This includes both acknowledgement for a wider variety of research creation and assessment roles, from protocol development through peer review, and a more representative range of research outputs, including information that contextualizes research articles and enables reproducibility.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/PLOS-response-to-the-NIH-Public-Access-RIF.pdf>

Description: Please find the above attached in PDF format, with hyperlinks

Email: lmorton@plos.org

Submit date: 4/21/2023

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

Name: Tom Ciavarella

Name of Organization: Frontiers Media Inc

Type of Organization: Other

Type of Organization-Other: Scientific and academic publishing company

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

On public repositories, we believe the NIH Public Access Plan rightly encourages and prioritizes the widest possible choices for researchers as they relate to publishing venue, as well as the principles of academic freedom. We think the Plan strikes the right balance by making PubMed Central (PMC) a convenient and compliant repository for research without privileging or mandating it.

On the fairness of the article processing charge (APC), we believe it is both fair and effective as it is a fee for a service. But although it is the most efficient and transparent method, it is worth noting this charge is not the only way to finance Gold Open Access (Gold OA) publishing. Indeed, we recognize that in some cases, it is not the preferred or most sustainable price structure for researchers, funders, libraries, and research institutions. And while we, like Others in the publishing industry, think the APC model is a good one, we are continually in touch with institutional partners to find solutions that meet their needs. And we are seeking new models to help authors cover the fair and actual cost of publishing, to make scientific knowledge accessible to the widest possible audience.

Within an APC framework, we have expanded our portfolio of institutional models to meet the tailored needs of our customers (recognizing, for example, the distinct needs of research-intensive “publish” organizations as well as high consumption “read” institutions and societies). Our success indicates a range of pricing options can meet the needs of a range of customers and institutions.

On the additional steps the NIH might take to ensure new inequities are not created, or existing ones reinforced, we believe the NIH should encourage researchers to publish in the Gold OA model - on the basis that the public funding of public access is efficient, scalable, and delivers value for money.

In our view, Gold OA publishing is the most effective way of securing that outcome. It offers a simple, transparent, and competitive way to unlock the benefits of fully accessible science; and it enables researchers, agencies, universities, libraries, and repositories to fulfil both the NIH Public Access Policy and the OSTP guidance.

Publishing in a Gold OA journal immediately facilitates the transfer of articles to a repository, with metadata in machine-readable formats. In this model, there are no embargoes and no superfluous or costly bundled services that are common in “hybrid” or “transformative” subscription options offered by legacy commercial publishers.

On public value for money, new federal guidelines seek public access but do not specify delivery models. We agree that openly accessible science can - and should - be delivered by more than one publishing

model. We welcome competition if it spurs innovation and the amount of rigorous science accessible to all.

But in judging those delivery models, federal agencies must make a robust and transparent assessment and a comparison for efficiency, scalability, and public value for money - guided by the objective of discoverability that underpins public access.

For example, public access known as “Green Open Access (Green OA)” clearly removes some barriers and does not create or perpetuate inequity. But the mechanisms for finding, reading, and sharing Green OA files vary widely. Substantial new funding will be required just to bring that variance down and lift standards for discoverability, with new investment in infrastructure for metadata enrichment. Those institutions unable to fund that investment are likely to face the continued cost pressure of paywall subscriptions that might only minimally ease search and discovery.

So, it is vital that the funding of public access is as efficient, scalable, and as good a value for money as possible, and in our view, Gold OA publishing is the most effective way of securing that outcome. It offers a simple, transparent, and competitive way to unlock the benefits of fully accessible science.

2. Steps for improving equity in access and accessibility of publications.

On the 12-month embargo, we strongly welcome the NIH’s decision to end it on publications. We believe that so-called Transformative Agreements (TAs) were worthwhile in their conception as a means of smoothing the transition to fully open access science, but in their execution have not effectively led to transformation and have instead become a blunt instrument.

TAs lack transparency, have complex bundles of often unnecessary services making it all but impossible to judge value for money, and come with no contractual commitment to a move to full open access (Green, Gold, or Otherwise) within a binding deadline.

Most of these TAs are large scale “read and publish” or hybrid deals. Publishers will often allow authors’ work to appear in hybrid journals without being charged (if their institutions pay), while at the same time maintaining the amount of science they publish behind paywalls.

We believe TAs help subsidize the market dominance of legacy publishers by controlling the pace of transition to fully open access science.

The worldwide scientific publishing oligopoly is a market estimated to be around US \$27 billion by revenues in 2021, as per Outsell Inc., Segment View: Scientific, Technical and Medical, 2021, cited in STM Global Brief 2021 - Economics & Market Size: https://www.stm-assoc.org/wp-content/uploads/2021_10_19_STM_Global_Brief_2021_Economics_and_Market_Size-1.pdf

Furthermore, the five largest paywall publishing houses (Elsevier, Wiley, Springer Nature, Taylor & Francis, and SAGE) have captured more than half of that market, as per the Livres Hebdo/Publishers Weekly 2021 ranking of top global publishers: <https://www.publishersweekly.com/pw/by-topic/international/frankfurt-book-fair/article/87466-frankfurt-book-fair-preview-2021-relx-rules.html>

On the basis the NIH seeks equity in access as well as transparency in costs, backed by financial sustainability, we believe Gold OA publishers can deliver.

On automated text processing, assistive devices, and Other inclusionary measures, we fully support the NIH's position. We consistently invest in measures that improve the accessibility of our publications. Many such requirements were mandated by the Coalition S initiative, which Frontiers fully supported, and which saw wide-ranging and progressive open access policies adopted in the United Kingdom and across Europe.

We firmly back public policies that promote equity of opportunity, the ability both to read and to publish research, and the scientific rigor, academic freedom, institutional values, and personal and professional recognition that underpin success.

We are committed to increasing research access, knowledge resources, and educational opportunities for all, especially for those groups, nations, and individuals who are historically marginalized, underrepresented, or disadvantaged.

On institutional success, we work to build communities and tackle the inadequacies and inequities often characterizing research dissemination. The shift toward open access represents an opportunity to expand access to knowledge in a significant way across academic institutions of all stripes, as well as to small businesses and the public.

We urge the NIH to draw on its influence to see that library, research, and educational institutions commit to investing in open access so that all parties can source sufficient funding for publishing. Several equitable open publishing models are readily available. It cannot be right if colleges and universities are encouraged to maintain robust publications budgets for subscriptions and then asked to make cuts to open access.

We believe there is enough funding in the system to make the transition to open access complete. But that funding can only be unlocked with public sector, policymaker, and buyer leadership, on the basis we look beyond legacy publishing models that have been responsible for a decades-long cost explosion in scholarly publishing.

See for example the University of Missouri analysis (<https://library.missouri.edu/news/lotte-health-sciences-library/scholarly-publishing-and-the-health-sciences-library>); the University of California San Francisco analysis (<https://www.library.ucsf.edu/about/subscriptions/journals-costs/>); and the Guardian analysis (<https://www.theguardian.com/science/2017/jun/27/profitable-business-scientific-publishing-bad-for-science>).

With the right policies and incentives, agencies can help drive the value of taxpayer-funded investment and spur innovation.

3. Methods for monitoring evolving costs and impacts on affected communities.

On financial costs, we welcome the NIH's interest in the commercial drivers of scholarly publishing, particularly in matters of access or equity.

Since our inception as a born-digital publisher, we have positioned ourselves as a researcher-centric organization focused on quality, speed, collaboration, and innovation. The governing principle of all scholarly publishing should be that the researchers have the most freedom possible to focus on their research. And so, all publishers compete to lower administrative and process-based burdens.

While the dissemination of research requires a complex ecosystem, we believe a wide-scale shift to open access would allow libraries and research institutions to free substantial resources now tied up in (paywalled) subscriptions, and to apply those resources to researchers' publishing costs.

A strong signal or directive from the NIH that research institutions should commit these freed-up funds - as well as grant money ringfenced for publication - to the widespread and immediate sharing of research would have a profound and positive impact on the drive to fully open access science.

On the perceived relative fairness of pricing regimes, and as we say in response to Question 1, it is worth noting the article processing charge (APC) is not the only way to finance Gold Open Access (Gold OA) publishing. Indeed, we recognize that in some cases, it is not the preferred or most sustainable price structure for researchers, funders, libraries, and research institutions. And while we, like Others in the publishing industry, think the APC model is a good one, we are continually in touch with institutional partners to find solutions that meet their needs. And we are seeking new models to help authors cover the fair and actual cost of publishing, to make scientific knowledge accessible to the widest possible audience.

Within an APC framework, we have expanded our portfolio of institutional models to meet the tailored needs of our customers (recognizing, for example, the distinct needs of research-intensive "publish" organizations as well as high consumption "read" institutions and societies). Our success indicates a range of pricing options can meet the needs of a range of customers and institutions.

The publishing industry at large is experimenting with pricing models and introducing new ones in its drive to innovate. Though the nomenclature varies - advance annual payment, fixed fee, flat fee, multi-payer, Subscribe 2 Open, waivers - all of these seek to offer more cost-efficient and sustainable alternatives to libraries' subscription expenditure.

4. Early input on considerations to increase findability and transparency of research.

On data sharing, we fully back the NIH's effort through its Public Access Plan to spur a better and more consistent use of persistent identifiers (PIDs) and metadata. In driving this effort, the NIH is providing critical leadership in the scholarly publishing ecosystem.

Moreover, we welcome the NIH's focus on the findability and transparency of research. Open data drives scientific and technological innovation and spurs collaboration; is critical to driving efficiency and scaling innovation; and in uniform standards can be verified, reproduced, and built upon.

If data is transparent and open to scrutiny and evaluation, it follows that trust and confidence in science are more likely to be sustainable. The infrastructure for open data is readily available and an increasingly frequent resource; what's more, many large-scale repositories already exist to make data open.

Examples include Figshare (<https://figshare.com/>), a commercial, field-agnostic repository; field-specific, non-profit databases like the society-supported FlowRepository for cytometry data (<http://flowrepository.org/>) and the commercial Protein Data Bank (<https://www.rcsb.org/pages/about-us/index>); and federally backed databases like NIH's data repositories (<https://sharing.nih.gov/accessing-data/accessing-genomic-data/accessing-genomic-data-from-nih-repositories>).

On data repositories, substantial funding will be required for operation and upgrades. And in the absence of funding committed to scaling up PMC, Frontiers would back a federated approach that focuses on shared standards and access across multiple repositories. By way of illustration, we deposit the full text or metadata of our 230-plus journals in more than 20 repositories when we publish articles.

As a Gold OA publisher, we have made thousands of peer-reviewed articles available online immediately, without embargo. Our starting point - and end point - is ease of discovery.

In simple terms, an article that cannot be found, cannot be shared, and cannot be cited also cannot spur vital collaboration and breakthrough. Publishing in a Gold OA journal unlocks discoverability. The articles and underlying data are transferred to a repository such as PubMed Central (<https://www.ncbi.nlm.nih.gov/pmc/>) or stored in commercial or Other non-profit databases.

Moreover, the metadata from Gold OA journals come in XML files and Other machine-readable formats to meet FAIR data standards of findability, accessibility, interoperability, and reuse. (<https://sharing.nih.gov/data-management-and-sharing-policy/data-management#:~:text=NIH%20encourages%20data%20management%20and,repurposing%20datasets%20for%20secondary%20research.>)

The metadata includes PIDs such as that of ORCID for author identification (<https://info.orcid.org/what-is-orcid/>), a Digital Object Identifier (DOI) for the article itself, and tags to the relevant grant funding or research institution. And compliance with JATS DTD for XML and Other PMC-recommended tagging enables an even more efficient search and discovery experience.

The new federal guidelines seek public access without specifying delivery models, and we agree that openly accessible science can - and should - be delivered by more than one publishing model. We welcome competition if it spurs innovation and the amount of rigorous science accessible to all.

But in judging delivery models, we believe federal agencies must make a robust and transparent assessment and comparison across efficiency, scalability, and public value for money - guided by the objective of discoverability that underpins public access.

For example, public access known as “Green Open Access (Green OA)” clearly removes some barriers and does not create or perpetuate inequity. But the mechanisms for finding, reading, and sharing Green OA files vary widely. Substantial new funding will be required just to bring that variance down and lift standards for discoverability, with new investment in infrastructure for metadata enrichment. Those institutions unable to fund that investment are likely to face the continued cost pressure of paywall subscriptions that might only minimally ease search and discovery.

So, it is vital that the funding of public access is as efficient, scalable, and as good a value for money as possible, and in our view, Gold OA publishing is the most effective way of securing that outcome. It offers a simple, transparent, and competitive way to unlock the benefits of fully accessible science.

We think it is possible to achieve the fullest possible access to our collective knowledge - for fairer outcomes in all parts of society - in a business model that is cost-effective, commercially sustainable, and underpinned by private sector innovation.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/Frontiers_response_NIH_RFI_2023-04-24.pdf

Description: A PDF version of the comments submitted via this webform, with a summary of the Frontiers position at the top of the document

Email: tom.ciavarella@frontiersin.org

Submit date: 4/21/2023

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

Name: Lauren Gross, J.D.

Name of Organization: The American Association of Immunologists (AAI)

Type of Organization: Professional org association

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The American Association of Immunologists (AAI) appreciates this opportunity to submit comments in response to NOT-OD-23-091: “Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research.” AAI is the nation’s largest association of professionally trained scientists dedicated to advancing the knowledge of immunology and its related disciplines, fostering the interchange of ideas and information among investigators, and addressing the potential integration of immunologic principles into clinical practice. Founded in 1913, AAI serves its members and the global immunology community by providing a center for the dissemination of information relevant to the field and its practices, organizing and sponsoring educational and professional opportunities, planning and hosting scientific meetings, addressing members’ issues and opinions, and advocating for funding and policy priorities that strengthen the biomedical research enterprise, particularly for immunologists. Central to AAI’s mission is its role as a scientific publisher: AAI owns and publishes The Journal of Immunology (The JI), the most highly cited journal in the field, as well as ImmunoHorizons (IH), a fully open-access, peer-reviewed journal dedicated to the science of immunology. As a not-for-profit scholarly scientific society, AAI invests the net revenue it receives from publications in programs and activities that advance immunology/related fields or that support AAI members’ research and work lives.

AAI understands and appreciates the Administration’s goal of increasing public access to the results of taxpayer-funded research. It is imperative, however, that NIH, as the nation’s premier and largest funder of biomedical research, adopt and implement a plan that will foster access to accurate, peer-reviewed, reliable scientific information, while also helping to limit the potential for unintended proliferation of poor-quality or unreliable scientific content. Public access for its own sake, without the safeguards provided by professional scientific societies like AAI (as described herein) and Other responsible publishers, could increase public distrust of science, delay scientific advancement, damage public health, and/or undermine the competitive edge the U.S. has long had in scientific research and development. In addition to the comments below, AAI calls to NIH’s attention important comments submitted by the Federation of American Societies for Experimental Biology (FASEB).

AAI supports the intent of the NIH Public Access Plan to maintain the existing broad discretion that allows authors to choose how and where to publish their research. Until recently, this was in fact the author’s choice: authors could use their grant (or Other) funds to publish in the journal best suited to their needs and their research findings. However, the White House Office of Science and Technology Policy (OSTP) memorandum on “Ensuring Free, Immediate, and Equitable Access to Federally Funded Research” (“Nelson memo”), published on August 25, 2022, has accelerated a trend set by European funders and a small group of U.S.-based funders: requiring authors to publish only in journals with specific open access models. As a result, fewer authors are submitting to hybrid or subscription-only journals, many of which are owned and/or published by not-for-profit professional scientific societies,

and some of which could be in financial jeopardy as a result of this impending policy. This “thumb on the scale” by the federal government has left researchers and authors in a bind: they may no longer be able to choose the journal that might best support them as authors or showcase their work as broadly and responsibly as they would like. Instead, they must find a publisher that satisfies their funder requirements, based on the model of the journal or a contractual agreement and not necessarily on its quality, mentoring, publication record, or any Other feature.

AAI does not believe that authors should be required to publish in journals with specific business models. As a not-for-profit professional society, AAI’s scholarly journals offer two different models (The JI is hybrid, IH is open access) and a shared commitment to peer review and mentoring. In keeping with AAI’s educational mission and in order to maintain the integrity of AAI journals’ scientific content, all AAI reviewers are Ph.D.-level scientists conducting active research in their fields. AAI staff scientists use a database of thousands of potential reviewers to find subject matter experts to serve as reviewers for each manuscript submission. This database, developed and maintained at AAI expense, includes but is not limited to members’ self-identified areas of expertise and information about the perceived usefulness and timeliness of past reviews. In the past five years, AAI secured more than 12,000 reviewers who were qualified and available to undertake a review. AAI also invests in preventing both real and apparent conflicts of interest (COI) with respect to research activities and collaborative or personal interactions. The careful solicitation of reviewers, managing the peer-review process, ensuring research integrity, and avoiding COI are essential steps toward ensuring that reviews are scientifically sound, impartial, professional, and equitable to all submitting authors. These activities require extensive time commitments from AAI staff as well as access to expensive software and tools.

Unlike most publishers, AAI peer reviews 94% of submissions; only articles considered out-of-scope are rejected before peer review. Offering this peer review is part of the AAI educational mission and ensures that high-quality peer review is available to virtually all immunological researchers regardless of laboratory, University/institution, or country of origin. It may be particularly helpful to early career scientists, some of whom may have little or no relevant mentoring at their institutions, who learn how to prepare a scientific paper for publication and are able to publish in a respected scholarly journal, which is necessary for career advancement.

Beyond funder restrictions is the matter of publication costs. AAI urges NIH to develop clear guidance on all ways in which investigators may charge these costs. In addition to allowing authors to charge reasonable publication costs to the direct portion of their grants, NIH should develop novel ways and funding mechanisms, and work with academia and institutions to consider alternatives, including the use of indirect funds, that do not require researchers to utilize grant funds intended for research. NIH should also acknowledge, and consider solutions for, the fact that using direct grant funding for publishing costs reduces the available funding for necessary research costs (including support for personnel, equipment and supplies, funding for experiments, etc.), which may decelerate scientific discovery and will almost certainly place an additional burden on less well-funded investigators and/or institutions. The NIH Public Access Plan’s removal of the 12-month embargo period, resulting in a fully open-access model, will likely cause publication fees to increase, perhaps dramatically, disproportionately and negatively impacting under-resourced investigators and institutions, especially those that do not have libraries with the means to enter into transformative agreements or Other arrangements that would not require authors to pay publication costs from the direct portions of their grants. NIH should monitor, and provide guidance on addressing, disparities in publishing opportunities.

NIH should consider ways to alleviate the potential increase in administrative burden that investigators will face if they become responsible for ensuring their publications are publicly and freely available (e.g., deposition of manuscripts to PubMed). Currently, this service is often provided by the publisher. With regard to The JI, AAI has deposited manuscripts on the author's behalf since 2011, a service that may have to be discontinued without the support of revenue currently received from subscriptions. Similarly, NIH should acknowledge and address the fact that not-for-profit scientific societies that publish scholarly journals, which provide tremendous value to the biomedical ecosystem, do not have the same resources as large publishers; NIH should assist these societies during and after the transition to ensure their continued ability to serve their authors, the federal government, and taxpayers, including reviewing and validating the accuracy and rigor of federally funded scientific research.

Finally, although not addressed in this RFI, AAI strongly supports the ability of authors to choose the copyright license that best suits the needs of their funders and themselves. A copyright license that restricts the reuse of derivatives maintains the scientific integrity of a researcher's work that could be misconstrued or misunderstood if presented in partial form. In addition, a copyright license that restricts the reuse for commercial purposes ensures that the work is not misappropriated.

2. Steps for improving equity in access and accessibility of publications.

All scientists and physicians conducting (or training to conduct) research in immunology or related fields are welcome to apply for membership in AAI. Members receive immediate access to The JI (and like the public, can access IH at no cost online). Nonmember scientists, physicians, and public health officials who wish to view The JI content before the 12-month embargo period ends often access it at their institution's (or government) library. As the most highly cited journal in the field, The JI is widely available, and as a publication of a not-for-profit professional society, it is reasonably priced and affordable to smaller institutions.

AAI is acutely aware of the importance of sharing scientific and medical information with the general public but believes that immediate and free dissemination of full-length scholarly journal articles is not the most effective or efficient way to accomplish this goal. (Scientific journal articles are tailored to experts in a specific field and are sometimes not well understood even by experts in a different subdiscipline of the same field, much less by a lay audience.) AAI has a long track record of programs intended to accomplish the goal of making scientific content accessible to the public. AAI develops educational materials for the public and for Congress and offers immediate and free online access to abstracts of all scholarly articles published in AAI's journals. Furthermore, AAI has invested in developing accessibility tools like "Key Points" (three-sentence lay summaries) and visual abstracts (lay-friendly graphic representations of the main points of articles) for published articles, free of charge and publicly available on The JI website (<https://journals.aai.org/jimmunol/issue>).

Additionally, AAI was a responsible contributor to the sharing of critically important scientific information throughout the COVID-19 pandemic and intends to respond with equal commitment to any future public health emergency. Most recently, the association launched a new initiative through which AAI members have explained the importance of vaccination and how it works to protect from illness, among other immunology topics, on television, radio, social media, and in print media.

AAI has been able to provide these important services to the public only because of the revenue generated by the AAI journal subscription model. Should AAI lose revenue as a result of the new public

access policy, the association may not be able to continue to provide programs and services that expand access and information to both scientists and the public.

3. Methods for monitoring evolving costs and impacts on affected communities.

AAI supports NIH's effort to monitor and share information regarding trends in publication fees. However, AAI recommends against any action that may inadvertently lead to inequities in publishing opportunity, favor high-volume rather than high-quality publishing, and/or negatively affect the quality of publications. Peer review, in which AAI heavily invests and which is essential to upholding scientific integrity, cannot be undertaken or accomplished at no cost, and any model that does not sufficiently compensate for providing peer review and ensuring Other critical aspects of scientific integrity (e.g., ethics, rigor, reproducibility, etc.) will inevitably lead to a reduction in publication quality and will ultimately slow, or could even reverse, the very scientific progress that NIH wishes to speed.

4. Early input on considerations to increase findability and transparency of research.

AAI encourages all authors to provide an ORCID ID, a unique, persistent identifier that can be obtained free of charge by researchers, with their article submission. In an effort to successfully capture AAI authors' funding information, AAI further customized - at additional expense - the AAI manuscript submission system to include funder(s), grant reference numbers, and investigators' name.

At considerable expense, AAI also added digital object identifiers (DOIs) to nearly 100,000 articles from its journal archive, dating back to 1916, and continues to utilize them for all publications. A DOI is a unique and never-changing alphanumeric string assigned to online journal articles, which makes it easier to search for and retrieve published works, and makes content more accessible to researchers, clinicians and public health officials, students and educators, and Other members of the public. AAI supports the adoption of DOIs for NIH grants; this would allow for efficient and consistent tracking of investigators' grants, publications, and research data.

AAI appreciates that NIH is asking about, and urges NIH to allow continued use of, persistent identifiers (PIDs) and metadata that have been commonly used by scholarly scientific societies. This is important to avoid unnecessary disruption, confusion, and cost.

AAI appreciates NIH's willingness to hear the concerns of scholarly scientific societies that wish to continue publishing high-quality, peer-reviewed scientific articles designed for experts in their discipline, and to engage in an iterative process to achieve a policy with broad consensus. AAI believes that there is a way forward to address the widespread desire for more public access to needed scientific information that can still preserve the unique and essential role of scholarly scientific society publishers to conduct the necessary review, editing, dissemination, monitoring (including corrections and retractions), and archiving of the manuscripts/articles that AAI publishes. AAI looks forward to continuing to work with NIH to ensure that that the association can continue to advance the field of immunology through publication and Other educational activities in the years to come.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/NIH-Public-Access-Plan-RFI.Final-AAI-Comments.4.21.23.pdf>

Email: lgross@aai.org

Submit date: 4/21/2023

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

Name: Douglas Kondziolka

Name of Organization: Congress of Neurological Surgeons

Type of Organization: Professional org association

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

see attached letter.

2. Steps for improving equity in access and accessibility of publications.

see attached letter.

3. Methods for monitoring evolving costs and impacts on affected communities.

see attached letter.

4. Early input on considerations to increase findability and transparency of research.

see attached letter.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/CNS-Response-to-NIH-RFI.docx_FINAL_4.17.23.pdf

Description: CNS response to NIH RFI

Email: Douglas.Kondziolka@nyulangone.org

Submit date: 4/22/2023

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

Name: Gerald C. Blazey

Name of Organization: Northern Illinois University

Type of Organization: University

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

NIH policy already allows supported researchers to charge reasonable publishing costs against their awards. However, because grants are often subject to an informal funding cap, less-resourced institutions, such as ERIs, will still be disadvantaged because the research authors are presented with the choice of diverting resources from research. NIH should consider mechanisms to avoid this, for instance, by allocating funding for a minimum number of publications from a special funding source AFTER the award is made. That is, ensure that the APC funds are truly and rigorously added “on top” of the research funds.

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

Authors at ERIs and early career authors are most likely to have limited resources for APCs. NIH should consider an extension or longitudinal study of the AAAS study Exploring the Hidden Impact of Open Access Financing Mechanisms. Informative extensions of the study would be to discriminate between large and emerging research institutions and low and high diversity institutions. Increased statistics for gender and race would also be helpful. NIH should also consider direct institutional inquiries to compare institutional APC contributions at large and emerging research institutions and low and high diversity institutions. Funding models should be adjusted to mitigate any inequities observed.

4. Early input on considerations to increase findability and transparency of research.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/NIU-Position-Paper-NSF-Reauthorization.pdf>

Description: Northern Illinois University Response to RFI

Email: gblazey@niu.edu

Submit date: 4/22/2023

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

Name: Jessica Polka

Name of Organization: ASAPbio

Type of Organization: Other

Type of Organization-Other: Advocacy organization

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

ASAPbio is a 501(c)(3) organization working to promote innovation and transparency in life sciences communication.

We are fully supportive of the 2022 OSTP directive to make all federally-funded research immediately accessible upon publication. Based on the public access plan the NIH has proposed in response to this memo, we appreciate the NIH's desire to ensure equitable access to research for diverse stakeholders, and to ensure that this is provided at reasonable costs that do not exacerbate existing disparities. Furthermore, we support the need to ensure that research outputs are findable and discoverable through robust infrastructure and standards.

Many of these goals can be supported by moving toward a model where preprints are the primary form of sharing; this would also provide a strong foundation for aligning researchers' incentives with the goals set out in the RFI. Many researchers now experience a disconnect between wanting to share work with the community and existing incentives for keeping data private. In a preprint-centric model, researchers would be recognized for sharing their work early and completely, which would also accelerate scientific discovery. Preprints also support rigor, reproducibility, and integrity by allowing broad engagement in public commenting and peer review. Given these benefits, we offer the following suggestions for using preprints to promote equitable, cost-effective, and discoverable publishing.

We appreciate the prioritization of equitable publication opportunities for researchers as well as access to research articles. Preprints provide a mechanism to meet both goals. Unlike many journal publishing models, preprints are free to post and free to access. Given racial disparities in federal funding, preprints create equity by including those who do not have access to funds for journal publication costs. We call on NIH to recognize preprints that are identical in substance to the latest article version as an option for compliance with its open access policy.

2. Steps for improving equity in access and accessibility of publications.

Preprints need to be open access, meaning licensed for reuse. NIH has already taken a positive step by recommending the CC BY license for preprints (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-050.html>). However, many preprints on popular servers are still not being published under these licenses, risking the creation of walled gardens. To remedy this, we urge NIH to require that supported investigators publish their preprints and Other publications under a CC BY or less restrictive license.

3. Methods for monitoring evolving costs and impacts on affected communities.

Operating costs for preprint servers are much lower than the average ~\$1,600 article-processing charge at journals that require publication fees (Morrison, Heather et al., 2021, "2011 - 2021 OA APCs", <https://doi.org/10.5683/SP2/84PNSG>, Scholars Portal Dataverse, V1). However, the sustainability of preprint servers is a critical question. They are currently supported by private funders, publishers, institutions and library consortia without long-term commitments. A publicly funded preprint infrastructure offers a sustainable way to achieve equitable access to publishing. We suggest that NIH directly fund the community-owned preprint servers that support the communication needs of its researchers.

4. Early input on considerations to increase findability and transparency of research.

The NIH could make preprints more discoverable by extending the NLM preprint pilot to all preprints, not just those that are NIH-funded. Furthermore, an increasing number of preprints now are being reviewed outside of journals (see groups listed at scity.org). These reviews should be indexed and connected to preprints on NLM's databases, and they should be visible on the SciENcv profiles of the reviewers who authored them. In addition, metadata for preprints and preprint reviews should be made freely available through appropriate infrastructures, such as the Crossref infrastructure.

Finally, we urge the NIH to move forward with an international focus. Scientific progress is a global endeavor, and implementation needs to be in line with broader frameworks rather than reinventing existing infrastructure. There is support for broad and equitable access to research works via government and funder initiatives in Latin America (e.g. SciELO and AmeliCA) and Europe (e.g. Open Research Europe (ORE)), and also mature infrastructure to enable the use of persistent identifiers (DOI, ORCID, ROR) and appropriate metadata. The NIH should ensure any new infrastructures make use of these common standards and are interoperable with these existing projects. Now is the time for global collaboration to make rapid progress on improving scientific communications infrastructure.

Email: jessica.polka@asapbio.org

Submit date: 4/23/2023

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

Name: Diane Gern

Name of Organization: American Thoracic Society

Type of Organization: Professional org association

Role: Institutional official

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/ATS-Letter-4.23.pdf>

Description: Official letter from the American Thoracic Society (ATS)

Email: dgern@thoracic.org

Submit date: 4/23/2023

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

Name: Stefano Bertuzzi

Name of Organization: American Society for Microbiology

Type of Organization: Professional org association

Role: Institutional official

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/ASM-Response-to-NIH-RFI-on-Public-Access-to-Publications_April-2023.pdf

Description: The American Society for Microbiology (ASM) appreciates the opportunity to respond to the National Institutes of Health's (NIH) request for information on the agency's plan to enhance public access to results of NIH-funded research. As one of the oldest a

Email: mwatts@asmusa.org

Submit date: 4/24/2023

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. How to best ensure equity in publication opportunities for NIH-supported investigators.

Elsevier shares the White House Office of Science and Technology Policy's (OSTP's) and NIH's goals of ensuring the wide availability of trustworthy and impactful research findings, as well as equity in publication opportunities for NIH-supported investigators. At Elsevier, we look forward to working collaboratively with NIH and Other key stakeholders to achieve these goals principally via the gold open access model. With support from NIH, we believe this will best ensure equity in publication opportunities for all.

We recognize that there is currently no 'one-size fits all' publication model that meets all the diverse needs, preferences and circumstances of authors, institutions, funders in the US or indeed globally. This is why we have long offered both the gold open access, or pay-to-publish, model as well as the subscription, or pay-to-read, model, so that institutions and authors can choose the right route for them depending on their funding environment, discipline, and research goals. We therefore respect - and generally reflect - NIH's agnostic stance in its draft policy as to publication model, we understand the need for choice, and we support free market dynamics to sustainably achieve shared objectives on public access.

Consistent with the above principles, we agree that publicly funded research outputs should be publicly accessible. We fully support and enable researchers to freely and immediately share research outputs that have not benefitted from publishers' investments - for example, datasets and preprints. Where, 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 will enable this through the gold open access (pay-to-publish) model.

Gold open access is a well-established and sustainable mechanism that ensures publishers are recompensed for the substantial value-added investments they make in these versions. These cover services that we and Other publishers provide, which include ensuring the quality, discoverability, and accessibility of research in perpetuity, safeguarding the integrity of published research by effectively managing editorial and peer review processes, and applying innovative technology towards continually expanding and enhancing all these services. Additionally, Elsevier is increasingly playing a critical role in tackling misinformation and fraud of unprecedented scale in science, as we validate the rigor of the research we publish in our journals. Sustainable funding models are vital if publishers are to continue providing these services to safeguard trust in science into the future, and for us to reinvest and innovate in a range of areas - including the examples related to equity outlined under question 2 - to advance

knowledge for society in the long term. Commensurately, we are committed to providing researchers with value for money in relation to our services, and to pricing fairly and transparently - themes we explore further under question 3.

We are supportive of choice and flexibility. Different publishers will provide different choices, services and business models. We will be unable to support publication models which rely on subscription-funded content being made freely and immediately accessible, and which also include requirements for authors to retain copyright via 'rights-retention'-like strategies, as we believe these models will prove unsustainable in the long-term. These measures do not provide a mechanism to recover our investments that enable us to continue innovating and ultimately providing value for NIH and the public. This position is shared by the vast majority of journals and publishers [Ref: <https://www.stm-assoc.org/stm-oa-position/>].

We therefore welcome that NIH's draft policy enables researchers to charge reasonable costs for publishing gold open access against their awards. Availability and take up of this funding will be critical for grantees to be able to comply with NIH's immediacy policy across the full spectrum of available journals, so they are supported to publish in the journal that will provide the best visibility for their research. This will meet NIH's goal for equitable publication opportunities: without funding, grantees seeking to comply with NIH's policy would only be able to publish in journals that allow researchers to immediately share research they publish under the subscription model (just 4% of Health Science journals according to recent research published by JISC [Ref: <https://research.jiscinvolve.org/wp/2022/12/14/subject-analysis-of-routes-to-compliance-for-ukri-funded-authors/>]), or that offer free open access publishing (8% of total articles across all subject areas were published in diamond journals based on 2021 Scopus data), which may be lower quality journals and regionally or institutionally focused titles.

Furthermore, to ensure equity in publication opportunities for all NIH-supported investigators, we suggest that all grantees should be provided with clear and consistent guidance on budgeting for the full cost of disseminating their research, and funds for publication should remain available after the end of the grant period. In so doing, all grantees will be afforded the same benefits of gold open access, including increased readership to maximize the reach of their work, a policy goal shared by NIH and OSTP.

There is much we can learn from Other markets as we work together to achieve the goals of OSTP's memo for immediate open access. The gold open access model is already widely adopted by the research community and successfully implemented across various countries [Ref: <https://www.stm-assoc.org/oa-dashboard/open-access-uptake-for-the-top-30-article-producing-countries-and-Other-geographical-groupings/>]. These include research-intensive countries such as the UK, Germany, Italy, Spain, Poland, and the Netherlands, where so-called 'combined' or 'read and publish' agreements with publishers have contributed to achieving immediate access to research through gold open access. All stakeholders have a role to play in developing solutions to enable gold open access in practice. At Elsevier, we draw on our experiences of co-creating agreements that already enable gold open access publishing across more than 2,100 institutions globally.

Finally, consistent with our commitment to evolving publishing practices, we welcome innovation in the marketplace. As publishers, we will continue to analyze, monitor and experiment with different publication models to ensure that we are serving our diverse communities as effectively as possible.

Notwithstanding, we have a responsibility to science and society to ensure that any approaches we endorse safeguard integrity, quality, discoverability, and accessibility of research in perpetuity. Thinking pragmatically about already proven mechanisms to support the OSTP's and NIH's policy goals for immediate public access, and acknowledging the limited time available to develop scalable solutions, at Elsevier we will therefore support the gold open access, pay-to-publish, model. This does not preclude continued experimentation to understand different publication models, or flexibility to test new models over time, in line with our long-standing tradition of working creatively with and for the scientific community to advance scientific knowledge sharing for the benefit of science and society.

Finding a solution that meets all OSTP's policy objectives, including equity, requires a collaborative and cooperative approach. We are committed to working with the research community, including NIH, towards finding workable solutions that will achieve these objectives for all.

2. Steps for improving equity in access and accessibility of publications.

We share OSTP's Equity and Excellence Vision and would welcome opportunities to collaborate with NIH and Others in the research community to leverage our equity work and to exchange insights and experience, towards our shared ambitions for helping both individuals and science to achieve their full potential.

As outlined in our response to point 1, at Elsevier, we will enable NIH's grantees to meet its policy goals, and fully support equity in access, by offering the gold open access model, which is a well-established mechanism to achieve access, integrity, and quality at scale. With measures in place to ensure consistent guidance for all grantees on budgeting for the full cost of gold open access publication, equity can be safeguarded.

As discussed above, there is currently no one-size-fits all model that will best resolve all issues in relation to equity. Ultimately, there are trade-offs to consider between equity in access and equity in the ability to publish. We've done much to address inequities in the pay-to-read or subscription model. We have a range of initiatives in place to provide access to subscription content, which are made possible in part through the revenue generated by our sustainable publishing models. These include: our participation in Research4Life through which we provide free or discounted reading and publishing to researchers in over 120 low- and middle-income countries [Ref: <https://www.elsevier.com/about/corporate-responsibility/research4life>]; providing free access to health-related articles for patients and caregivers and establishing dedicated emergency resource and information centers, most recently for the novel coronavirus (COVID-19) [Ref: <https://www.elsevier.com/connect/coronavirus-information-center>] and Mpox [Ref: <https://www.elsevier.com/connect/monkeypox-information-center>]; supporting authors to share their publications peer-to-peer [Ref: <https://www.elsevier.com/authors/submit-your-paper/sharing-and-promoting-your-article>]; and supporting interlibrary loans. Unfortunately, an open access world presents new kinds of inequities, and we are now working to develop solutions to mitigate these. These include: our vast programs of waivers/discounts on publishing, where appropriate; our work with institutions to fairly and equitably transition costs for reading to publishing as part of commercial agreements so institutions can fund publishing; and our piloting of new commercial models to address issues of equity head on. By way of an example, our pilot with California Digital Library works to meet gaps in funding for publication fees in an equitable manner [Ref: <https://www.elsevier.com/about/press-releases/corporate/University-of-california-and-elsevier-sign-ground-breaking-transformative-agreement>].

We understand that mitigating inequities in the global research community requires that we look beyond publication models, and we have therefore undertaken a range of actions to identify issues and develop solutions towards equity in research. We have done this both as an individual publisher [Ref: <https://www.elsevier.com/about/inclusion-and-diversity>], supported by our I&D Advisory Board [Ref: <https://www.elsevier.com/about/inclusion-diversity-board>], and as a sector via the Joint Commitment for Action on Inclusion and Diversity in Publishing [Ref: <https://scholarlykitchen.sspnet.org/2021/04/21/joint-commitment-for-action-on-inclusion-and-diversity-in-publishing-an-interview-with-laura-norton-and-nicola-nugent-of-the-rsc/>]. We work with our editors and reviewers, and the broader publishing community, to nurture inclusion and diversity, to widen participation in journals at all levels, and to ensure that researchers' work is assessed fairly on its scientific merits. We also employ innovative approaches, such as Registered Reports and Results Masked Review, to ensure research is judged on the merits of the research question and methodology. This aims to minimize the risk of publishing bias and supports accessibility to all federally funded research output, not only that which delivers a positive result.

With regards to accessibility, our accessibility policy ensures that we consistently and proactively endeavor to make our products fully accessible to all users, regardless of physical abilities [Ref: <https://www.elsevier.com/about/accessibility>]. We are thrilled that the 2023 WebAIM million report ranks ScienceDirect as the #1 most accessible home page on the internet, ensuring an optimized experience for individuals with disabilities and impairments [Ref: <https://webaim.org/projects/million/lookup?domain=sciencedirect.com>]. This incredible achievement is supported in part through the insights from a collaborative working group we have convened since 2011 comprising University leaders in assistive technology and web accessibility from six US institutes [Ref: <https://www.elsevier.com/solutions/sciencedirect/librarian-resource-center/web-accessibility>].

We are also proud to support health equity, and as part of recent additions to our 3D platform, Complete Anatomy [Ref: <https://www.elsevier.com/solutions/complete-anatomy>], we have introduced a full female model, and a range of skin tones and facial feature options. These enhancements allow educators to visualize, edit and teach anatomy from diverse perspectives.

These activities all require substantial investments. At Elsevier, we will continue to make a wide range of research outputs more accessible to a greater group of potential readers, to help researchers' work achieve the greatest impact, and to help advance research progress and efficiency so that funders such as NIH can maximize the value of their investment in research. We would welcome discussing these ideas and collaborating on further initiatives with NIH regarding both accessibility and initiatives or models for equitable access to content and publishing.

3. Methods for monitoring evolving costs and impacts on affected communities.

Feedback from researchers demonstrates that they value the publishing process and feel that the work we do has a material impact [Ref: <https://www.elsevier.com/connect/how-scientific-publishing-supports-research-what-authors-are-telling-us>]. We are heartened that 90% of researchers tell us the changes made by our journals' teams to their articles improved the clarity of their research. We want to continue to serve the research community by maintaining and building on this work, which is why we

will continue to seek researchers' input on how we can improve our services and their experiences with us.

We strive to offer researchers real value, and we are continuing our commitment to pricing our journals competitively with an underlying principle of pricing lower than the market for like-for-like quality.

Moreover, we follow this pricing principle even though our commitment to quality means we must invest resources to assess many more articles than we eventually publish. Elsevier journal articles account for around 18% of global research output and 28% of citations, further demonstrating our commitment to quality, significantly ahead of the industry average. We further recognize the importance of providing the research community with transparent and straightforward information about our journals and pricing on our public-facing pages, to help them make data-led decisions. As a responsible business we take care to ensure we work within the parameters permitted by law, and to a degree that avoids market alignment, that would Otherwise risk disadvantaging customers.

Key demonstrations of this commitment include:

- Our pricing policy page, covering the components that factor into our pricing, details of our strict no double dipping policy, and links to our subscription and APC list prices [Ref: <https://www.elsevier.com/about/policies/pricing>].
- Sharing journal-level metrics for many of our journals, including acceptance rates, and average review and publication times, via Journal Insights pages (e.g., <https://journalinsights.elsevier.com/journals/1072-7515>) and our Journal Finder tool [Ref: <https://journalfinder.elsevier.com>].
- Analysis of our publishing volumes under subscription and open access business models for individual journals (e.g., <https://journalinsights.elsevier.com/journals/0021-9991>) and the whole of Elsevier [Ref: https://www.elsevier.com/_data/assets/pdf_file/0010/616474/elsevier-journal-and-article-ecosystem-2021-summary.pdf].

We hold ourselves accountable for continuing to build on this transparency across the more than 2,800 journals we publish. We welcome views and will continue to ask for feedback from the research community, including partners such as NIH, as we enhance this offering, to provide helpful and meaningful insights to the communities that we serve.

4. Early input on considerations to increase findability and transparency of research.

We support NIH's goals to increase the discoverability and transparency of research. Below are examples of platforms and initiatives that we provide to enable these. We welcome further dialogue and collaboration with partners in the research community, including NIH, to continue to build on this work.

Example 1: Improving research discovery via our ScienceDirect platform

All the content Elsevier publishes, including both journals and books content, is hosted on the ScienceDirect platform [Ref: <https://www.sciencedirect.com/>]. ScienceDirect is completely free to search and browse in a number of ways; it serves around 50 million unique monthly users of which over 60% are not institutional customers, demonstrating that its use extends far beyond subscribers. Key

elements of an article published under the pay-to-read model are available to all readers irrespective of their access status e.g., the abstract and reference list. The introduction and 'section snippets' are in the process of being rolled out across all articles. All readers are further signposted to related relevant articles to help them continue their search and deepen their understanding of a particular topic. Furthermore, our dedicated Topic pages support researchers with gaining easily digestible introductions to new subjects, drawing from subject matter expert insights, and content highlights from our foundational resources [Ref: <https://www.sciencedirect.com/topics>].

Example 2: Enabling and encouraging transparent research data sharing

Transparent sharing of the data underlying research output enables research to be validated, supporting the quality and integrity of research. Data sharing also promotes greater reuse of research outputs, supporting research efficiency, reproducibility and maximizing the value of funders' investments by avoiding duplication of efforts and engendering new discoveries and research developments beyond the scope of the original study. This ultimately brings benefits for wider society and helps build trust in science.

We are committed to collaborating with stakeholders from across the research community, and to playing our role in enhancing data sharing practices to support and enable researchers and institutions to store, share, discover and effectively (re-)use data. At Elsevier we provide infrastructure and workflows in support of this: our research data management solutions support the end-to-end research data management workflow [Ref: <http://www.elsevier.com/rdm>], from providing Mendeley Data, an NIH Generalist Repository Ecosystem Initiative (GREI) supported open and free generalist repository [Ref: <https://datascience.nih.gov/news/nih-office-of-data-science-strategy-announces-new-initiative-to-improve-data-access>], to Data Monitor, which enables institutions, and ultimately funders, to track and monitor compliance with data sharing mandates. During our submission process we prompt and enable authors to share links to their datasets, made available in a repository of their choice, and to provide data availability statements in their publication.

Example 3: Surfacing metadata fields and persistent identifiers

Elsevier surfaces metadata fields and persistent identifiers (PIDs) to support discoverability, access, and compliance monitoring by research institutes and funders. We are actively participating in community discussions and initiatives on these topics, such as those led by the Open Research Funders Group. We would welcome further discussion with NIH and Other stakeholders on ways to improve on discoverability and transparency of research.

We already open a number of metadata fields for articles and their references within Crossref. In terms of identifiers, we use industry standards, such as article DOI and Fundref, and where there are a range of identifiers in use across the industry, we enable interoperability, for example, users can import their Scopus profiles into ORCID or link ORCID identifiers to Scopus profiles.

Example 4: Nurturing research integrity

The OSTP memo pointed to the role that metadata and PIDs can play in nurturing research integrity. We thus wish to highlight the broader role that publishers, including Elsevier, and learned societies play to ensure research integrity throughout all stages of submission and publication so that researchers and readers are assured of the quality and trustworthiness of research outputs. We do this by: screening

submissions for integrity issues; carefully managing the editorial and peer review process; supporting authors to develop and share transparency statements which are published alongside the published manuscript; and maintaining the integrity of the scholarly record through post-publication updates. We develop screening tools ourselves, as well as contribute to industry-wide approaches to nurture research integrity, for example via the STM Association's Integrity Hub [Ref: <https://www.stm-assoc.org/stm-integrity-hub/>].

As you would expect, in all these aspects we seek to maintain the highest industry standards and best practice, as developed and maintained by the Committee on Publication Ethics (COPE), International Committee of Medical Journal Editors (ICMJE) and the like. We are keen to share our learnings and would welcome further dialogue with NIH and stakeholders regarding transparency and integrity of research.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/Elseviers-Response_Request-for-Information-on-the-NIH-Plan-to-Enhance-Public-Access-to-the-Results-of-NIH-Supported-Research.pdf

Description: Elsevier's Response: Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research

Email: k.eve@elsevier.com

Submit date: 4/24/2023

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

Name: William B. Coleman, PhD

Name of Organization: American Society for Investigative Pathology

Type of Organization: Professional org association

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

It is generally regarded that the NIH's public access policies represent an unfunded mandate that may impose financial hardship on many funded researchers. While NIH policy may allow "...reasonable publishing costs..." it should be recognized that researchers would rather preserve their funds for costs directly related to research projects than to use their funds for open access fees, which are more expensive than typical publication costs. Productive laboratories might publish numerous manuscripts in the course of a year and if these publications carry open access fees, could significantly impact modular budgets. Most researchers would advocate for the NIH to provide for publication costs in a manner that does not impact the budget that directly supports the funded research project (outside the modular budget). Further, the NIH should recognize that requirement to publish open access may force some researchers to publish less due to financial constraints. This represents an unintended consequence of the public access policy. When researchers are forced to choose what they publish (because publication of all research results would be cost prohibitive), their measures of productivity and their impact on the field decreases. This potential consequence of the public access policy would disproportionately affect young investigators who have less research funding and need to prioritize research productivity that reflects generation of results and publication of those results to build a successful research program.

Submission of published papers or final manuscripts to PMC is often accomplished by commercial publishers on behalf of the authors (which is the case for the ASIP journals), reducing the burden to the individual researcher. However, when this service is not provided by the publisher, the requirement does present a burden to the researcher. This burden could be diminished by allowing authors to deposit the pdf version of their final published paper rather than requiring upload to PMC of the manuscript's deconstructed component parts (necessary for PMC format).

The NIH should also be sensitive to the need of journals (and their publishers) to receive data on the numbers of times that their manuscripts are accessed and downloaded from PMC. These metrics are particularly important to non-profit societies that publish journals as these data contribute to the overall measures of their journal's value in the current era where impact factor (based upon citations) is only one dimension of the overall contribution the journal makes to the advancement of science.

2. Steps for improving equity in access and accessibility of publications.

The 12-month embargo is absolutely necessary for the survival of journals that operate on a subscription or hybrid business model. At such time when research becomes immediately available upon publication, the need for institutions and individuals to subscribe to journals will disappear. This would likely force many quality journals that are not among the elite few out of business. That would result in fewer

respected journals in which to publish and a broadening of the impact gap between those who publish in Nature, Science, Cell, etc. and those who have to publish in journals with questionable review practices. The unintended consequence would be a dilution of good science and a widening of the gap between the “haves” and the “have-nots.” Again, this would disproportionately affect junior investigators.

Elimination of the embargo period will force journals that primarily publish results from NIH-supported researchers to convert to 100% open access or would force authors to choose the open access option. While both of these scenarios are plausible, both would result in increased costs for publication that would be passed on to the researcher (discussed above). When NIH-funded researchers are required to publish all their work in open access journals or utilizing open access options (to comply with the elimination of the embargo period), the financial burden to individual investigators will increase, which would disproportionately affect young investigators and may negatively impact on the amount of research results that are published.

The NIH should also consider the current practice by many researchers of utilizing preprint servers and how this impacts public access to NIH-funded research. Servers such as arXiv, bioRxiv, and medRxiv, host preprints that reflect a large volume of biomedical research. Preprints are attractive to researchers because it allows them to establish a time-stamp on their work while the results are submitted for peer-reviewed publication. Preprints are accessible at no cost and may provide a more appropriate resource for the public, particularly non-scientists. While most journals do not allow citation of preprints, authors are allowed to submit the work contained in the preprint for publication since preprints by definition are not yet published. We note that the National Library of Medicine is running a pilot study to make preprints resulting from NIH-funded research available on PubMed Central (which includes all of the preprint servers listed above (<https://www.ncbi.nlm.nih.gov/pmc/about/nihpreprints/>)).

3. Methods for monitoring evolving costs and impacts on affected communities.

Publication costs vary considerably across journals and publishers. This is true for subscription-based journals, hybrid journals and open access journals. With many journals now being online-only (no print), there are cost savings, particularly in the area of color figures and page charges. However, the production of a journal issue (whether print or online) continues to require technology, expertise, and personnel, all of which contribute to the publications current cost structure for any given journal. Commercial publishers have the need to make a profit from their publications in order to continue to provide journals to disseminate research results. If/when journals become less profitable we may see some journals disappear - reducing the number of outlets for publication of research results. Hence, reasonable publication costs must be viewed from the perspective of the publisher, as well as from the perspective of the author and their funders.

We commend the NIH for committing to monitor the costs of publication and how this affects the laboratory finances of their funded researchers. We would encourage the NIH to make monitoring of publication costs a required reporting element of NIH progress reports. This would allow the NIH to assess the total cost of publication of NIH-funded research (collectively and on the basis of the individual researcher) and generate a database of publication costs by publisher, journal, journal-type, and nature of the published work. This reporting requirement would not significantly increase the burden on the investigator beyond what currently exists. NIH grantees routinely report their publications as evidence

of productivity, and the new reporting requirement would simply ask for investigators to disclose the cost of each publication.

4. Early input on considerations to increase findability and transparency of research.

As researchers and publishers, we agree that the use of PIDs (or Other sorts of DOIs) is important and should be implemented to enhance transparency and discoverability of published research. We commend efforts on the part of the NIH to provide appropriate linkages between published research results, investigator/authors (utilizing ORCID IDs), and sources of research funding. In this manner, assigning a PID/DOI to funded research grants would benefit the connectivity and traceability of these elements of research (people-funding-results).

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/ASIP-RFI-NIH-Plan-to-Enhance-Public-Access-to-NIH-Supported-Research-4-24-2023-FINAL.pdf>

Description: Letter containing response to RFI on public access.

Email: wbcoleman@asip.org

Submit date: 4/24/2023

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

Name: Caroline Sutton

Name of Organization: STM (The International Association of Scientific, Technical and Medical Publishers)

Type of Organization: Professional org association

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Changing access requirements within the scientific ecosystem are likely to solve inequities from a reader aspect, but concerted and collaborative action will be necessary to ensure sustainability and equity across the ecosystem. Agencies can minimize the risk of creating new inequities, especially for scientists from traditionally marginalized communities, as well as early career researchers, by ensuring that these researchers and institutions have the funding support necessary for their research to flourish and choose the publishing option that best suits their needs. Publishers are doing their part by supporting new approaches, including Read and Publish Agreements, that provide opportunities for all to participate and access scholarly communication. Ultimately, a financially sustainable scientific publishing system is critical to advance trusted and impactful science, and attention to these issues can ensure that this is achieved.

To promote publishing equity, NIH needs to make appropriate and enduring funding available to the researcher and their research institution, together with appropriate and enduring support and guidance on the use of funds and the options for providing access. In order to ensure equity for all researchers, such funding and guidance needs to be provided alongside Other guidance for researchers, and in a manner that ensures author choice for whatever journals they choose to advance their research and impact. This funding also needs to 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. Finally, NIH should provide clear and prominent guidance on planning and budgeting and the explicit acknowledgement throughout the guidance that publication has real costs that need to be addressed in the proposal, as it has with the NIH Data Sharing and Management requirements.

Agreements with institutions or funders like Read and Publish Agreements or Other pooled payment agreements have the potential to reduce inequality by making OA publishing available to all researchers. Publishers are actively working to develop and promote these models, which can reduce inequity for researchers at participating institutions and also can help increase compliance with policy and reduce administrative burdens. We have received reports of the success of such efforts, thanks to the real-world experiment of growth of transformative agreements around the world.

Another aspect of equity in publishing opportunities relates to the promotion of equity and diversity in the research enterprise. Support for diverse publishing outlets is critical to such efforts, although to proactively drive further change requires input from stakeholders across the research ecosystem. One way in which publishers encourage equity and diversity in the research enterprise is by providing an

objective space in which work can be assessed by peers (though our impartial oversight of an independent peer review process). More specifically, in recent years publishers have established industry-wide initiatives such as the Joint Commitment on Diversity and Inclusion and C4DISC which are developing consensus-based standards and best practice (e.g., developing guidelines around the peer review of articles and data; creating policies to support authors with deadnames; etc.).

Finally, publishers support and invest in various initiatives to enable researchers to participate in the scholarly dialogue. This includes support for educational efforts and funding programs that expand participation to underrepresented groups and ensure quality and integrity. For example, Research4Life, a UN-publisher partnership, supports researcher skill development, provides Research Lifecycle Training Webinars, and enhances the ability of LMIC researchers to publish with participating publishers. Many publishers support and partner with AuthorAID, a global network that provides free resources and training, including in article writing, for researchers in low- and middle-income countries. Publishers offer various funding programs to support the participation of less-well-resourced researchers, including discounts and waivers, both individually and through collective approaches like Research4Life. Publishers also work with Other stakeholders to provide resources to identify trusted outlets to present their work (e.g., Think. Check. Submit. (thinkchecksubmit.org) a cross-industry initiative) and promote integrity in scholarly research and its publication through the Committee on Publication Ethics (COPE, www.publicationethics.org) and Other efforts.

2. Steps for improving equity in access and accessibility of publications.

Publishers invest significantly in efforts to provide access, accessible formats, and accessible modes of dissemination for publications. It is important to note that for access and accessibility to be provided, first the publications and infrastructures must be created and disseminated. Therefore, it is a necessary precondition to improve equity in access and accessibility of publication that NIH work to ensure the viability of a robust ecosystem of scholarly communications that drives innovation, supports quality and integrity, and ensures appropriate infrastructure to enable accessibility to diverse users.

As alluded to in the introduction to this response, steps to improve access and accessibility could be broken down into three requirements: 1) sufficient, enduring, and appropriate funding, 2) encouragement and education of researchers to budget for and choose open science, and 3) flexibility for researchers and organizations to enable diverse modes of communication.

Appropriate and enduring funding is fundamental to achieve the open science goals outlined in the draft NIH plan and in the August OSTP memo and make sure that NIH's revised policy can promote equity in access. This is because the sustainability of publishing is a precondition to the availability, utility, and accessibility functions of scholarly communications.

Encouragement and education of researchers is also key, as they will ultimately be responsible for ensuring that the articles that they write are available to the public. Experience with funder requirements and compliance around the world indicates that researchers are often confused about grant requirements, including on how and when to provide access to publications, and a significant percentage of researchers erroneously believe that it is an inappropriate use of grant funds to pay for publication. STM's members' experience with guidance and education indicates that such efforts can make a big difference in researchers willingness to choose open access and compliance with funder and Other requirements.

Flexibility is needed to promote diversity in publication, ensure author choice, and support access to publishing in ways that work for researchers. As noted earlier, different publishers may offer distinct approaches to provide access, each of which may be appropriate to the communities they serve, and each of which should be allowed as a method for researchers to ensure access to any article they author that reports on NIH-funded research. A diversity of publication outlets, enabled by flexible approaches to implementation of the NIH policy, supports diversity in research.

Publishers invest significantly to ensure that articles are accessible in various human and machine-readable formats and are available to those with diverse needs. Many publishers have invested in technology and infrastructure to build towards, meet, or exceed Section 508 accessibility and have created a diverse ecosystem of accessible resources available to diverse audiences with or without assistive technologies. Some of our members were leaders in developing braille resources in multiple languages, screen reading technology implementation, and Other innovations. These additional infrastructure and formatting investments are enabled by sustainable business models.

STM also notes various initiatives that we or our members have promoted to ensure access and accessibility for diverse audiences. These include Research4Life which provides access to researchers in Low- and Middle- Income countries; efforts to share plain language summaries to broaden the accessibility of cutting-edge research to non-experts; and investments in the promotion of articles to the media and through social media channels.

Finally, STM notes that equity in access requires that publications that are made available are accurate and trustworthy. STM and its members invest significantly in ensuring research integrity and the quality and reliability of the scholarly record. For example, STM Solutions recently launched the Research Integrity Hub (<https://www.stm-assoc.org/stm-integrity-hub/>), a robust and holistic set of tools to safeguard the integrity of science through a combination of shared data and experiences and by harnessing technological innovation. Individual publishers are working individually and in partnership with Other organizations to prevent misconduct and ensure the integrity of the system. Safeguarding research integrity can only be done through collaboration with all stakeholders in the scholarly ecosystem, and in an environment where continued investments can be made.

3. Methods for monitoring evolving costs and impacts on affected communities.

STM's members compete in a dynamic environment that drives them to provide the widest possible access to the articles that they publish at the lowest possible cost to the research and user communities. Costs and revenue streams can vary significantly from one publisher to another, and even from one journal to another, depending on many factors such as audience, circulation/reach, ranking, number of articles published, field/specialty, and distribution method. These differences need to be considered when evaluating the market dynamics and taking a broad average of dissimilar journals is not recommended.

More broadly, it is important to consider the changing dynamics of how scholarly publication is supported when attempting to monitor trends. Historically, publishers' costs have been spread across those that consume the research (readers / subscribers) of which there are many. The NIH plan may move associated costs to Other payers, of which there are fewer. The cost burden will therefore increase for some (e.g., research-intensive universities) while many Others will no longer contribute to

the costs (e.g., commercial industries, which traditionally subscribe to journals without publishing extensively in them).

When considering the budget for supporting public access to high-quality, peer-reviewed articles reporting on NIH-funded research, it is important to look beyond a single aspect of pricing (i.e., APCs) and consider the total investment in scholarly communications, which includes subscriptions, APCs, transformative agreements, and Other inputs. The cost and pricing structures are very different for different disciplines - medicine, physical sciences, social sciences, and humanities - and for different types of journals based on selectivity, services, technology, and Other features.

That said, APC prices are virtually always transparent. Our members are committed to the maximum possible transparency around pricing, in accordance with regulation and antitrust concerns, and note that APCs may vary across journal titles based on a variety of factors. Our members are also committed to ensuring that every researcher - regardless of geographic location, discipline or personal circumstance has relevant and realistic options available to them to publish their work, so that no researcher is left without a voice, regardless of funding source. Consistent with this commitment publishers have developed Read and Publish Agreements with institutions and maintain active waiver and discount programs to serve researchers.

STM is not aware of any Other NIH efforts to monitor expenses for specific research services or outputs and cautions that any efforts to look at trends in publishing must be carefully interpreted in the context of an evolving and dynamic ecosystem. Those who monitor APC prices and perform market analysis are aware that any trends in this data always need to be contextualized with respect to Other trends in publishing (e.g., the growth in the sharing of research outputs) and revenue (e.g., subscription rates and transformative agreements) and with respect with efforts to ensure equity in publication opportunities (e.g., provision of waivers and discounts).

A diverse, financially sustainable, and robust publishing system which provides authors with broad choice is the most effective way to ensure fair and competitive pricing and address any cost concerns. Hard price caps will likely drive existing industry trends toward publisher consolidation and volume-based models which could compromise integrity, quality, and author choice. The research enterprise, and the impact of NIH-funded research on innovation and public health, is best served by diversity that is enabled by flexibility and full support for open access publishing options.

In addition, care must be taken with respect to interventions that seek to ensure fees and policies remain reasonable and equitable, as they may lead to unintended consequences or constitute anti-competitive market interference under antitrust laws. As STM and Others have recommended in Other contexts, NIH should seek legal advice regarding competition law and any undue influence on industry market pricing. Finally, we underline that the goals of the NIH policy are best achieved through NIH efforts to ensure that researchers are budgeting appropriately for publications.

4. Early input on considerations to increase findability and transparency of research.

We divide our response into two sections, as the concepts and needs of findability and transparency, while interrelated, are also quite distinct.

- a. Findability (including persistent identifiers (PIDs), metadata, and Other infrastructure).

STM and its member publishers would welcome collaboration with NIH to support approaches to findability that leverage and build on existing standards, technologies, infrastructure, and protocols. Publishers have committed to and invested significantly in ensuring the findability of articles and research data. Our experience suggests that additional efforts to support the use and development of persistent identifiers throughout the research ecosystem would bear additional fruit, including identifiers for articles and research data as well for funding agencies, grant awards, facilities, and the like.

Where possible, NIH should leverage existing standards and systems, as supported by publishers, institutions, and Other stakeholders. The primary existing PID and metadata structure, enabled through organizations including CrossRef and DataCite, should be adopted and adapted as necessary to minimize disruption, promote compliance, and prevent unnecessary duplication of effort and investment in the scholarly communications system.

Publishers already invest heavily in creating persistent identifiers and machine-readable metadata that promote greater visibility of research findings and data, and these help to promote trust, reliability, and transparency for the scientific system. Cross publisher and industry initiatives around PIDs include researcher (ORCID), institutional (Ringgold), and funder (Open Registry of Funders) PIDs embedded in our content workflows as standard across the majority of the scholarly communication ecosystem. Embedding standards supports our infrastructure development to build better links between interrelated research outputs and improve visibility from funding through to publication. In general, PIDs used or recommended by NIH should be those used by the community, as those can be validated and maintained. Where NIH needs additional or bespoke PIDs, efforts need to be made to ensure they map well to Other PIDs that are already well embedded in the ecosystem.

Specifically, STM recommends that NIH support the use of community-adopted PIDs through the grant application process (e.g., ORCIDs for researchers, organization IDs for the institutions(s) affiliated with each researcher, and Funder IDs for the distinct funders of the grant). While organization IDs are not as well-established or robust as researcher IDs (with ORCID), there are several emerging options for organizations, and NIH should consider recommending one of the following PIDs to ensure harmonization and avoid unnecessary duplication in the scholarly record: Ringgold (a global organization identifier system); ISNI (ISO standard name identifier system); ROR (the Research Organization Registry); and CrossRef's Funder Registry; along with ORCID. NIH should also ensure there are metadata fields for all of these.

In addition, publishers have invested significantly in discoverability, search engine optimization, and Other efforts to make sure that published articles can be found and used to advance scientific research. To support the findability of both articles and research data, NIH should also engage with and implement community-based standards and infrastructure initiatives that link and promote access to the best available versions of articles and research data. These include open protocols like Scholix, a multi-stakeholder initiative to link scholarly literature and research data, and services like CHORUS, that helps the public find and access articles reporting on federally-funded research. Initiatives such as seamlessaccess.org, a service designed to help foster a more streamlined online access experience by leveraging an existing single-sign-on infrastructure, and GetFTR, a tool that streamlines access to journal articles on discovery tools and collaboration networks, are also available to enable and accelerate access. STM would welcome additional dialogue to discover which existing initiatives could best be

utilized to support findability and access to articles and research data related to NIH-funded research, and to collaboratively develop solutions where services or infrastructures do not already exist.

b. Transparency (including reproducibility and trust in science)

Findability is necessary to promote transparency, but it is not sufficient to enable it. Transparency needs to be fostered through education and the research culture and enabled by infrastructure. Publishers continually invest in such systems and infrastructure and promulgate policies that encourage open sharing to promote trust. This includes efforts to promote trust and transparency through the sharing of research data (e.g, STM's Research Data initiative) and especially the use of FAIR (Findable, Accessible, Interoperable, and Reproducible) principles in sharing research data. Innovations in open peer review, the broadening of publishable articles to include negative results, the introduction of registered reports, and Other efforts to make publication and the publication process more transparent have the potential to improve public trust in science and the utility of research. Many of our members have signed on to Transparency and Openness Promotion (TOP) Guidelines and engaged with Other initiatives to drive transparency.

STM recommends that NIH leverage existing resources to promote transparency and avoid creating duplicative resources. For example, NIH can point to existing resources to support researchers in making their research outputs more transparent. Some potential examples include a manifesto for reproducible science designed to optimize key elements of the scientific process and "STAR Methods: Structured, Transparent, Accessible Reporting," designed to provide a structure for experimental methods that increases reproducibility. Existing, robust infrastructure should be considered before recommending or developing new systems.

We note that new modes of scientific inquiry are providing opportunities to improve scholarly practices, including with respect to transparency and integrity, but these may also carry risks that are not fully understood at this time. NIH's policies must be flexible enough to address any issues that might arise in these new modes of scholarship, as well as provide support for new and existing infrastructure and services that can help provide the review and analysis needed to ensure quality and integrity of both new and existing systems.

Finally, we note that the most important action that NIH can take to ensure transparency, quality and integrity in scholarly communication is to support and encourage the systems and services that currently provide these benefits for the research enterprise. These include, but are not limited to, market incentives that encourage the development of high-quality publication outlets for scholarly communication such as those produced by STM's members.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/STM-submission-to-NIH-public-access-RFI-2023.pdf>

Description: STM full response to RFI

Email: caroline@stm-assoc.org

Submit date: 4/24/2023

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: Professional org association

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The Council of Medical Specialty Societies (CMSS) is a coalition of 50 specialty societies representing more than 800,000 physicians across the house of medicine. CMSS works to catalyze improvement across specialties through convening, collaborating, and collective action. We are pleased to provide input on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research (NIH Public Access Plan) and the 2022 White House Office of Science and Technology Policy (OSTP) memo on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research.

As non-profit society publishers, we bring our best practices to the peer review of the articles and to wide dissemination of this content in support of the scholarly communication enterprise. Our long history of working together with our research communities has resulted in publication of some of the most impactful and practice changing content. The integrity of peer review is vital to sharing research findings in a way that assures accuracy, integrity, and the transmission of science that promotes new evidence vital to patient care; our comments raise questions that are important to carefully assess in order to preserve that US research enterprise as a source of high-quality scientific information.

Shifting of Revenue Streams

While the proposed policy allows publication in journals with varied publishing models, it does not address the impact that NIH Public Access Plan will have on publishing fees. Opening papers prior to the current 12-month embargo will result in the loss of subscription revenue from institutions and individuals and, for many publishers, a corresponding decrease in advertising revenue. In order for publishers to provide the scientific community with the support it has become accustomed to, including, but not limited to, maintaining the integrity of the science, robust peer review, support for discoverability, reproducibility and dissemination of the science, the financial burden will shift to the authors. Diligent peer review, management and public disclosures of conflicts, and data and figure integrity checks are vital parts of a responsible publication process. Threats to the integrity of the content, such as plagiarism, paper mills, inappropriate AI generated content, and fraudulent data, are always present and require steady attention. While no system is perfect, peer-review increases the opportunity to mitigate these risks and protect the public from ensuing harm.

Publishers also provide additional benefits to their communities by providing educational material, alternative metrics and enhanced metadata that may also suffer due to diminishing revenue. All of this requires resources that are likely to be endangered if publishers lose the revenue that currently sustains this work. Such losses could occur in the form of cancelled subscriptions, insufficient total article processing charge (APC) income, and lost licensing fees for approved reuse of content, among Others.

Each publisher will have their own budgetary tipping point when decreased revenues force a decision to discontinue vital services now protecting the integrity of research published in our journals, but all will face this challenge, and all will have to make cost-saving changes to maintain a viable publishing enterprise.

Policies that restrict publishers' abilities to collaborate with authors to realize their protection of rights under United States copyright law would further limit revenue streams on which we depend, including royalties, licensing, reprints, and advertising. We urge the NIH not to include rights retention language or license requirements in the final policy Other than the grantee's right to deposit the manuscript. Preserving a Green OA route presents a sustainable business model that should be embraced. Expanding rights retention policies beyond the deposition of the manuscript would also erode the publisher's ability to monitor usage of the content in support of the author's intellectual property.

Our specialty societies strongly recommend a two-year delay to adhere to the mandate. This time would allow us to work with you to develop policies that sustain reliable, equitable, high quality scientific content.

Access to funding

OSTP and NIH state that grants can be used to cover publication costs, which is a positive step; however, it is important that NIH increase the total amount of grant funding per award so that the additional Article Processing Charges, including potential fees to deposit papers into PubMed Central for example, will not reduce the funds available for research.

There are Other concerns to consider. Certain grants do not permit use of funds for publication fees. As such, CMSS recommends that NIH exempt certain types of infrastructure-related grants (e.g., cancer center support grants, CTAs, NCORPs) and teaching grants (K awards, T awards) from reporting funding to journals and thus requiring deposit.

The broad reach and impact of this proposed plan will be a challenge to implement and enforce if compliance is mandated for all NIH funded authors regardless of how much funding they received or how small a role any given individual plays in a research project or manuscript. The NIH should instead apply a minimum threshold of funding and/or level of participation by authors and researchers before subjecting the papers to the proposed mandate.

Copyright protection

Copyright protection is the first line of defense for any author against the misuse of their research, and publishers stand ready to defend investigators' intellectual property. Journals customarily allow authors to post their paper on their institutions' site, make use of their work at conferences, but this policy needs to clearly state that making the content freely accessible does not give anyone the right to create derivative products without permission. Clarification that the rights remain with the copyright holder needs to be articulated. The final guidance should also clarify that authors are obligated to follow the NIH Guidelines only for the papers they author as a result of NIH funding.

Definition of First Publication

There is confusion in the community concerning the definition of First Publication. We are interpreting NIH's draft language regarding first publication to mean that the manuscript uploaded to PubMed

Central in compliance with this policy will be embargoed until the first appearance of the final typeset article. Are we also correct in understanding that the Pub Med Central first publication will include a link to the publisher's site? Clarification of this matter in the final policy is strongly recommended to avoid confusion in the community.

2. Steps for improving equity in access and accessibility of publications.

Removal of the currently allowable 12-month embargo period for NIH-supported publications will improve access to these research products for all. As noted in the NIH Public Access Plan, NIH also plans to continue making articles available in human and machine-readable forms to support automated text processing. NIH will also seek ways to improve the accessibility of publications via assistive devices. NIH welcomes input on Other steps that could be taken to improve equity in access to publications by diverse communities of users, including researchers, clinicians and public health officials, students and educators, and Other members of the public.

Access and accessibility of publications

Journal publishers have long been collaborating with various stakeholders to develop and implement collaborative projects that enhance the public access, utility, preservation, and discoverability of materials that report on and analyze and interpret results of federally funded research. Publishers participate in a multitude of services that enhance discoverability, including ORCID, Crossref, the Committee on Publication Ethics, and provide guidelines that are not influenced by pharmaceutical companies as well as making sure conflicts of interest are accurately noted. Federal agencies should collaborate with publishers and Other stakeholders to ensure minimum standards, share best practices, and minimize duplication of work.

Providing immediate access to all scientific research comes with significant issues and significant financial/labor costs of compliance. We want to make sure that authors' intellectual property remains accurately presented on the worldwide stage; we are concerned that the research could be pirated by outside bodies that may misinterpret the results to suit their needs. While publisher's efforts to support free, immediate access to COVID-19 research were a boon to scientists, we also saw a rise of misuse and misunderstanding of research among the public. As the medical and research community collectively works to increase the public's trust in health and science, these proposed changes could unintentionally foster misinformation. Strong intellectual property protections are a necessary safeguard against the acceleration of this trend.

We recommend that NIH support publisher's ability to enforce copyright protection by maintaining publishers' rights in and to the content published.

3. Methods for monitoring evolving costs and impacts on affected communities.

NIH proposes to actively monitor trends in publication fees and policies to ensure that they remain reasonable and equitable. NIH seeks information on effective approaches for monitoring trends in publication fees and equity in publication opportunities.

Diverse Publishing Landscape

Publishers continually develop enhancements to the peer review and publishing processes, and this requires constant investment that would be slowed or stopped by a lack of funds. Many publishers

currently provide checks against plagiarism and graphic manipulation which ensure the veracity of the new literature and protect previously published works. Publishers work tirelessly to ensure the reproducibility of science which in turn protects patients. It is also worth noting that requiring all publishers to supply financial information in pursuit of fixed pricing conflicts with fair trade.

4. Early input on considerations to increase findability and transparency of research.

Section IV of the NIH Public Access Plan is a first step in developing the NIH's updated plan for persistent identifiers (PIDs) and metadata, which will be submitted to OSTP by December 31, 2024. NIH seeks suggestions on any specific issues that should be considered in efforts to improve use of PIDs and metadata, including information about experiences institutions and researchers have had with adoption of different identifiers.

Consistent Guidance

There are many examples of advancements already accepted by the industry such as DOIs, ORCID, funder registries, discovery tools for content mining, and use of JATS for structured metadata. If NIH wants to aggregate these data, they should collaborate with various stakeholders to create and engage in guidance for authors and publishers regarding standards to ensure best practices and minimize duplication of work.

Email: hburstin@cmss.org

Submit date: 4/24/2023

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

Name of Organization: Alliance for Nursing Informatics

Type of Organization: Professional org association

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/NIH_Public-Access-Plan_ANI-Comments_2023.04.24.pdf

Description: Alliance for Nursing Informatics Comment Letter

Email: sharon.giarrizzo-wilson@cuanschutz.edu

Submit date: 4/24/2023

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

Name: Lizbet Boroughs, MSPH Associate Director of Federal Relations and Kate Hudson, JD, Associate Vice President and Counsel

Name of Organization: Association of American Universities

Type of Organization: Professional org association

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The Association of American Universities (AAU) thanks the National Institutes of Health for the opportunity to comment on NOT-OD-23-091, the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research. Founded in 1900, AAU is composed of America's leading research universities. AAU's 65 research universities transform lives through education, research, and innovation.

AAU strongly agrees with NIH's statements that "increasing access to publications and data resulting from federally funded research offers many benefits to the scientific community and the public," and that access "can accelerate research, generate higher quality scientific results, encourage greater scientific integrity, and enable future inquiry, discovery, and translation for NIH-supported research." Indeed, in 2021, AAU and its sister organization, the Association of Public & Land-grant Universities (APLU), published a joint Guide to Accelerate Public Access to Research Data to help inform our respective member institutions' activities on accessible research data. Leading up to the publication of this document, with funding from NIH and the National Science Foundation (NSF#1837847 and #1939279), AAU and APLU held a series of workshops and conferences with researchers, senior research officers, librarians, chief information officers, and organizations in support of increasing public access to research.

Given our past work and strong interest in public access, AAU is carefully monitoring various federal research agencies' implementation of the August 2022 guidance released by the Office of Science and Technology Policy (OSTP). Our joint response with APLU in January 2020 to NOT-OD-20-013 highlighted that additional specific clarification, outside the scope of the RFI, would enable robust participation and engagement by researchers and universities with NIH's Data Management and Sharing Policy. AAU's comments on NOT-OD-23-091 are informed by our collaborations and discussions with our members, APLU, the Association of American Medical Colleges (AAMC), the Federation of American Societies for Experimental Biology (FASEB), and the Council on Governmental Relations (COGR).

AAU appreciates that NIH is engaged in clarifying reasonable costs for publications that can be charged directly by individual PIs to grants. This approach should also encompass cost considerations at the broader University level. Preparations for publications are not only supported by direct costs but also pooled mechanisms such as facilities and administrative costs, library subscriptions, and additional University support from Other available revenue sources. Indeed, oversight of Data Management and Sharing (DMS) is a collaborative process and not solely the researcher's responsibility during an award's arc. Data curation; compliance with federal, state, and tribal laws; metadata requirements related to fields of study; and proper data storage are tasks that require resources and an integrated approach

well beyond the individual researcher's scope of direct costs. Universities with robust financial resources, data infrastructure, and library and faculty support may have the capacity to leverage these resources to respond to the added costs involved in ensuring that the new public access requirements are met, however, many institutions and their faculty may struggle to support these additional costs.

AAU suggests that NIH could ensure data access and help minimize costs by creating and supporting one agency-wide data repository, similar to the creation of PubMed Central, to serve this purpose for publications. This would be particularly useful for areas where no current NIH-supported disciplinary repository exists. AAU also suggests that agencies create overarching disciplinary-specific repositories to ensure that universities do not create a myriad of different repositories, which will diffuse the accessibility of data access overall.

Additionally, we urge the NIH to explore ways to ensure that faculty and institutions have the means to receive support for publication and data storage costs well beyond the length of an individual grant. Without financial support after the terms of a grant, researchers and universities will be unable to comply with open access and data management standards for NIH without incurring the costs themselves, which will undoubtedly have a more significant and inequitable impact on researchers and institutions without robust research infrastructure funding.

AAU appreciates NIH's continued engagement with the community on the unanticipated costs of its DMS policy.

2. Steps for improving equity in access and accessibility of publications.

Ultimately, data is limited in its utility if research data stewardship is not fundamental to the research endeavor. Conceptualizing and planning for data access and interoperability is a continually iterative process involving researchers, funders, institutions, health professionals, and the public. Data technology and analysis are not stagnant, and their evolution will require flexibility within NIH's public access guidance and continual training for program officers at the individual NIH institutes.

AAU is, therefore, supportive of NIH's collaborations with scientific societies, such as FASEB's "DataWorks! Help Desk," to improve data management at the individual researcher level. AAU also strongly supports the creation of disciplinary based data repositories to improve and ensure access to federally funded research results and believes that it is important for NIH to support and facilitate the creation of such repositories. As previously stated, we also recommend the creation of one overall NIH-supported data repository for areas where disciplinary repositories do not currently exist or are not feasible.

3. Methods for monitoring evolving costs and impacts on affected communities.

NIH proposes to actively monitor trends in publication fees and policies to ensure that they remain reasonable and equitable. This monitoring will be very important as we are concerned that the impact of the new public access policy could result in increasing publication fees in the form of Article Processing Charges (APCs), making the affordability of the costs of publishing significantly more challenging for some researchers and institutions. NIH's evidence of trends should also encompass not only fees and policies, but also monitor which institutions, disciplines, and labs have decreasing appearances in the most accessed journals to provide a more accurate picture of this effect.

Additionally, AAU emphasizes that publication fees are only one narrow measure to determine evolving costs and impacts of the NIH public access policy, and that simply monitoring trends in publication costs will not fully encapsulate this impact. We echo our colleagues at FASEB who stated in their response to NOT-OD-23-91 that the scientific peer review process required to ensure the highest standard of scientific integrity is not adequately reflected in publication fees. The human effort of oversight and compliance, long-term data access, and impacts on society journals must be considered, too.

4. Early input on considerations to increase findability and transparency of research.

AAU supports NIH's efforts to provide near term data points for utilizing Persistent Identifiers (PIDs) for different research products and metadata. We remain concerned, however, that without clear standards on PIDs and metadata, different approaches will inadvertently hamper accessibility and reproducibility. As NIH refines its recommendations regarding certain PID platforms and metadata storage, consistency across federal agencies will be key to effectuating more robust adoption; we applaud NIH's continued collaboration with the National Institute of Standards and Technology (NIST) and their efforts to develop a Research Data Framework. Developing and adopting standard metadata approaches could help facilitate the use of metadata across different datasets and disciplines, reducing barriers to sharing and reusing data.

The Association of Research Libraries, the California Digital Library, APLU, and AAU released a report, *Implementing Effective Data Practices: Stakeholder Recommendations for Collaborative Research Support*, in 2020 with recommendations for data practices supporting an open research ecosystem. AAU stands by the 2020 recommendations. The report identified five core PIDs that are fundamental and foundational to an open data ecosystem. Using these PIDs will ensure that basic metadata about research is standardized, networked, and discoverable in scholarly infrastructure:

1. Digital object identifiers (DOIs) to identify research data, as well as publications and Other outputs
2. Open Researcher and Contributor (ORCID) IDs to identify researchers
3. Research Organization Registry (ROR) IDs to identify research organization affiliations
4. Crossref Funder Registry IDs to identify research funders
5. Crossref Grant IDs to identify grants and Other types of research awards

We encourage NIH's efforts to identify and pilot a DOI system that would overlay existing NIH grant identifiers to allow for greater interoperability. NIH's current award identifiers have extremely limited utility outside of NIH. Such a DOI system should be further coordinated with Other federal agencies and affected research stakeholders. Further, the use of services and tools such as DataCite, ORCID, Crossref, figshare, and Others should be allowed as a direct cost in the grant proposal. Many of these tools require membership fees or charge fees for additional services. These entities are critical to local data management on University campuses and may require significant campus investment through direct fees or human capital.

Conclusion

AAU commends NIH's outreach and engagement with the scientific community to inform refinements to its DMS policy. A collaborative approach with stakeholders is imperative to ensure public access to federally funded research outputs. AAU strongly urges NIH to consider the creation and maintenance of discipline-specific repositories and to address the need for financial support following the end of a grant in order to allow for greater compliance with open access and data management obligations.

In addition to the specific areas delineated within NOT-OD-23-091, AAU suggests Other areas for further engagement in NIH's DMS policy: (1) longer-term costs of data to researchers and universities, (2) data interoperability challenges, (3) more clarity on researcher compliance guidance, and (4) the broad definition of "scientific data." AAU looks forward to additional opportunities for discussion.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/AAU-comments-NIH-RFI-Public-Access-to-Research-April-2023.pdf>

Description:

Email: lizbet.boroughs@aau.edu

Submit date: 4/24/2023

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

Name: Beth Mathews-Bradshaw

Name of Organization: The Alliance for Aging Research

Type of Organization: Patient advocacy organization

Role: Patient advocate

- 1. How to best ensure equity in publication opportunities for NIH-supported investigators.**
- 2. Steps for improving equity in access and accessibility of publications.**

The Alliance for Aging Research agrees with removal of the 12-month embargo period. Accessibility to articles when first published is vitally important to patients affected by disease, particularly those relying on new research for effective therapeutics. It is also important to note that if the data is being referenced in publicly available news articles, e.g. The New York Times, patients affected by that disease should be able to access data that is the result of trials funded with taxpayer dollars. The Alliance would also like to see greater use by publishers, with access through PubMed, of allowing a free copy to patients for articles still under embargo, such as Elsevier does with its Patient Access program.

- 3. Methods for monitoring evolving costs and impacts on affected communities.**
- 4. Early input on considerations to increase findability and transparency of research.**

The Alliance for Aging Research notes that the PubMed website is not easily used by the layperson. The FAQs and user guide sections are extremely long. The section on MeSH Terms is incredibly dense. That said, it is not hard to get search results; it is harder to know that you are getting the best results. The Alliance believes a less technical user guide specifically for the layperson would be helpful. Examples of searches illustrating how to focus results would also be beneficial.

Email: bbradshaw@agingresearch.org

Submit date: 4/24/2023

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

Name: Carter Alleman

Name of Organization: American Society for Pharmacology and Experimental Therapeutics

Type of Organization: Professional org association

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Item III.D.1 notes “NIH intends to develop supplemental information that elaborates on and clarifies allowable costs for publication, consistent with these conditions.” ASPET encourages NIH to include that such supplemental information covers all allowable paths for charging publishing costs, including from indirect costs and Other University general or restricted funds. ASPET also encourages NIH to include in this guidance coverage for all costs, such as open access fees, page charges, and submission fees among Other costs.

Inequities in the publishing world already exist, with those researchers at larger universities having the benefit of administrative support and scale in terms of libraries, while those in underserved areas and populations do not have the level of support at institutes to assist them with publishing. NIH should allow all avenues to be available for publication and should not limit how a grant is to be used for publications. Whether this will require an increase in the grant amount, or NIH including publication costs within the grant, is a matter for future study by NIH. However, if NIH has the goal to increase publications from these communities, NIH needs to make all efforts available and provide maximum flexibility.

NIH should also allow for flexibility and choice for both the authors and publishers in publishing research so that the appropriate reuse of articles can be determined by the author and publisher. ASPET encourages NIH to permit CC BY-NC license options that allow for the free reuse of content by the public (in line with the goals of NIH) but not for commercial purposes.

2. Steps for improving equity in access and accessibility of publications.

Scholarly societies, such as ASPET, are a unique partner in this area of improving equity in access and accessibility of publications. Operating simultaneously in the scientific enterprise, in education, and in business, societies can pull best practices and implement them across multiple sectors at once. However, financial support for equity efforts is lacking. With proper funding, scholarly societies would be ideal partners to improve equity in access and accessibility. Examples of practical steps that could be taken more broadly include plain language summaries, alt text for images, creating more videos, working with media on news stories, and engaging through social media. Societies are also well-situated to develop educational materials and facilitate training to support researchers and the broader diverse community on improving communication around the scientific process and a specific field of science. To facilitate this, resources from NIH could be specifically allocated to address the financial need for domain-specific experts, including scholarly societies.

3. Methods for monitoring evolving costs and impacts on affected communities.

ASPET recommends that NIH not monitor publication fees, which could lead to a system that favors quantity over quality. Any “one-size fits all” pricing structure which is the logical result of this type of monitoring does not enhance the publication’s quality; it just streamlines the bookkeeping.

While there might be an interest in monitoring whether funded researchers are requesting more total resources in the direct versus indirect portion of the grant and resultant changes in awarded amounts over time, this would be challenging to monitor without an effective baseline. The determination of the baseline will shift as this Policy is implemented as there should be more articles published and discoveries occurring with more public access. While there are also the dangers, such as AI produced manuscripts and paper mills, that will need to be guarded against, that will also shift future baselines. Ultimately, NIH should allow the marketplace and competition between publishers to determine the reasonable publication costs.

If NIH feels there needs to be more publication avenues, there could be further discussion. However, if NIH’s goal is to increase those affected communities’ publication rates, NIH should work with its scientific societies to improve resources and education to allow those impacted to publish in existing journals.

Monitoring equity in funded grants will be important, as is understanding where and how the system is developing and evolving. To obtain a snapshot of the current environment and assess impact of policy changes, NIH could compare the total, median, and mean number of publication fees in the direct portion of grants for different stakeholder groups over time and as a percentage of total published articles funded by the agency.

4. Early input on considerations to increase findability and transparency of research.

ASPET supports NIH’s commitment to engage with existing identifier infrastructure and standards already in use across many scholarly societies. Requiring ORCID (Open Researcher and Contributor ID) for the corresponding and/or submitting author has been seamless for integration into societies’ manuscript submission, peer review, and publication systems; requiring ORCID for all co-authors has posed more challenging but is improving with time. ASPET supports NIH adoption of a DOI (Digital Object Identifier) overlay on existing grants; this activity could foster a more connected ecosystem of grants, publications, and data.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/ASPET-NIH-Public-Access-Plan-RFI-Response.pdf>

Description: ASPET Official Comment

Email: calleman@aspet.org

Submit date: 4/24/2023

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

Name: Kelsey Badger

Name of Organization: The Ohio State University

Type of Organization: University

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

While we support the prioritization of public access that is inherent in the removal of embargo periods, we encourage the NIH to evaluate the increase in administrative burden this shortened timeline will place on institutions and their researchers when reporting article compliance in a timely fashion. We recommend that the NIH proactively establish additional agreements with publishers that will streamline the automatic deposit to PubMed Central.

Inequities in publishing opportunity can apply to both scholarly publication and research data. While we applaud the NIH's support of established data repositories under the DMS policy, we are concerned that gaps in existing repository infrastructure create inequities in some researchers' ability to comply with this expectation. In particular, the repository options for sharing sensitive human subjects research data are limited and often require a substantially higher cost than the options available for data that can be made openly available. The NIH has previously demonstrated leadership in developing the capacity of research data repositories, most notably through its support of the Generalist Repository Ecosystem Initiative. We encourage the NIH to continue this leadership by evaluating infrastructure gaps for the sharing of human subjects data and exploring opportunities to fund the development of the needed repositories.

We also recommend that the NIH clarify acceptable adjustments to data sharing timelines in the case of pending intellectual property claims. The lack of clear guidance on this issue places an undue burden on researchers who are making a good faith effort to comply with the DMS Policy.

2. Steps for improving equity in access and accessibility of publications.

The influx of publicly available research data under the NIH DMS Policy will create new opportunities for the development of interactive tools, lesson plans, and Other educational scaffolding that make data more accessible to the general public. We recommend the NIH collaborate with Other federal agencies to fully explore these opportunities for enhancing scientific and data literacies. Instructive examples include My NASA Data and the USGS Youth and Education in Science (YES) office.

3. Methods for monitoring evolving costs and impacts on affected communities.

We support the monitoring of article publication charges (APC) that are passed on to authors and propose that the NIH also consider extending this monitoring effort to the deposit fees that are assessed by research data repositories.

In both cases, we encourage monitoring efforts that do not rely exclusively on budget data from awarded studies. Because additional funding has not been allocated for managing data and sharing

research outputs, researchers may prioritize the use of data and article repositories that do not assess fees. As a result, the budget information from awarded studies may provide the misleading impression that preservation and public access do not require additional funding.

We strongly recommend increasing funding thresholds to account for the added costs of high-quality data management and sharing. When researchers are incentivized to find the lowest cost option for sharing data, they may not consider Other factors that are important in selecting a repository, such as whether data is curated to enhance discovery and potential for reuse.

This is a particularly critical issue when the data includes human subjects. Sufficient funding must be available for any and all necessary protections, including expert support for de-identification and the fees associated with repositories that offer disclosure risk assessment, mediated/controlled access, and the processing of legal documents such as data use agreements. It compromises the privacy and confidentiality of research participants to expect data sharing without fully funding these costs.

4. Early input on considerations to increase findability and transparency of research.

We applaud the supplemental funding the NIH awarded in 2022 to help existing NIH-funded data repositories increase their alignment with the OSTP Desirable Characteristics for Data Repositories. We recommend that additional cycles be considered. Moreover, we encourage the NIH to undertake an agency-wide audit of the current compliance of NIH-funded repositories with these characteristics. It is especially important to evaluate the extent to which NIH-funded repositories are currently using DOIs or comparable PIDs and to accelerate the adoption of this practice, which is essential to data discovery.

We encourage the NIH to collaborate with Other federal agencies in exploring the use of Machine Actionable Data Management Plans (maDMPs) as a strategy for increasing the findability and transparency of research outputs. Public presentations by the Research Data Alliance (RDA) have demonstrated how maDMPs can serve as important linking agents between existing systems for persistent identification of publications, datasets, authors, and institutions.

Submit date: 4/24/2023

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: Professional org association

Role: Member of the public

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/AAP_Response_NIH_RFI_NOT-OD-23-091_04242023.pdf

Description: PDF of Association of American Publishers Response to NOT-OD-23-091, Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research

Email: cmaxwell@publishers.org

Submit date: 4/24/2023

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

Name: Mary M. Langman

Name of Organization: Medical Library Association & Association of Academic Health Sciences Libraries

Type of Organization: Professional org association

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The complexity of the current process for depositing publications requires significant infrastructure, training, and time that often falls on the lowest paid employees at major research institutions, especially administrative assistants, grant coordinators, and librarians. While this is already an undesirable effect of the policy on staff members at research institutions, the basic existence of these support positions privileges investigators at large research institutions over smaller institutions that primarily serve rural populations and communities of color. This is harmful to the research landscape as these constraints make it even harder to perform research that meets the needs of vulnerable populations. It is in the best interest of the scientific community and the NIH to limit the complexity of processes that fall to investigators and their support staff, but instead leverage or mandate the resources of publishers. Managing this complexity should be of primary concern when executing Section III.A.3.b.

Also see attached file.

2. Steps for improving equity in access and accessibility of publications.

The NIH can improve equity in access and accessibility of publications by mandating that NIH-funded research be openly licensed for reuse, through a license such as CC-BY (Creative Commons Attribution), which unambiguously enables a variety of re-use possibilities and allows authors to retain rights to their published work. This would concretely clarify issues raised in section III.C.1, while relying on already existing legal infrastructure. Language surrounding this issue should be clear, so as to prevent publishers from taking advantage of CC-BY licenses by requiring authors to transfer their copyright to the publisher prior to assigning a CC-BY license, which is currently the practice for many publishers.

Also see attached file.

3. Methods for monitoring evolving costs and impacts on affected communities.

There also seems to be significant confusion about the difference between Public Access and Open Access and the ultimate goal of the NIH Public Access Policy. MLA and AAHSL recommend that the NIH clarify that while article processing charges are allowable costs for NIH awards, there are multiple options for meeting public access requirements, and gold open access publishing is only one of them. MLA and AAHSL agree with several elements of the Ivy Plus Libraries Confederation's comments (<https://ivpluslibraries.org/2023/03/iplc-letter-to-the-office-of-science-technology-policy/>) on the Office of Science and Technology Policy's 2022 Memorandum, in particular their points about avoiding over-reliance on article processing charges and the importance of establishing a research dissemination infrastructure that is not the product of commercial publishing interests.

Also see attached file.

4. Early input on considerations to increase findability and transparency of research.

MLA and AAHSL call for the development of a robust infrastructure to ensure that NIH supports the findability of research data, potentially separate from PubMed Central, in particular the development of a single search tools to find datasets across multiple repositories. This single search could take advantage of the “Associated Data” field currently available for articles, while allowing data to be searched for directly, rather than publications that have associated data. bioCaddie’s dataMED (<https://datamed.org/about.php>) is an example of the kind of NIH-supported search interface that would be especially useful, or potentially expanding the scope of the new NCBI Datasets interface (<https://www.ncbi.nlm.nih.gov/datasets/>) beyond genetic data.

MLA and AAHSL agree with and affirm the need for a DOI-equivalent for data, and for an infrastructure that easily links datasets to published articles consistently. NLM already has an ecosystem for linking citations (PubMed) to full text (PubMed Central); we recommend that NLM add another layer to link both of those to deposited data. Key to these efforts is the consistent use of standard identifiers across research disciplines, and the establishment of standard methods for citing datasets.

Also see attached file.

Also see attached file.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/2023_MLA-AAHSL_comments_NIH-pub-access-plan.pdf

Description: Medical Library Association and Association of Academic Health Sciences Libraries complete set of comments Re: Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research

Submit date: 4/24/2023

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

Name: Andrew Bostjancic

Name of Organization: Taylor and Francis Group

Type of Organization: Other

Type of Organization-Other: Academic Publisher

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

T&F is committed to delivering a range of publishing options and content types that are inclusive, holistic and provide opportunities for researchers working across career stages and disciplines. We are keen to continually develop approaches to ensure equity and diversity in publication opportunities and we know that this requires input and collaboration between multiple stakeholders from across the scholarly ecosystem. Specifically, it requires publishers to help researchers and more marginalized communities across career stage by providing training to navigate the publishing landscape - and understand the options available. It requires funders to investigate their processes for grant selections, so that grant opportunities are not exclusively awarded to the same highly resourced researchers and institutions. University efforts to expand opportunities through institutional grants can help to reduce inequities and provide a diversity of voices. Collaborative commitment to tackle the challenge of increasing equity from diverse stakeholders ensures that all knowledge makers are given the opportunity to contribute, irrespective of race, ethnicity, gender, geography, language, discipline, or funding source. NIH can be a leader in convening these stakeholders to help discuss ways to broaden equity.

T&F is committed to equity in publication opportunities and has taken the following steps to answer this call to action.

T&F offers over 300 dedicated OA journals, and more than 95% of our venues offer an OA pathway. We work with authors to find the best home for their work. Across our portfolio we also offer an increasing number of tailored fully open access publishing venues which increase the opportunities for researchers to publish research outside of more selective venues, and ensures that regardless of the results (e.g. negative, null, incremental research), there is an outlet for researchers to make their findings discoverable and accessible to all. This includes our 'open research' publishing venues provided by F1000. The F1000 publishing model combines the speed of preprints with the benefits of full publication. This includes functionality that ensures the robustness, quality, and transparency of research using rigorous editorial checks, open data, and invited open peer review. Authors are given autonomy throughout the entire publishing process.

Publishing venues that operate on this basis help to remove the barriers to publication that many researchers face, particularly early career researchers, and are entirely aligned with the DORA principles. T&F is signed up and committed to the DORA declaration, the Managing Director of our imprint F1000, is a member of DORA's Board of Advisers - and through this we are developing ways to support

researchers across all career stages and disciplines to share the outputs of their research in more transparent and accessible ways.

In addition to providing more trusted and reputable routes for researchers to publish their work, our role as a publisher is to support initiatives to build capacity and skills to help deliver trust and value in the research we receive and publish. An example of this is when in 2019, T&F launched the 'Excellence in Peer Review: Taylor & Francis Reviewer Training Network'. This aims to provide clear practical advice to researchers to improve the quality of their reviews and introduce the key principles to early career researchers and researchers from under-represented groups. This initiative encourages greater inclusion and participation in peer review.

We support the initiative for Transforming Institutions by Gendering contents and Gaining Equality in Research (TRIGGER). This aims to understand and address the causes behind under-representation of women in Science, Technology, Engineering, Mathematics, and Medicine (STEMM) subjects.

We were also the 2021 publisher winner of ABC International Excellence Award for Accessible Publishing, recognized by the Award's judges for an "innovative approach to alternative text for images, graphs, and diagrams."

T&F believes in the importance of public access to amplify and communicate research that delivers change and improves lives. We would like to encourage the NIH to collaborate actively with publishers to ensure we are positioned to provide the services that are needed to drive equity and access to research.

Question 1 Recommendations

1. Convene a cross-stakeholder discussion/s to refine NIH's requirements and ensure implementation of the plan in the most optimum way to deliver equity.
2. Continue active collaboration with the academic publishing community to elicit feedback on the implementation of the plan - and provide a route for us to share the global and disciplinary specific feedback we receive around access and equity issues.

2. Steps for improving equity in access and accessibility of publications.

Ensuring all functionality and content is accessible to all people is a laudable ambition. Developing clear guidelines for formatting with a focus on accessibility will improve access for everyone. One of the primary roles of publishers is to transform content from authors into a final product through typesetting and copyediting. This labor-intensive effort alongside the creation and sharing of article metadata is critical for making content machine readable and discoverable.

Across the company, T&F is developing new formats and tailored views of research that are designed to support access, use, and reuse of research. One of the emerging tools is the implementation of Plain Language Summaries (PLSs). These additional abstracts allow us to succinctly summarize the key points from a piece of scientific research to a non-technical audience. Creating PLSs tailored views of content is an important way to increase access, engagement in research content and findings to the various communities and stakeholders who are the ultimate users of research, including policymakers, students, educators, and the public.

Through our society partners, funders and Other expert community links, we have a wealth of experience in developing research access and dissemination strategies and solutions. By collaborating alongside knowledge creators and federal agencies, publishers can create models and formats that are designed to deliver the requirements of our stakeholders. Emerging scientific innovations require training for authors to remain at the forefront of their fields. T&F works alongside our expert academic editors and societies and we have a depth of experience in providing research communication, sharing, and dissemination training to researchers across the career stages and across disciplines e.g. How to manage and share data; How to publish for reach and impact; How to peer review effectively. We are willing and able to support the NIH in providing training to its various cohorts of grantees.

We provide guidance and best practice to our authors and editorial boards to ensure that content is published with adherence to various accessibility standards. For example, we have in-house experts who can provide authors with a guide to alternative text so that they can provide the best descriptions. We also provide content in a variety of formats including PDF, ePub2, ePub3, and HTML formats to expand equity and accessibility. T&F has adopted this practice and works to provide a suitable format - we provide these formats on request from individuals and institutions.

In 2022, T&F brought on our first Accessibility Officer to provide oversight, coordination, guidance, and leadership to the organization's Accessibility Working Group. This addition has already provided the organization with a more effective and efficient accessibility strategy. If not done so already, the NIH could consider appointing staff resources with specific remit and responsibility for ensuring accessibility.

Question 2 Recommendations

1. Provide training to grantees on key aspects of how best to communicate and disseminate research in ways that ensure compliance of NIH requirements. Ensure awareness of best practice and standards to support discoverability and access.
2. Collaborate with publishers to develop more tailored research use-focused findings and output - to maximize the potential for research to reach its target audience/s.
3. Create guides encouraging the use of alternative text for visual or print impaired individuals.
4. Appoint staff resources to support NIH Accessibility requirements.

3. Methods for monitoring evolving costs and impacts on affected communities.

T&F acts as a responsible steward with the funds we receive from researchers in return for the publishing services that we provide. Our role is to preserve academic freedom and provide routes to share, disseminate, and deliver impact from research. We provide options for researchers working across all career stages and disciplines to reach their intended audiences and their communities of interest and help build careers and research capacity. We do not support blunt measures and restrictions on where researchers can publish - instead preferring to develop solutions collaboratively to deliver sustainable publishing solutions that preserve academic freedom and choice, while maximizing the reach, access and potential impact of research.

When calculating prices for APCs, T&F aims to be transparent with our costs and mitigate inequities with our stakeholders. We continue to balance this transparency with market considerations and remain compliant with U.S. antitrust price fixing laws. List price APCs across T&F journals range from US \$600 to

US \$4,800. The list price APC is reviewed at least annually across journals and varies across several factors, including:

Funding available for the journal: this varies by discipline. Additionally, some journals are supported through grants, typically from their owning society, meaning charges are subsidized.

Impact: highly selective journals typically charge higher APCs. The APC on the accepted article also covers the work and analysis put into rejected content.

Discipline: we set APCs based on funding patterns within the field, as well as benchmarking against APCs on related journals to ensure that rates are realistic and equitable among communities.

Demographics of submissions / publications: considering the geography of submissions allows us to price fairly to market.

The type of research output: shorter article types and non-traditional formats typically incur lower APCs.

It should be noted that many customers do not pay the list price APC, benefitting from flexible funding options including:

- Discounts of up to 100% where a professional member association or learned society provide additional support.

- Discounts due to their organization's participation in a membership scheme or transformative agreement, which usually allow researchers to submit without any individual payment on their part.

T&F is committed to cost transparency and providing our published authors with world class services so that their work can have the greatest impact on society.

Recommendations Question 3

1. Empower authors to make the decisions for disseminating their research.
2. Provide training materials for authors and grant managers to collaborate on finding the best route to publish.

4. Early input on considerations to increase findability and transparency of research.

We are entirely aligned to support any push that the NIH has in promoting the use and integration of persistent identifiers (PIDs), research descriptors, and metadata into grant and publishing workflows.

PIDs and associated metadata are the essential foundation blocks to enable the discoverability and access of research and its findings. Like many publishers, T&F is a member of Crossref and ensures high quality metadata around all the research it publishes; we are also building our capabilities for inclusion of funding and grant data associated with articles by utilizing the Crossref Funding Registry.

Several funding agencies are also now members of Crossref (e.g. Wellcome) and register DOIs for all their awarded grants. By assigning a PID (e.g. a DOI) to its grants, the NIH would provide an identifier that can be captured by publishers in the article submission workflow and thereby allow grant output connections to be made and greatly simplify impact-related (and ROI) tracking for the NIH.

Adding grant IDs would add new information into this network of PIDs and provide increased transparency and create the possibility for robust ROI calculations for funders. This wider network of PIDS would include:

- Researcher IDs - e.g. ORCID
- Institution IDs - e.g. ROR or Ringgold
- Funder IDs - e.g. FundRef
- Project IDs e.g. RAID
- Research object IDs e.g. DOIs for publications, data, preprints, code and Other outputs

Adding all (or a selection) of these PIDs into the metadata of research articles and objects stored in Other online locations (e.g. data repositories) will ensure progress to a more machine-readable ecosystem to enable analysis and ROI for funders. Most of the PID issuing agencies - ORCID, Crossref, Datacite, RRIDs - operate on a not-for-profit basis and are the commonly used standards across the research system. To support the simple capture of relevant research and researcher meta-data in its grant workflows, we recommend the NIH consider:

- Providing integrated links
- Drop-down lists
- APIs to Other websites

Recommendations Question 4

1. Align with Other funders to assign common PIDs for NIH grants - consider using the established framework provided by the Crossref Funding Registry.
2. Utilize current and prevalent PID infrastructure where possible to avoid creating additional learnings (and need for interoperability building) for researchers.
3. Adopt researcher-centered practices to capture key descriptive information - using auto-complete/ integrated links, drop-down lists, and APIs to Other websites to keep simple, avoid manual entry, and ensure accurate completion; include PIDs assignment for grant-related information in existing NIH systems/those used by its researchers where possible.
4. Monitor and adopt industry and global standards and best practices where applicable.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/TF-NIH-Public-Access-Plan-RFI-Comments.pdf>

Description: Full comments plus additional compliance clarification request

Email: andrew.bostjancic@taylorandfrancis.com

Submit date: 4/24/2023

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

Name: Holly Sue Zullo

Name of Organization: Huntsman Cancer Institute

Type of Organization: University

Role: Institutional official

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/HCI-Response-to-NOT-OD-23-091.docx>

Email: holly.zullo@hci.utah.edu

Submit date: 4/24/2023

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

Name: Jennifer Regala

Name of Organization: American Urological

Type of Organization: Professional org association

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Responses to this question, as given by the collective letters the American Urological Association (AUA) signed as detailed in our introduction letter (attached as a PDF to the RFI), state our position well and in detail. The AUA does want to emphasize these very important points:

- Peer review adds value to our high-impact research. Our flagship journal, The Journal of Urology®, is more than 100 years old, and is highly regarded in urology and in medicine at large. This peer review comes with a high financial and intellectual cost, and we ask that the NIH consider this considerable investment by the AUA when studying financial realities of implementing Open Access policies.

- We widely and generously distribute our research despite subscription paywalls. Non-subscribers around the world have a plethora of ways to absorb our research in a multitude of valuable formats, from podcasts to social media to author-written insights of articles.

CMSS has asked, and we echo this request, for a 2-year delay to the mandate so all stakeholders can work together to develop sustainable policies focused on reliable, equitable, high-quality scientific content. We agree with and want to reinforce an important point in the CMSS letter:

“Policies that restrict publishers’ abilities to collaborate with authors to realize their protection of rights under United States copyright law would further limit revenue streams on which we depend, including royalties, licensing, reprints, and advertising. We urge the NIH not to include rights retention language or license requirements in the final policy Other than the grantee’s right to deposit the manuscript. Preserving a Green OA route presents a sustainable business model that should be embraced. Expanding rights retention policies beyond the deposition of the manuscript would also erode the publisher’s ability to monitor usage of the content in support of the author’s intellectual property.”

2. Steps for improving equity in access and accessibility of publications.

- We agree with the fundamental importance of accessibility to premiere urological AUA research publications. Green Open Access remains a viable solution to this question of access.

- We do innovate in deliverability and accessibility of our content as a main goal of each of our publications.

- We strive to deliver our content in a way that eliminates or at least avoids dissemination and promotion of misinformation, which we believe will be diminished if “open” research is posted without context and/or curation.

3. Methods for monitoring evolving costs and impacts on affected communities.

It is undeniable that the AUA works tirelessly to publish the most rigorously peer-reviewed, impactful urological research. We also make every effort to provide the ability to reproduce the outputs we publish.

We highlight another crucial point from the CMSS letter we signed: “It is also worth noting that requiring all publishers to supply financial information in pursuit of fixed pricing conflicts with fair trade.” The AUA’s position is that any monitoring should be done by market because of the variances.

4. Early input on considerations to increase findability and transparency of research.

In principle, the AUA agrees with the importance of discoverability and transparency of research. In practice, though, we need to work with our extensive scholarly publishing community - researchers, librarians, vendors, society publishers, commercial publishers, government representatives, and beyond - to build the infrastructure that will support all affected entities. The future of research depends on slow, deliberative collaboration to adopt the changes that will advance science in the United States and across the world.

To emphasize the CMSS letter: “As the medical and research community collectively work to increase the public’s trust in health and science, these proposed changes could unintentionally foster misinformation.”

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/NIH-OA-RFI_AUA-Response_April-24-2023_FINAL.pdf

Description: The attached letter is the American Urological Association’s official response to the NIH RFI. Each RFI question is also answered individually in the above response boxes.

Email: jregala@auanet.org

Submit date: 4/24/2023

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

Name: Jennifer Griffiths

Name of Organization: Springer Nature

Type of Organization: Other

Type of Organization-Other: Publisher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Summary: To ensure equity in implementation of both publishing and open data aspects of the NIH Public Access Plan, NIH-supported investigators need the resources to support and enable their choice of compliance route.

Ensuring equity in publication opportunities for NIH-supported investigators means ensuring that every investigator, regardless of field, career stage, grant size, gender, ethnicity and institutional affiliation, has the resources available to them to choose where to publish and the route for compliance that enables that choice.

The plan in its current form allows compliance through either deposition of the “final peer-reviewed manuscript upon acceptance” (III.A.3.a. - i.e. “Accepted Manuscript” submission without any embargo / zero embargo green OA) or final published article submission (III.A.3.a. - i.e. submission of the “Version of Record” / gold OA). Most journals in which NIH investigators currently choose to publish - including our own - support only one of these two routes: Gold Open Access - where the Version of Record is made freely available at publication.

By contrast, most journals and their publishers do not support the zero embargo green OA route - where an unfinished Accepted Manuscript is made openly available at the same time that the Version of Record is published. Such a model is simply not sustainable: it undermines the subscription model that supports it and slows progress towards the sustainable and scalable options for public access that gold OA enables. Gold OA is the only sustainable model for trusted open access. So, to best ensure equity in publication opportunities NIH must make sure the funding is in place to support any NIH investigator that might wish to publish in journals which only support the Gold OA route.

Our work has also shown that authors complying through the Gold OA route are likely to achieve greater reach and impact for their papers than if they had elected for compliance via the Accepted Manuscript route. This dichotomy has the potential to exacerbate existing inequities between NIH-fundees and/or create new ones. Researchers that are less well-funded (which is more common for early career researchers, those in fields with small grant sizes, and those at minority-serving institutions or HBCUs) can be further disadvantaged because they are more likely to have to comply via zero-embargo Green, missing out on the impact and reach of gold OA .

The zero-embargo Green access approach is also unsustainable since it prevents maintenance of subscription income to pay for the costs and work of publishing. So ultimately it is essential that sufficient funding is made available to pay for reasonable APCs for Gold OA publication. The calls on NIH funding can be minimized where such funding is pooled with University library budgets via

Transformative Agreements (TAs). Ultimately to achieve a full transition to sustainable open access there needs to be a way to align and maximize use of available funds to spread the load. TAs don't solve all sustainability and equity issues but, by combining funder and library funds, they are a strong step in the right direction ... one that has proven to be a scalable solution that substantially reduces the administrative burden on researchers. Regardless of whether NIH grant funds are used to contribute to centralized TAs or to support author-mediated payments to enable Gold OA, the NIH needs to budget for, and monitor, such costs.

Specifically, we recommend that to avoid creating new inequalities or exacerbating existing ones during this transitional phase NIH should ask grantees to include an estimate of reasonable publishing costs for articles arising from the grant as a standard budget line item.

This approach will ensure that authors that are planning to comply via Gold OA will have requested sufficient funds to cover reasonable APCs. It will also enable NIH to better monitor and track potential inequities arising from, or being exacerbated by, differences in impact between the two different compliance routes.

We are aligned with STM's recent position statement regarding zero embargo Green OA / "Rights Retention Strategies" and their response to NIH's RFI. In particular we support the argument that many journals need exclusive publishing rights to support sustainable business models and continued investment. Our longstanding position on this topic is clear: mandatory obligations being placed on grant fundees (already overburdened with compliance obligations), to openly license unfinished versions of their papers put them in a difficult position, undermine progress towards full sustainable public access for research papers and force publishers to maintain paywalls and defend subscription revenue.

To demonstrate their commitment to maintaining researchers' free choice about where to publish, as well as the integrity and independence of the QA processes that publishers implement, NIH should not place any such burden upon the researchers it funds.

The scientific data requirements of the NIH Public Access Plan also put a substantial compliance burden on NIH-supported investigators. Publishers are ideally placed to support requirements to make scientific data "freely available and publicly accessible by default at the time of publication" through policy and infrastructural support for integration of machine readable persistent identifiers (PIDs). However, as for achieving equity in publishing opportunities, to achieve full open data compliance will require sufficient support to be put in place for every investigator, regardless of field, career stage, grant size, gender, ethnicity and institutional affiliation.

2. Steps for improving equity in access and accessibility of publications.

Summary: To improve equity in access and accessibility of publications NIH needs to monitor and maximize the proportion of NIH-supported publications complying through Gold OA.

Gold OA maximizes access not only by enabling free online access to humans and machines but also by enabling re-use, re-formatting, aggregation, and Other procedures to make the content discoverable, accessible and usable by diverse communities according to their specific needs. The Version of Record, which Gold OA makes accessible, is the complete, authoritative and up-to-date version of the paper,

curated and maintained by publishers and editors. Our work shows that researchers prefer the VoR over the unfinished Accepted Manuscript, both as readers and authors.

So there are significant disadvantages for those that do not have access to the VoR. Therefore to maximize the equity benefits as the NIH Public Access Plan is implemented it is important that the proportion of compliance through Gold OA is maximized and monitored. The full equity benefits of the NIH Public Access Plan can only be realized when there are no paywalls around any NIH-supported VoRs. Until then less-well resourced researchers and, more importantly, a large proportion of the US public, including many clinicians, public health officials, students and educators, will only have access to unfinished inferior versions of any papers that have complied with the plan via the zero embargo Green route.

Given this: we recommend that NIH should include an explicit preference / encouragement for compliance via Gold OA in its guidance for researchers, as for example included in the FAQs for the NASA policy for the Science Mission Directorate

3. Methods for monitoring evolving costs and impacts on affected communities.

Summary: To monitor costs and impacts of the NIH Public Access Plan, the NIH should, where possible, work with institutions and their libraries to leverage Transformative Agreements and Other equivalent centralized payment arrangements. Differences in impact between green and Gold OA compliance paths and their knock-on effect on equity should be monitored.

The only sustainable publishing model requires payment of publication fees (APCs) so there should be guidance to grantees that these need to be estimated and included in their applications. The funding burden on NIH for these can be minimized if grant money is pooled with University library money and this is best achieved via Transformative Agreements (TAs). These TAs can then be used to monitor and report on these costs to universities and funders like the NIH.

TAs don't solve all sustainability and equity issues but, by combining funder and library funds, they are a strong step in the right direction that has proven to be a scalable solution that substantially reduces the administrative burden on researchers. Regardless of whether NIH grants are used to contribute to centralized TAs or to support author-mediated payments to enable Gold OA, the NIH needs to budget for, and monitor, such costs.

Our work has shown that authors complying through the Gold OA route are likely to achieve greater reach and impact for their papers than if they had elected for compliance via the Accepted Manuscript route. This dichotomy has the potential to exacerbate existing inequities between NIH-fundees and/or create new ones. Researchers that are less well-funded (which is more common for early career researchers, those in fields with small grant sizes, and those at minority-serving institutions or HBCUs) can be further disadvantaged because they are more likely to have to comply via zero-embargo Green, missing out on the impact and reach of Gold OA .

Therefore we recommend that differences in impact between green and gold OA compliance paths and their knock-on impact on potentially disadvantaged NIH-investigators should be quantified and regularly reported.

4. Early input on considerations to increase findability and transparency of research.

Summary: Publishers are key partners in deploying and integrating metadata and PIDs to enable a more efficient, transparent and impactful open science ecosystem

Publishers are ideally placed to support increasing findability and transparency of research through policy and infrastructural support for integration of machine readable persistent identifiers (PIDs).

We would welcome the chance to work through with NIH the most beneficial PIDs and metadata and their use cases. These are some of the PIDs and metadata we are already including in our publications:

DOI (Digital Object Identifier) for outputs/publications, i.e. eBooks, ejournals, journal articles and chapters

ORCID (Open Researcher and Contributor iD) for persons, i.e. authors and editors

Crossref Funder ID for grant-giving organizations

GRID ID (Global Research Identifier Database iD) and ISNI ID (International Standard Name Identifier) for research organizations/affiliations.

Grant Numbers: we collect “Grant Numbers” and incorporate them in our metadata that is also deposited at Crossref

Conference Series ID

Clinical Trial ID

Article, Issue Copyright Holder

Article, Issue Copyright Year

Keywords

Registration, Received, Accepted, Issue Online Dates

Article Citation ID

We also actively contribute in multiple ways to cross-industry efforts in this area through STM, Crossref, ORCID, CHORUS (for example our participation in the CHORUS/CSIRO pilot on research resources and facilities) and Others.

We recommend that NIH works closely with publishers in general, and particularly these pre-existing cross-industry organizations, to maximize the impact of the revised plan for PIDs and metadata.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/Springer-Nature-NIH-RFI-response-FINAL.pdf>

Description: Fulltext with links and additional points

Email: jennifer.griffiths@us.nature.com

Submit date: 4/24/2023

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

Name: Roy Kaufman

Name of Organization: Copyright Clearance Center

Type of Organization: Other

Type of Organization-Other: CCC is a not-for-profit organization founded in 1977 at the suggestion of Congress to facilitate collective copyright licensing for the text sector.

Role: Member of the public

- 1. How to best ensure equity in publication opportunities for NIH-supported investigators.**
- 2. Steps for improving equity in access and accessibility of publications.**
- 3. Methods for monitoring evolving costs and impacts on affected communities.**
- 4. Early input on considerations to increase findability and transparency of research.**

The following text, with attachments and links, has been uploaded in PDF format. For convenience, text is pasted herein as well. We recommend using the PDF version.

Response of Copyright Clearance Center (CCC) to Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research (RFI)

Notice Number:

NOT-OD-23-091

CCC welcomes the opportunity to submit this response to Question 4 of the NIH's Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research. More importantly, we welcome NIH's interest in the use of PIDs and metadata to increase findability and transparency of scientific research.

Background on CCC.

CCC is a not-for-profit organization founded in 1977 at the suggestion of Congress to facilitate collective copyright licensing for the text sector. Presently, among Other lines of business, CCC provides licenses to content from over 10,000 rightsholders for whom we serve as an agent. We provide these licenses to more than 35,000 business organizations (Business Users) around the world. CCC is a supplier of knowledge management software called RightFind®, which is used by a subset of these Business Users to manage and access content. We also provide (1) Other software services, (2) library staffing, (3) content enrichment, data and metadata services, and (4) content delivery. On October 19, 2021, U.S. Secretary of Commerce Gina Raimondo announced that we were awarded a Market Development Cooperator Program grant, administered by the Commerce Department's International Trade Administration, to support our work with standards development organizations.

Our fastest growing business is managing the agreement- and fee-administration process on behalf of publishers who collect fees or Otherwise track usage from authors, institutions, consortia, government and Other funding bodies for immediate open access (OA). We do this primarily through our RightsLink®

for Scientific Communications software platform (RLSC). RLSC is by far the market leader in managing open access agreements and payments, doing so for many of the top publishers of NIH-funded research.

PIDs and Metadata.

Through both our knowledge management work with Business Users and our work on behalf of publishers, CCC experiences firsthand the promise of persistent identifiers (PIDs) when applied early, consistently and persistently. We are also painfully aware of the problems related to the entropy that results from lack of early, consistent, and persistent application thereof.

A healthy research and publishing ecosystem requires PIDs and robust, rich, quality metadata to make connections among people, organizations, places, and digital objects. For example, in RLSC alone, we depend on dozens of author, institution, and manuscript metadata elements to apply the appropriate business logic and workflows necessary to automate and scale OA on the path toward open science.

Also, even within a seemingly unified sector such as scientific publishing, it is sometimes necessary to accommodate multiple PIDs serving the same purpose, such as organizational identifiers. While in some ways accommodating multiple PIDs increases work and decreases interoperability, PIDs have different scope, attributes, and audiences. Some users prefer PIDs with ISO certification, while Others prefer PIDs with established business models to ensure sustainability and maintenance, while Others focus on ability to use without cost to access PIDs. When one PID has been selected for use by a stakeholder as part of master data management, being forced to accommodate a different PID can have significant costs and introduce unnecessary friction. Accordingly at CCC, we accommodate a variety of organizational IDs in RLSC and have long preferred the features of Ringgold for our primary use.

Review of data quality of bibliographic records from the MEDLINE database

In 2022, three CCC colleagues reviewed the data quality of bibliographic records in the Medline database. A paper detailing the results of their research have been posted on bioRxiv and is attached to this document (Bramley, R, Howe, S, Marmanis, H 2022, Notes on the data quality of bibliographic records from the MEDLINE database, doi: <https://doi.org/10.1101/2022.09.30.510312>; hereafter, “Bramley, et al”). As noted in the paper:

[T]he PubMed database, which contains over 33.8 million records collected over many decades, suffers from several data quality issues. These issues relate to, in part, character encodings, the absence of persistent identifiers, differences in human languages, and schema changes. These shortcomings should not be surprising since PubMed aggregates information produced by different publishers and XML providers, a fact that leads naturally to the presence of “multi-source” problems.

Among the conclusions of the paper are (1) “[g]iven the incompleteness and uniqueness of identifying fields, the disambiguation of author names remains a significant problem for PubMed, particularly for records dating before 2014, and (2) [o]verall, there is an improvement in the use of identifiers; in particular, records created since 2015 exhibit an increase in external identifiers. However, the data quality for institutional identifiers is poor and their use has been diminishing over time.”

Mapping metadata management across the research lifecycle.

In late 2022, CCC and Media Growth Strategies undertook a thorough examination of metadata management across the research lifecycle. This review builds on an existing body of work to uncover

multiple system complexities and breakages, which - separately and together - create missed opportunities for the communities for whom OA and open science models are designed to serve.

CCC has made this information publicly available in interactive infographic form at <https://www.copyright.com/stateofmetadata/>, and we have attached a chart summarizing where metadata breakages occur throughout the research lifecycle and how they impact various stakeholder groups.. Drawn directly from research interviews, the infographic depicts the significant economic impact that a fragmented metadata supply chain is having today on researchers, institutions, funders, and publishers. Researchers in particular shoulder a significant administrative burden that ultimately disrupts and delays the process of scientific discovery.

The infographic is a living document which will be updated and modified based on ongoing community feedback.

As the scholarly communications community continues its shift to OA and open science, stakeholders require a robust network of interoperable systems for making critical and necessary improvements, and much progress is underway. In that environment, a dedication to data stewardship across each stakeholder group, and the service providers supporting them, will lead to greater data sharing; reliable, trustworthy metrics on research impact; and a responsive, equitable rewards system. NIH can lead the way.

Question 4 of the RFI states: "NIH seeks suggestions on any specific issues that should be considered in efforts to improve use of PIDs and metadata, including information about experiences institutions and researchers have had with adoption of different identifiers."

First, we recommend that NIH review the research, findings and recommendations set forth in Bramley, et al.

Second, NIH, as the premier funder of biomedical research in the US, is well positioned to help research and lead by example by requiring PIDs at appropriate points. As can be seen in the above-referenced infographic, grant application is one of the first organized parts of the lifecycle where PIDs can be effectively mandated. Once mandated and used, PIDs can flow throughout the lifecycle to improve everything from grant management to expression in PubMed. We urge NIH to review the infographic, sign up for updates, and provide feedback should NIH believe there are amendments and changes needed.

We have three specific recommendations with respect to mandated use of PIDs.

1. NIH should mandate that grant applications include organizations IDs for the institutions(s) affiliated with each researcher listed on the grant application, and Funder Registry IDs for the distinct funders of the grant. The requirement should insist that grant applications include at least one of the following organizational identifiers used in the scholarly publishing ecosystem and NIH should make metadata fields available for all four:

- A. Ringgold- a proprietary global organization identifier system owned by CCC with over 600,000 unique records and rich hierarchical metadata used today by (1) most large and mid-sized commercial and non-commercial publishers, and (2) a range of critical infrastructure providers in the publishing ecosystem. For publishers, Ringgold often is part of a master data management strategy. Ringgold is also used by

some funders, academic institutions, and consortia. Ringgold maps one-to-one with ISNI and the Funder Registry.

B. ISNI- ISO standard name identifier system with 1,697,000 unique organizational records of which a minimum of 500,000 are relevant to the research sector. ISNI is free to use and has been adopted by many national libraries. It lacks the hierarchical metadata of Ringgold but enjoys the rigor and authority of ISO accreditation. The relevant organization records in ISNI map one-to-one with Ringgold.

C. ROR- Research Organization Registry (ROR) is a global, community-led registry of open persistent identifiers for research organizations. ROR is free to use and has been adopted by some publishers, institutions, and overseas funders. It contains 104,000 unique identifiers and some hierarchical metadata. It can map to ISNI and the Funder Registry, but not on a one-to-one basis.

D. Funder Registry (formerly known as FundRef) -Funder Registry is an open registry of grant-giving organization names and identifiers, with 32,000 unique identifiers for funders. It is donated by Elsevier to CrossRef and is updated approximately every 4-6 weeks. The Funder Registry ID can be used for author affiliations where the funder and affiliation are one and the same.

2. NIH should mandate that grant applicants include one or both of the following individual identifiers for all researchers in grant applications, and NIH should make metadata fields available for both.

a. ORCID- ORCID, which stands for Open Researcher and Contributor ID, is a global, not-for-profit organization sustained by fees from member organizations. ORCID is the most broadly adopted identifier system for individuals in scientific publishing.

b. ISNI- While not as well adopted as ORCID in research and science, ISNI has been broadly adopted in adjacent and non-adjacent fields.

3. NIH should mandate that appropriate PIDs be used at each stage reporting, while remaining flexible as to which PIDs it mandates, and should reevaluate its mandated PIDs on an ongoing basis. New PIDs such as RAiD (Research Activity Identifier) and DataCite (DOI-based system for research outputs) are being developed regularly and can help connect people, places and research. Likewise, Other existing PIDs such as, e.g., Scopus Affiliation ID (AF-ID) and Author ID (AU-ID) are currently used in certain relevant applications. Appropriate PIDs should be mandated at each stage of the workflow, while recognizing that the needs of researchers and the availability of PIDs change over time.

As a final recommendation, we suggest that NIH follow the lead of Wellcome Trust and the Bill and Melinda Gates Foundation, among Others, in registering grants for DOIs. This will help enable connectivity of PIDs and the discoverability of the grants, maximizing return to US taxpayers.

Respectfully submitted for Copyright Clearance Center by,

Roy S Kaufman

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/NIH-RFI-with-attachments.pdf>

Description: The attached PDF contains our full response with attachments and links.

Email: rkaufman@copyright.com

Submit date: 4/24/2023

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

Name: Lisa Braverman

Name of Organization: American Society for Radiation Oncology

Type of Organization: Professional org association

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

At the American Society for Radiation Oncology (ASTRO), we recognize author groups are diverse and have obtained varying levels of federal funding. Requiring zero-embargo Open Access favors researchers who have sufficient funding to pay Article Publication Charges (APCs). Such a policy disadvantages early career researchers and research teams that, for reasons including family/medical leave, have received lower levels of funding. To combat this significant disparity, free Green OA routes should be publicized as the primary method of compliance with the OSTP mandate.

ASTRO strongly encourages the NIH to request a two-year extension from OSTP for mandate compliance, to January 1, 2028. The additional time will allow for greater author education and will help minimize disparities created by this policy.

2. Steps for improving equity in access and accessibility of publications.

ASTRO supports a requirement that all publicly available versions of an article be linked to the publisher/professional society-supplied version of record. A two-year delay of required compliance with the OSTP mandate will enable a more robust, automated technical system to be implemented that will enable linking to occur by default. While research accessibility is critically important, confusion about medical article versioning is a danger to public health and must be avoided.

3. Methods for monitoring evolving costs and impacts on affected communities.

4. Early input on considerations to increase findability and transparency of research.

DOIs have been successful and should be preserved. DOIs should be used to denote article versions of record. Preprints, Green OA depositions, research data, and any related materials should link back to a single DOI of the version of record. To enable this process and reduce confusion and public health threats regarding article versioning, federally funded research made publicly accessible within one week of article publication should be considered in compliance with the OSTP policy.

Email: lisa.braverman@astro.org

Submit date: 4/24/2023

I am responding to this RFI: On behalf of myself

Name: Roy Kaufman

Name of Organization: Copyright Clearance Center

Type of Organization: Other

Type of Organization-Other: CCC is a not-for-profit organization founded in 1977 at the suggestion of Congress to facilitate collective copyright licensing for the text sector.

Role: Member of the public

- 1. How to best ensure equity in publication opportunities for NIH-supported investigators.**
- 2. Steps for improving equity in access and accessibility of publications.**
- 3. Methods for monitoring evolving costs and impacts on affected communities.**
- 4. Early input on considerations to increase findability and transparency of research.**

Please see the attached PDF, which contains our entire submission on these questions, with recommendations, attachments and links.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/NIH-RFI-with-attachments-1.pdf>

Description: CCC's submission with recommendations, attachments and links.

Email: rkaufman@copyright.com

Submit date: 4/24/2023

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

Name: Abigail Goben

Name of Organization: Research Data Access and Preservation Association

Type of Organization: Professional org association

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/RDAP_NIHRFIResponse_PublicAccess_NOT-OD-23-091.pdf

Description: A response related to the NIH RFI addressing concerns about data sharing.

Email: agoben@uic.edu

Submit date: 4/24/2023

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

Name: Janine Chiappa McKenna

Name of Organization: American Gastroenterological Association

Type of Organization: Professional org association

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The NIH-proposed plan mandates zero embargo, which is intended to be more equitable for readers by making research more rapidly and freely available, and researcher-authors by allowing them to self-archive their manuscript in a public repository (i.e., “green” open access) without having to pay article processing charges (APCs, i.e., “gold” open access). However, the increase in free content will lead to difficult decisions for publishers that could result in greater inequities for researchers, as outlined below.

1. PUBLISHING OPTIONS FOR RESEARCHER-AUTHORS MAY BECOME LIMITED TO FEE-BASED OPEN-ACCESS JOURNALS. Currently, the publishing ecosystem includes journals that are fully open access, exclusively subscription-based, or “hybrid,” meaning they offer both open access content as well as content behind a subscription paywall. This gives researcher-authors diversity in choice depending on their preferred publication method. Further, the existence of hybrid journals allows “green” open access as a cost-effective publishing option. Biomedical and clinical journals, such as those published by AGA, publish high volumes of manuscripts resulting from NIH-funded research. With the increase in free content inevitably leading to a decline in individual and library subscription revenue, hybrid journals will likely convert to a fully online, open access model meaning that researcher-authors will be increasingly limited to journals requiring article processing charges (APCs) and “green” open access will no longer be available as a cost-effective publishing option.

2. PUBLISHING MAY BECOME RESTRICTED TO ONLY RESEARCHER-AUTHORS WITH SIGNIFICANT GRANT FUNDING. The work of publishers and the services they provide will not decrease because a journal converts to fully open-access, meaning that expenses will not change and existing revenue coming from subscriptions will need to be covered by raising APCs for researcher-authors. Further, the NIH Public Access Policy will apply to all NIH-funded authors regardless of their total funding or how small a role they play in a research project or manuscript. Therefore, the policy may create inequities in that only well-funded investigators or those at institutions with additional resources will be able to afford these fees, or authors must reallocate grant funds from research expenses to publication costs. Early-career researchers in particular may be penalized.

3. CLARITY FOR RESEARCHER-AUTHORS ON WHEN THE PUBLIC ACCESS MANDATE APPLIES WOULD LIKELY REDUCE THEIR BURDEN. We suggest that the NIH indicate a minimum threshold of funding and/or level of participation by researcher-authors at which the immediate public access mandate would apply to a particular manuscript. This is particularly important as science increasingly moves to a “team science” model with large, collaborative research teams developing manuscripts that can have tens or even hundreds of authors who are not contributing equally. Minimal contributions to studies or

use of funded shared resources by NIH-funded researchers should not qualify a paper for the proposed mandate.

4. PROVIDE PUBLISHERS THE ABILITY TO MAKE THEIR OWN DECISIONS REGARDING RIGHTS RETENTION. As NIH seeks to make peer-reviewed content accessible without an embargo, AGA requests that the NIH refrain from requiring reuse rights under licenses that restrict our ability to establish copyright. Instead, AGA should retain the rights associated with the final version of record, both as a resource for the association as well as to ensure an author's research isn't misappropriated and turned into derivative works that could lack integrity or worse, cause patient harm. Under copyright provisions, we guard against misuse of author content by requiring third parties to follow our policies regarding appropriate use of published content.

2. Steps for improving equity in access and accessibility of publications.

We have outlined several suggestions below regarding guidelines and procedures that may help improve equity in access and accessibility of publications resulting from NIH-funded research.

1. EDUCATE AUTHORS ON APPROPRIATE REPORTING OF FEDERAL FUNDING IN MANUSCRIPTS AND WHEN THE PUBLIC ACCESS MANDATE APPLIES. Overreporting is commonplace and even incentivized as researcher-authors attempt to demonstrate significant progress on their funded research through the volume of publications. However, we are aware that grantees, or work done on their behalf from Other institutions, have inappropriately deposited articles in PubMed Central because NIH funding was acknowledged in a manuscript that was loosely related to but not a direct result of the funded research. Therefore, we urge NIH to provide clear conditions under which authors should acknowledge NIH funding in their manuscripts and adhere to the public access mandate. Consistent communication and education to the research community regarding these conditions will also be essential.

2. SOLICIT FEEDBACK FROM THE RESEARCHER-AUTHOR COMMUNITY ON NECESSARY PUBLICATION COSTS AND PROVIDE CLEAR GUIDANCE ON BUDGETING PUBLICATION FEES. Although NIH states publication fees are an allowable expense, AGA members have shared experiences of publication budgets in their grants being reduced from their original proposal. As a result, there is not enough funding in their grants to cover publication fees for the multiple papers that will typically result from a single grant. Based on public comments thus far from NIH, it seems unlikely that there will be increases in agency funding to sufficiently cover researcher-authors' publication costs. We urge NIH to continue open dialogue with the researcher community to understand their challenges toward developing potential solutions.

3. REDUCE DUPLICATION OF WORK BY PUBLISHERS AND THE NATIONAL LIBRARY OF MEDICINE THROUGH PARTNERSHIPS THAT STREAMLINE THE PROCESS OF DEPOSITING MANUSCRIPTS. Currently, the National Library of Medicine (NLM) duplicates the work of publishers by preparing text files for online publication in PubMed Central. We urge NLM to consider seeking licensing agreements with publishers in which publishers would provide high-quality machine-readable, highly tagged extensible markup language (XML) in exchange for a fee rather than both parties doing similar work. This licensing arrangement would also ensure compliance of deposits into PubMed Central.

Alternatively, PubMed Central could become a centralized bibliographic database that links to journal websites rather than separately hosting its own full-text journal articles. This would be an innovative

approach that would also incentivize publishers to develop more ancillary content and enhance user features.

3. Methods for monitoring evolving costs and impacts on affected communities.

Budgets submitted by grant applicants could be an informative tool for monitoring publication costs, if there was a system by which this data could be pooled across NIH institutes and centers and categorized by different types of research. We also welcome ongoing dialogue with NIH regarding equity in publication opportunities as this is a priority area for AGA's publications under our AGA Equity Project, an organization-wide initiative prioritizing diversity, equity and inclusion in our policies, processes, and programs. For example, AGA participates in Research4Life and offers fee waivers for researcher-authors who require financial assistance, such as early-career researchers or researchers from under-resourced regions or institutions who may lack sufficient funds to cover our journals' publication fees.

4. Early input on considerations to increase findability and transparency of research.

We urge NIH to engage with publishers and the PID community to use or adapt what has already been created, rather than creating its own system. For example, PubMed currently replaces publisher DOIs in the references of papers in its repository; by removing publisher DOIs from reference links or choosing to include links to the PubMed Central version instead of the version of record (VOR), the NLM is depriving the user of access to associated editorials, letters to the editor, infographics, and Other ancillary materials that may provide additional value and context to the reader.

For researchers, we suggest that NIH employ DOIs for grants and require them for datasets published. By adopting PIDs already in use in scholarly publishing, journals can include persistent links to critical pieces of research for users to access.

Email: jmckenna@gastro.org

Submit date: 4/24/2023

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

Name: Gwen Twillman

Name of Organization: American Society for Nutrition

Type of Organization: Professional org association

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The American Society for Nutrition (ASN) broadly supports the efforts of NIH to develop educational materials and standards to improve article accessibility and PubMed Central procedures for processing.

Increasing diversity, equity and inclusion in nutrition and related sciences is a strategic priority for ASN. ASN allocates publication waivers for underrepresented and early career scientists. NIH could further its goals by dedicating publication resources for underrepresented scientists and the scientific societies that support them.

ASN also encourages NIH to follow a model like that of the Bill and Melinda Gates Foundation for coverage of publishing fees. The Gates Foundation uses a central budget to pay for article processing charges and publisher fees. Grantees do not have to use funds out of their research budget or seek reimbursement from the Foundation. Instead, invoices are directed to the Foundation for payment from the central budget directly to the publisher or service provider. The Gates Foundation supports publication of research funded, in part or whole, by the Foundation and only requires a valid Gates grant number. The central budget covers open access publishing fees and additional publishing costs such as page charges. The grantee is responsible for managing any publisher agreements and covering any additional costs beyond these fees. It is ASN's understanding that fees are paid at any point in time from this central budget, even after the end of a grant funding period.

2. Steps for improving equity in access and accessibility of publications.

ASN is committed to the translation of science to a variety of audiences - researchers, clinicians, policymakers, public health professionals and lay audiences. Sample tactics include blog posts, statements of significance, press releases and outreach to traditional and social media, as well as journal features such as Great Debates in Nutrition, Nutrition for the Clinician, and AJCN in Press podcast. Training researchers to properly communicate their science also is an ASN priority.

Financial support for activities to translate science and improve equity in access is lacking. NIH funding to help scientific societies continue and increase these efforts will help ensure their sustainability.

3. Methods for monitoring evolving costs and impacts on affected communities.

Scientific research societies that publish scholarly journals, such as ASN, invest the income from their journals back into the scientific research community by supporting professional development and educational opportunities, including training for the next generation of scientists, meetings, and awards. ASN encourages NIH to consider additional support for the scientific research community in the form of professional development activities, particularly those helping early-career and underrepresented

researchers prepare and support scholarly publications, such as training young professionals to serve as peer reviewers.

Income from publications also funds editorial expenses that ensure a rigorous and fair peer review process, foster scientific integrity and trust in science, and furthers science advancement.

Activities that monitor evolving publication costs must also consider and evaluate any negative consequences on organizations that prioritize rigor and reproducibility of science over publication volumes. For example, the American Society for Nutrition funds the following activities to ensure a peer review robust process: compliance with industry and ethical standards in the conduct and reporting of research; compensation of editors to oversee peer review, a Statistical Review Board to confirm data analysis, and senior-level staff to monitor trends; plagiarism screening; management of ethical investigations; and Other best practices.

4. Early input on considerations to increase findability and transparency of research.

Email: gtwillman@nutrition.org

Submit date: 4/24/2023

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

Name: Edward Pentz

Name of Organization: Crossref

Type of Organization: Other

Type of Organization-Other: Non-profit, open scholarly infrastructure provider

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Researchers should be free to publish their manuscripts in the most appropriate journal that meets the NIH Public Access Plan requirements. By registering its grants with Crossref and getting Crossref Grant DOIs, NIH can ensure that published outputs from NIH-supported researchers are easily connected to the related grant without any additional burden on the researchers. With over 18,000 members from 150 countries and over 100,000 journals, Crossref metadata and DOIs will support connecting the publications of NIH-supported researchers to the global research discovery ecosystem wherever they publish. Our growing membership includes many new formats and models for publishing, with incentives in place such as our new GEM Program (Global Equitable Membership) which enables zero-fee participation in the system by members in the least economically-advantaged parts of the world. Crossref also encourages critical metadata that are used for downstream analysis, such as references, data citation, and increasingly important for assessment - abstracts.

2. Steps for improving equity in access and accessibility of publications.

Open persistent identifiers and metadata are essential to providing equitable access to publications. Crossref encourages NIH to register Crossref grant DOIs and metadata, including ORCID IDs and ROR IDs. Our open and robust API is open to everyone, used by tens of thousands of systems across the research ecosystem, and is heavily relied upon for text-mining and Other machine uses.

3. Methods for monitoring evolving costs and impacts on affected communities.

Open persistent identifiers and metadata are essential to monitoring trends with publication fees and where research outputs from NIH-supported researchers are made available. To enable this, Crossref encourages NIH to register Crossref grant DOIs and metadata, including ORCID IDs and ROR IDs.

NIH could encourage its grantees to publish in outlets that provide the richest possible metadata and therefore increased evidence and accessibility for the community.

4. Early input on considerations to increase findability and transparency of research.

In looking at identifiers and metadata and how to improve their use, we encourage NIH to focus on a number of critical questions: How open are they? How are they funded and how sustainable are they? How are they integrated with the global scholarly research ecosystem? How broadly are they used? What services are available to register, resolve and disseminate the persistent identifiers and metadata? Are there complementary services available that support Other goals such as research integrity? How

and by whom are they governed? How global/wide-reaching are they? The answers to all of these questions will also answer how truly persistent and trustworthy the operation and services are.

Crossref would be happy to collaborate with the NIH on connecting NIH grants with the wider open scholarly infrastructure that Crossref provides. As the leading Registration Agency providing DOI services, we represent by far the largest community of stakeholders involved in documenting the progress of science, so updates and future enhancements can be developed and—crucially—adopted at scale.

The Grant DOI program is unique to Crossref and has been ramping up for the last couple of years. We currently have over 76,000 registered grants, including 8,700 from the US Department of Energy's Office of Scientific and Technical Information (DOE-OSTI), with Other US federal agencies actively exploring membership and grant registration.. Crossref is ready to fully support NIH registering its grants with us so they too can connect with the global network of research metadata.

We look forward to working with the NIH alongside our work with Other agencies on meeting the shared goal of “a robust, connected ecosystem where institutions, researchers, research outputs, and funding sources are linked consistent with FAIR principles”. In Other words: the Research Nexus.

Ensuring free, immediate, and equitable access to metadata that captures the scholarly record is an essential part of meeting the goals of the NIH Public Access policy and the OSTP memo and supporting Open Science globally.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/Crossref-NIH-Public-Access-RFI-1.pdf>

Description: Letter from Crossref with detailed feedback on the Public Access Plan

Email: epentz@crossref.org

Submit date: 4/24/2023

Name: Simon Bacon

Name of Organization: Behavioral Medicine Research Council

Type of Organization: Nonprofit research organization

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

See attached paper

2. Steps for improving equity in access and accessibility of publications.

See attached paper

3. Methods for monitoring evolving costs and impacts on affected communities.

See attached paper

4. Early input on considerations to increase findability and transparency of research.

See attached paper

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/Segerstrom-et-al.-2023.pdf>

Description: This is our recent BMRC position statement on open science which covers a number of elements from the aspects detailed above

Email: simon.bacon@concordia.ca

Submit date: 4/24/2023

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

Name: Megan von Isenburg

Name of Organization: Data Discovery Collaboration

Type of Organization: Professional org association

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The Data Discovery Collaboration (DDC) is a multi-institutional consortium that works together in order to address concerns around data discovery through discussions of metadata, outreach, software development, and systems and metadata interoperability. In preparing this response, multiple members of the DDC came together to respond to this RFI from the lens of data discovery, based on the perspective that data deposit is a publication opportunity and that data publications are increasingly common.

Many journals require data publication with article publication that may exceed NIH Data Management and Sharing Policy requirements. Some researchers may have larger-than-ordinary data needs (e.g., working with human subjects data, working with complex imaging and 'omics data, working with very large datasets) that cannot be satisfied through PMC supplemental files size limits. These inequities in data publication are particularly stark for human subjects research, which may have costly and time-consuming requirements. Additionally, some researchers may come from institutions with limited financial and infrastructural resources or differential expertise in data sharing. Thus, the NIH should examine how to best support researchers across fields and across levels of institutional support and resources for data publication. If they do not do so, it is likely that some researchers will have access to publication opportunities that Others will not. This issue is particularly relevant as high profile journals like Nature tend to have these types of requirements.

To address these issues, we suggest increased monetary support, exploration into a PMC-style repository designed according to data standards, or a federated data repository or catalog interface for data associated with PMC articles.

2. Steps for improving equity in access and accessibility of publications.

The DDC suggests two steps for improving equity in access and accessibility of publications. The first is workforce development training for licensing options and copyright. Authors do not always know what rights and licenses are available to them, such as Creative Commons licenses. Providing education could help even the playing field for writers as well as ensure broader access for readers.

Second, there should be standards set for Data Availability Statements (DAS) to allow for clearer and machine-readable information about when and how data associated with a publication is available. Currently, DASs are not standardised and the quality of DAS's can vary greatly across publications and articles.

3. Methods for monitoring evolving costs and impacts on affected communities.

It is important for the NIH to monitor trends in publication fees and policies, including those related to data deposit. There is some risk in researchers turning to external open access options with costly APCs if the NIH does not make enhancements to researcher ability to deposit data associated with a publication within PMC and Other NIH repositories.

4. Early input on considerations to increase findability and transparency of research.

From the perspective of data as a publication and product of research, it is essential to enhance the findability of data sets resulting from NIH research regardless of which repository is used. We encourage development in federated search and data catalog options to increase findability.

In addition PIDs should be used to link data sets to their associated publications in PMC, journals, and Other systems. Data availability statements should be standardised and machine readable.

Ideally, no new PIDs should be created wherever industry standards exist, such as DOI, ORCID, and ROR. If industry standard PIDs are unable to be programmed into NIH systems or to be explicitly required by NIH, then cross-walking NIH PIDs with industry standard PIDs will be essential.

Data published as a supplementary file in PMC should be discoverable independently from their associated articles from multiple points, including topic, author, affiliation, etc. Supplementary data files are not adequately searchable at present. Ideally, published data and published articles stemming from the same research should be linked but independently discoverable.

Description: The Data Discovery Collaboration (DDC) is a multi-institutional consortium that works together in order to address concerns around data discovery through discussions of metadata, outreach, software development, and systems and metadata interoperability. I

Email: megan.vonisenburg@duke.edu

Submit date: 4/24/2023

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

Name of Organization: American Society of Hematology

Type of Organization: Other

Type of Organization-Other: Medical Specialty Society

Role: Member of the public

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/ASH-Response-to-NIH-Guidelines-4.24.23.pdf>

Email: sleous@hematology.org

Submit date: 4/24/2023

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

Name: David Mellor

Name of Organization: Center for Open Science

Type of Organization: Nonprofit research organization

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

We believe that an interface that does not focus on journal name but rather clear results reporting can satisfy both the spirit of these open access plans (which is to increase access to research findings) and also the need to improve scholarly communication. It will do so by reducing the implication that the value of a research finding is associated with the name of the journal that publishes that finding. Such associations bias the research process by incentivizing novelty over rigor.

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

The increasing cost of publications- both through traditional subscription models and through the rising costs of APCs- are a cause for concern as it shunts money away from Other public benefits in higher education and scientific research. While there are reasonable concerns about placing a cap on the price per publication fee, namely that such a cap would become the new standard price for publishing, we encourage NIH to define "reasonable publication fees" in a manner that is not too ambiguous or that encourages further, unchecked growth in these fees. Specifying a maximum percentage that a proposed grant application budget would be one key signal to indicate how excessive could be defined.

Another key strategy to reigning in the cost of publication fees is transparency. Currently, there are very high barriers to even knowing how much money is spent on such fees. A relatively simple method to increase awareness about these costs is to disclose the amount of money earmarked for publication fees in funded grant applications. This process can be accomplished in an aggregated way, which would still provide the community with information about the total costs.

Together, these two steps (clearly defining reasonable costs and reporting how much money is spent annually on them) will help monitor the growing costs associated with publishing.

4. Early input on considerations to increase findability and transparency of research.

We believe that there are two important steps that NIH can take in order to increase the findability and transparency of research outputs. The first is to include the Data Management and Sharing Plans (DMSP) as part of the reviewer-scored criteria during the grant review process. Currently, these plans merely have to pass administrative review and be deemed acceptable or appropriate for the grant to be submitted and reviewed for consideration of funding. While this is an understandable first step, it does not go far enough to ensure that these plans are truly as good as they could be. The current workflow reinforces the idea that data sharing is an administrative burden and not an integral part of the process of scientific research. Since grant reviewers are themselves experts within the discipline and of the

proposed methods, they will best be able to determine if the proposed plans are feasible, high quality, and meet the realistic expectations of the community. For example, when dealing with particularly sensitive datasets or those that include data about indigenous communities, the panel of expert reviewers are best able to know if the plan meets ethical norms and considerations of the field. Likewise, in areas where data sharing poses fewer ethical constraints, the reviewers will take that into consideration and place higher expectations for broad sharing and preservation of the data. Only through scoring proposed DMSPs will grant authors take as much care and consideration as they could with the details of the plans. This will elevate data sharing and improve data quality in ways administrative review cannot.

The second step is to assign DMSPs persistent, unique identifiers (ideally DOIs) and to make these DMSPs publicly available for all awarded grants. The rationale for not publicly posting many grant materials is fully justifiable, as the intellectual property of the proposals remain that of the submitters. However, DMSPs do not contain, and should not contain, original ideas or Other IP that can give away any competitive advantage from grantees. They should merely assist future researchers in finding research outputs from funded work by specifying where data and related items will be hosted. This will also help increase accountability with proposed data sharing plans, as there will be an easier way to determine how data are created and preserved. We believe that transparency in this setting will help readers, future researchers, and members of the public see how data are generated, stored, and reused in order to maximize the benefit of public research investments.

These two steps- making data management plans part of the scored reviewer criteria and making them publicly available- will increase the quality and accountability of data-generating research.

Email: david@cos.io

Submit date: 4/24/2023

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

Name: Karen Caputo

Name of Organization: Case Western Reserve University Libraries

Type of Organization: University

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Investigators would benefit from education and promotion of PMC manuscript submission (Green OA/repository deposit) since it eliminates financial barriers to complying with NIH's policy. When working with researchers to deposit manuscripts into our institutional repository, we often have to educate researchers on manuscript versions, publisher policies, and the differences between OA publishing and repository deposit. Some assume that once they publish their article they cannot share any version of it or can only do so if they publish open access and pay an APC. Many are happy to learn that they can publish in their preferred journals and still make their AAM available in the repository. NIH should be explicit in stating that there is no charge for manuscript deposit in PMC, and any charges from a publisher are for publishing with that journal not for complying with NIH's policy. In our resources for federally funded researchers, we are encouraging repository deposit first to comply with these policies, but it would help to have that reiterated by funders themselves.

In working with researchers at our institution, many are not aware that they can ask to retain rights, so NIH's proposal to offer rights retention language to investigators will greatly help investigators with PMC manuscript submission. In addition to the language though, specific instructions and resources on rights retention would help investigators navigate the process and understand why it is important. Our institution is considering passing a rights retention policy (Faculty OA Policy), but many researchers are confused by this process and need more explanation on how rights retention works.

NIH should also encourage investigators to consider publishing options that do not charge for publishing, such as open access journals that do not charge APCs (Diamond/Platinum Journals). Studies have found that APC costs disproportionately affect early career researchers, female researchers, and researchers from less well resourced institutions. We encourage our researchers to consider the free publishing options available to them, but many are still unaware these options exist. These options eliminate financial barriers for researchers and support more equitable publishing models.

Recently, our institution joined HELIOS. NIH should consider working with a group like HELIOS to encourage incentives for investigators who comply with public access policies.

Finally, NIH might consider providing academic libraries and research offices with tools to help researchers comply with this policy. NIH could provide academic research offices with targeted language on steps to consider to comply with this policy that they could include in their instructions to investigators when applying for and fulfilling NIH grants. NIH might also consider providing grant applicants with a list of NIH designated repositories.

2. Steps for improving equity in access and accessibility of publications.

Again, rights retention language and support would improve access and accessibility of publications. NIH should ensure investigators are retaining the right to make their final peer-reviewed manuscripts freely available and also reusable. Open licenses like Creative Commons licenses should also be considered since they provide free access and reuse rights. Open licenses are easy to understand for both researchers and users, so more users can access and reuse content, and more researchers can provide access to and reuse of their work. Open licenses also allow use of content on assistive devices, as well as enabling text and data mining.

3. Methods for monitoring evolving costs and impacts on affected communities.

NIH should consider publicly tracking APC fees for publications that are the result of NIH supported research whether NIH covered that cost or not. This tracking would increase transparency around these costs, reveal affected communities, and provide an understanding of how these publishing costs are taking funds away from research.

4. Early input on considerations to increase findability and transparency of research.

Repository metadata varies considerably, so support of more standardization across repositories would be helpful and encourage reuse of this metadata. The U.S. Repository Network would be a good partner in this effort. As far as PIDs, NIH should consider commonly accepted external identifiers for researchers, publications, data, grants, etc. that are open and are useful outside of NIH's systems.

Email: karen.caputo@case.edu

Submit date: 4/24/2023

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

Name: Tayler Williams

Name of Organization: American Medical Informatics Association

Type of Organization: Professional org association

Role: Member of the public

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/NIH-public-access-plan-comments-GPJ-submitted.pdf>

Email: carrie@korrisgroup.com

Submit date: 4/24/2023

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

Name: Laura Weidner

Name of Organization: Epilepsy Foundation

Type of Organization: Patient advocacy organization

Role: Patient advocate

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Costs to publish in open-access journals are shifted to authors, compared to subscription-based journals. These shifts in cost could result in publishing discrepancies, especially for underfunded and/or under-resourced institutions and groups, as well as unestablished early career researchers. Additionally, these discrepancies have downstream effects, including limiting the accessibility and dissemination of research produced by these populations. The NIH should consider the limitations of open access journals faced by underprivileged groups and potential solutions to promote equity across publishing. Suggestions for improving equity in publication opportunities are as follows.

Equity

-The NIH should consider the creation of stakeholder working groups to gain feedback on potential disadvantages and limitations of the proposed policy. These working groups should include, but are not limited to, under-resourced groups, under-represented groups, early career investigators, and students/trainees.

-Elaboration/clarification on allowable publication costs is necessary. Proposed requirements, stipulations, and exceptions for allowable costs should be presented to the public for feedback. It is important to ensure that the plan promotes equity and does not create unfair limitations on underprivileged groups.

-The implementation of policies that promote equitable publishing opportunities should be considered. Potential examples include fee waivers, voucher programs, and/or discounts for under-resourced and under-privileged groups.

-Some institutions have already entered into agreements with publishers that subsidize or even fully cover open access fees. This could have a big impact on institutions with a smaller institutional funding base and/or lead to a smaller investment in libraries. The potential impact should be monitored to ensure equity between institutions with varied resources.

Preprint Servers

-An additional pathway to increase publishing equity could be NIH support for preprint servers, as they encourage feedback, allow for rapid publication, and increase audience reach. Support for preprint servers could be done by generating discussions with publishers regarding the potential elimination of preprint restrictions. For example, ensuring unformatted pre-editorial papers are deposited in the NIH's PubMed Central repository is one effective way NIH increases access to NIH sponsored research.

Data Collection

-Inequities and barriers in publishing opportunities that may arise from the updated policy should be monitored and publicly reported, perhaps via surveys. Potential variables of interest could include publication tracking (under-resourced/under-represented groups) and accessibility, usability, and compliance as they relate to the PMC platform.

-NIH should consider supporting the ability to directly link published papers with publicly available data, and should encourage academic institutions to place a high value on published data sets when considering faculty for promotion.

2. Steps for improving equity in access and accessibility of publications.

Accessibility

-NIH should ensure compliance with Section 508/Web Content Accessibility Guidelines (WCAG) by the Web Accessibility Initiative (WAI) for the PMC platform to ensure publication accessibility for all. The Foundation works in concert with Other disability organizations to ensure accessibility of all websites. For people with disabilities, accessibility of websites is a civil right necessary for equal opportunity. Accessibility of online information is not limited to those with sensory disabilities; many individuals with Other disabilities, such as those who use augmentative and alternative communication devices, those with intellectual and developmental disabilities, and many more find that they are unable to access online systems that are integral to modern daily life.

-Potential methods for providing publications in multiple languages on the PMC platform should be considered and develop a plan for implementation. Multilingual options increase accessibility to science and research for those not fluent in English.

Training and Education

-The NIH should provide training and education on accessing publications. Potential education areas of interest include how to access and use research products, best practice on how to search and find articles of interest, and a research article overview (i.e., the different sections, what's included in each section, where to find what information, how to "read through" the science).

Stakeholder engagement

-Non-profit organizations, patient societies, and community stakeholders are all involved in providing research to the public, yet often cannot afford the institutional subscription fees to access the latest scientific findings. Feedback from these entities would offer valuable insight regarding unforeseen or unexpected barriers to access.

-It is also important to note that these stakeholders face a paywall in regard to accessing research. As a result, these organizations, who are usually the bridge between science and families, are unable to share relevant information with their communities. To combat these limitations, NIH incentivize journals to provide open access options that allow non-profits access to research articles and reviews.

-Funding agency collaboration would promote discussions on best practices, increase equity and accessibility efforts, and encourage joint initiatives.

3. Methods for monitoring evolving costs and impacts on affected communities.

Data Collection

-The NIH should consider stakeholder (i.e., publishers, researchers, institutions, non-profits) surveys that ask about factors that may affect equity in publishing opportunities (i.e., publication fees, open access policies/impact of publication models, paywall limitations/article access costs for non-academic organizations). Additionally, longitudinal surveys would offer the opportunity to examine trends and changes over time, which could be useful for future policy updates.

-A publication cost analysis would identify the different components that make up publication fees. We recommend creating a publicly available report of the results to increase transparency. Such findings could also promote ideas or provide direction to the NIH on how to support researchers in the mitigation of those costs.

-Pre-post data collection, via publisher collaboration and/or publicly available data, on publication fees and policies could provide insight on changes implemented as a result of the updated policy. Data collection would also promote consistency and transparency and could include annual or bi-annual public reports.

-Transparency and consistency among cost and impact analyses will be important. One option to promote effective and equitable monitoring could be an NIH developed open access data analysis tool.

4. Early input on considerations to increase findability and transparency of research.

N/A - no response on this section.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/EF-Public-Access-RFI-Comments-Intro.pdf>

Email: lweidner@efa.org

Submit date: 4/24/2023

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

Name: Chris Bourg

Name of Organization: Massachusetts Institute of Technology - MIT Libraries

Type of Organization: University

Role: Institutional official

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/RFI_NIH_plan-to-enhance-public-access_20230423_MITlibraries.pdf

Email: nurnberg@mit.edu

Submit date: 4/24/2023

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

Name: Claire Redhead

Name of Organization: OASPA

Type of Organization: Other

Type of Organization-Other: Open Access Scholarly Publishing Association

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Opportunities to publish open access are not equitable at the moment, and OASPA believes that policy can help with this.

OASPA has studied the OA market, and is concerned about consolidation and lack of diversity in the way in which OA is being achieved. In a separate study across well over 4 million OA articles published over the last 12 years, we see that in 2022 just 10 publishers accounted for 83% of OASPA members' OA output (as reported here). Market concentration is increasing rapidly - in 2020 these figures were six publishers accounting for 75% of OA output.

Although the NIH policy allows for a number of ways in which to achieve public access, we expect that the NIH would care about this market consolidation as there are both equity concerns as well as a cost element involved. A reasonable proportion of NIH funded work is published via the Gold-OA route, which our research on the OA market tells us would primarily, therefore, be via APC payments or transformative agreements. As we argue in the following paragraph, there are legitimate concerns that these prevalent (APC) and developing (transformative) models of open access publishing tend to exclude authors of particular career stages, particular genders, and particular institutions in addition to also excluding those from certain world regions.

OASPA notes a raft of evidence and views supporting the problematic nature of the APC, from this 2020 commentary to this 2022 review and this 2022 study stating that open access is leading to closed research. OASPA also notes this 2019 blog post that asserts "unfairness lies at the core of the APC problem". This 2020 study examining content published by US-based researchers between 2014 and 2018 in over 25,000 academic journals reveals that, in general, the likelihood for a scholar to author an APC-OA article "increases with male gender, employment at a prestigious institution, association with a STEM discipline, greater federal research funding, and more advanced career stage (i.e., higher professorial rank)."

The APC is most often the 'basic unit' used to compute and derive terms around newer 'transformative' deals which increase access to OA publishing for researchers at select (mostly the best-resourced) institutions.

A predominance of these APC and 'transformative' routes to OA would have negative impacts for equity. However, it should be recognised here that for many publishers these routes are the only reliable means to achieve open access. Funding for Other (more equitable) models that could be adopted is as yet not

well established. This needs attention and structural support to enable the move to more equitable routes of immediate open access that also allow for the widest possible reuse.

More on this topic is available in OASPA's blog reporting from our first 'Equity in OA' workshop held on 7 March 2023 which brought together publisher, librarian and funder participants from a wide range of countries including the USA.

Given that 47% of articles received into PMC are via publisher-deposits from some 3000 journals [as per ref 16 here] and also given that the NIH wishes to keep a handle on costs, although the NIH policy is focused on public access, OASPA is convinced that making OA better, and most importantly, increasing equity and diversity in the routes to OA, will help the NIH's aims around equitable public access and increase publication opportunities for NIH-supported investigators.

OASPA's suggestions are:

Push for more responsible practice and support reasonable publishing costs

How specifically publication venues/journals could be judged as delivering equitable open access has not yet crystallized, but work that OASPA and Others are doing in this area will reveal more answers in the coming year or so. Specifically, OASPA is aiming to develop ways in which publishing organizations can demonstrate their portfolios' adherence to principles around equity and organizational efforts to increase inclusion and equity so that there is better and greater access to participation in OA publishing.

The NIH already has a plan to develop more details and supplementary information around this space. The NIH could potentially consider adding a condition around journals' adherence to certain principles of equity in achieving OA of the final published version of articles. We would love to work with federal agencies on this and/or provide inputs from the work we are doing in this area if seen to be relevant. OASPA is working on Equity in OA in parallel with the library and funder communities that are also taking steps to define such principles. See also the response to point (3) below involving a future 'Equity in OA' OASPA workshop.

Change the language around "reputable" journals mentioned in III.D.1. This word is tied up with a current, perverse, research-assessment and incentives culture. It also is a barrier for the establishment of new models and the experimentation and innovation that is needed for open access to be more broadly adopted. This language can reinforce an unnecessary drive towards higher cost OA-publication venues and greater market consolidation across publishing venues that have greater brand presence where a diversity of publication venues exist and more cost-effective routes would suffice. The very nature of 'reputable journals' is, in itself, a major contributing factor of the exclusionary research culture that is prevalent today.

Stay in touch and/or work with OASPA and Other stakeholders building equity in scholarly communications. OASPA's recent work has revealed that differentiated pricing on the basis of the ability to pay and automation in discounting and waiver practices for Gold-OA publications (that rely on APCs) would be helpful as short-term fixes in addressing equity issues. There are as yet no bases for such pricing mechanisms in the scholarly publishing industry, but potential solutions were aired and discussed last month as part of OASPA's Equity in OA workshop series. OASPA is a proven convener of stakeholders for constructive conversation and is keen to work with the NIH and Other funders and agencies to continue to develop models and solutions that foster equity in open access publishing.

(links to support the points made above can be found in the uploaded version of our response)

2. Steps for improving equity in access and accessibility of publications.

OASPA believes that when we focus more (or solely) on access than reuse then we all stand to lose out on the full benefits of both public access and open access. Using the paywalled/subscription route with zero-embargo deposits to PMC removes a cost barrier and broadens participation, but it's important to make sure that discoverability and re-use are maximized. Accessibility and equity should also be about making content as useful to the public as possible, and to achieve its full potential that content needs to be reusable. By also including strong requirements for PIDs and metadata, visibility of published outputs can be widened.

To be truly equitable and inclusive, and to support the broadest possible human engagement (to sit alongside machine-readability and mining as well), the sharing and re-usability of outputs needs to be more specifically supported.

The NIH policy already says: "NIH will continue to promote the broadest possible reuse of its supported articles, while limiting inappropriate uses, such as redistribution of PMC content for sale." This could go further to specify that re-use licensing on deposited accepted manuscripts (AMs) and published articles should specifically articulate and facilitate appropriate reuse.

(links to support the points made above can be found in the uploaded version of our response)

3. Methods for monitoring evolving costs and impacts on affected communities.

In the publishing sector today, the APC is able to 'pull in' research-funder investment (albeit in the US these are often via convoluted routes, with APC monies nested in research grants or only available through trade offs - more on this within the survey findings from an October 2022 report from the American Academy for the Advancement of Science (AAAS) . Nonetheless, awareness of funding requirements for APCs is established. However, there are scant (no?) routes that OASPA is aware of for equivalent support for models involving collective action, S2O or diamond routes all of which deliver OA with no researcher-facing fees for reading or publishing.

OASPA recommends greater normalization of investment for these additional routes to support a more equitable form of OA enabling greater participation. We believe that this will drastically alleviate the impacts on affected communities because: (1) with additional funder support available, more US institutions and librarians may find it easier to repurpose existing spends from paywalled to OA titles that rely on collective action and or diamond routes; (2) fewer NIH-supported researchers will see or need to deal with invoices at the individual article level.

While the NIH (and the OSTP policy) is clear that it is model-agnostic, failure to provide support (through policy and funding) for more equitable OA models such as collective action and Diamond OA will only serve to entrench the currently dominant modes of Gold OA publication (via APCs and transformative agreements) that are inherently inequitable as argued above.

OASPA will be holding future 'Equity in OA' workshops in June 2023 where we hope that multi-stakeholder conversations around shared principles for equity in OA agreements can be developed. We aspire to next-generation agreements and publishing practices with equity and inclusion central to their conception devised to help secure and establish equity in OA regardless of business model.

It's important though to note here - as we have covered in points above - that costs are not the only barrier preventing researchers from contributing and so Other factors should be addressed alongside, such as format, language, incentives, assessment, and the notions of quality and prestige.

(links to support the points made above can be found in the uploaded version of our response)

4. Early input on considerations to increase findability and transparency of research.

OASPA's suggestion is to ask that this behavior in the community of scholars is specifically and actively rewarded. The NIH has the opportunity to help build credit and benefits for those researchers who deposit data and follow open-publishing practices. An additional option would be to consider making open access and open data prerequisites for grant funding. OASPA would welcome participation from the NIH in work with institutions to build rewards and incentives for open practices into career evaluations.

This also links to better uptake of PIDs and usage of metadata, both of which contribute to the findability and transparency of research. OASPA is actively involved in initiatives which are focussed on implementing more widespread adoption of PIDs and supports the uptake of new identifiers such as ROR. The OA Switchboard, a community-led initiative founded by OASPA, is also helping to increase PIDs and participation provides a practical mechanism for improving publisher metadata. There is a timely opportunity for all of us to collaborate.

Unsurprisingly, OASPA advocates for as much openness as possible throughout the whole publication process and for all components, including citations and abstracts. OASPA has been a supporter of I4OC and I4OA since they were founded. We encourage data sharing, under FAIR principles, and actively support our members regarding data citation.

Findability and transparency of research is also directly linked to research integrity and is a key area of OASPA's work which we have always placed great importance on. It enables the ability to combat all bad actors, not just researchers. Other aspects can also support this, such as having more information available regarding peer review - we encourage NIH to think beyond current practices and to explore open access to Other research outputs connected to publishing, for example peer review reports. Encouraging this through research assessment reform will also help with proliferation of such behaviors throughout the researcher community.

(links to support the points made above can be found in the uploaded version of our response)

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/OASPA-response-to-NIH-RFI-2023-1.pdf>

Description: OASPA response to NIH RFI 2023

Email: claire.redhead@oaspa.org

Submit date: 4/24/2023

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: Professional Publisher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Please see attached.

2. Steps for improving equity in access and accessibility of publications.

Please see attached.

3. Methods for monitoring evolving costs and impacts on affected communities.

Please see attached.

4. Early input on considerations to increase findability and transparency of research.

Please see attached.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/Wolters-Kluwer-NIH-RFI-response-04.24.23.pdf>

Description: Wolters Kluwer Response to National Institutes of Health (NIH) Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research 04.24.23

Email: jennifer.brogan@wolterskluwer.com

Submit date: 4/24/2023

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

Name: Maria Gould

Name of Organization: Research Organization Registry (ROR)

Type of Organization: Other

Type of Organization-Other: Infrastructure provider

Role: Member of the public

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/NIH-Public-Access-RFI-Research-Organization-Registry.pdf>

Email: maria@ror.org

Submit date: 4/24/2023

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

Name: Mary Lee Kennedy

Name of Organization: Association of Research Libraries

Type of Organization: Professional org association

Role: Institutional official

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/ARL-comments-NOT-OD-23-091.pdf>

Description: ARL comments on the NIH draft public access policy.

Email: cvitale@arl.org

Submit date: 4/24/2023

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

Name: Jessica Sebeok

Name of Organization: Wiley

Type of Organization: Other

Type of Organization-Other: Publishing company

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Please see attached comments.

2. Steps for improving equity in access and accessibility of publications.

Please see attached comments.

3. Methods for monitoring evolving costs and impacts on affected communities.

Please see attached comments.

4. Early input on considerations to increase findability and transparency of research.

Please see attached comments.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/Wiley-NIH-RFI-submission_NOT-OD-23-091_04_24_2023.pdf

Description: Wiley comments on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research

Email: jsebeok@wiley.com

Submit date: 4/24/2023

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

Name: Seventeen Science Societies

Type of Organization: Nonprofit research organization

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/Scientific-Society-Letter_NIH-RFI-PublicAccess_v2.pdf

Description: A letter signed by seventeen professional scientific societies and associations.

Email: jcarney@aaas.org

Submit date: 4/24/2023

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

Name: Kathryn Richmond

Name of Organization: The Allen Institute

Type of Organization: Nonprofit research organization

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Exciting options exist for NIH to better ensure equity in publication opportunities, and these span both policy updates and broadening programmatic support and compliance.

To allow greater equity in publishing, opportunities exist upstream during publication creation and include providing additional resources for NIH-funded manuscripts in the form of support for technical writers and writing workshops. This could occur through partnering with external organizations. NIH leadership would also be pivotal in providing researchers clear guidance on rights retention given the complex landscape of copyright law and the need for authors to retain sufficient rights so that they may make their publications available in PubMed Central.

Additionally, while the proposed NIH guidance supports compliance through the archiving of articles in specific repositories (PubMed Central for NIH), we also strongly support depositing manuscripts onto preprint server(s).. In addition to the final published article, such public access must also consider all the materials required to ensure results can be reproduced. For reproducibility of results in the life sciences, we should aspire to include the following:

- Availability of the detailed research methods and procedures to generate the primary data
- Availability of all the metadata that materially affect the interpretation of results
- Availability of the full analysis details including intermediate results

The NIH and Other funders should pay attention to incentives to encourage adoption with these requirements. Examples of incentives may include data supplements on existing grants and data acquisition and reproducibility grants. And for those with a track record of equitable sharing of data, that this is taken into consideration when researchers submit for new NIH -funded grants.

2. Steps for improving equity in access and accessibility of publications.

Assuming the publication is freely available, an additional step to improve equity in access and accessibility of publications may be to require all NIH-supported work to include high-level plain language summaries that can be more accessible to the public, as well as to support language translation options and the ability to publish in native languages. Likewise, there could be an incentive to encourage publications to follow current data standards and best practices for their work, as well as funding to create such standards and organize data repositories. At this time, there is great potential in leveraging artificial intelligence approaches to ease the implementation path for these processes.

Lastly, NIH leadership would again be pivotal in providing researchers clear guidance on open access terms and/or utilization of licenses (ex. Creative commons options).

3. Methods for monitoring evolving costs and impacts on affected communities.

An important element of monitoring the publication cost landscape is creating more transparency across this dynamic area, and this could be accomplished by providing grants to study and report on such costs and their impacts.

4. Early input on considerations to increase findability and transparency of research.

While persistent identifiers (PIDs) are helpful and allow users find and understand data and research products (particularly regarding institutions, authors, funders, and publications), ideally PIDs would be expanded to include their use for reagents, metadata, and protocols, etc. so as to enhance the findability of all research outputs.

Another suggestion to increase transparency in research would be to have publications include comprehensive results summaries alongside the published manuscripts for indexing on a summary website. The inclusion of such summaries would support good faith training.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/FINAL-Allen-Institute-NIH-RFI-Response_4.24.23.pdf

Email: kathrynr@alleninstitute.org

Submit date: 4/24/2023

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

Name: Andrew Herrin

Name of Organization: Society for Industrial and Applied Mathematics (SIAM)

Type of Organization: Professional org association

Role: Institutional official

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/SIAM-NIH-Open-Access-RFI-Response-April-2023-Final.pdf>

Description: RFI Response

Email: andrew@lewis-burke.com

Submit date: 4/24/2023

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

Name: Karen McDonnell & Liz Borkowski

Name of Organization: Women's Health Issues

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

We recommend that NIH revise its draft policy in order to avoid creating financial pressures that lead to peer-reviewed journals adopting policies and practices that reduce equitable opportunities for researchers. Please see our attached comments for details.

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

4. Early input on considerations to increase findability and transparency of research.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/WHI-comment-on-NOT-OD-23-091.pdf>

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

Email: borkowsk@gwu.edu

Submit date: 4/24/2023

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

Name: Tina Baich

Name of Organization: U.S. Repository Network

Type of Organization: Not applicable

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Please see attached PDF document.

2. Steps for improving equity in access and accessibility of publications.

3. Methods for monitoring evolving costs and impacts on affected communities.

4. Early input on considerations to increase findability and transparency of research.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/USRN-NIH-RFI-Response.pdf>

Description: RFI Response from U.S. Repository Network

Email: tina@sparcopen.org

Submit date: 4/24/2023

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

Name of Organization: American Society of Mechanical Engineers

Type of Organization: Nonprofit research organization

Role: Institutional official

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/ASME-NIH-RFI-Response.pdf>

Email: fakesp@asme.org

Submit date: 4/24/2023

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

Name: Kacy Redd

Name of Organization: Association of Public and Land-grant Universities

Type of Organization: Professional org association

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Public access to data used in federally funded research in peer-reviewed journals is essential for rigorous science, discovery, and the reproducibility of research. Public universities are committed to sharing the results of their research whenever possible. For this reason, the Association of Public and Land-grant Universities (APU), in collaboration with the Association of American Universities (AAU), and with funding from the National Science Foundation (NSF#1837847 and #1939279) and National Institutes of Health, held a series of workshops and conferences with researchers, senior research officers, librarians, chief information officers, and organizations supporting increasing public access to research. Many of the concerns outlined in this RFI were discussed by the research community during these convenings, and we draw upon that insight in our responses below.

NIH is a recognized world-leader in facilitating public access to research publications in the biomedical sciences with the creation, support, and management of PubMed Central. APLU appreciates that the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research allows for flexibility in where researchers publish and that the plan allows researchers to charge reasonable publishing costs to their awards. We have provided some suggestions for determining what are reasonable publication costs in a later section. The flexibility in where to publish and covering reasonable costs are critical elements in protecting our current peer review system in that the peer review system relies on the coordination of journal editors and publishers. However, these elements of the NIH plan are not necessarily sufficient to ensure equity in where and how researchers can publish their peer-reviewed scholarship. Reasonable costs might not cover all costs, which might preclude being able to publish in journals with the broadest reach and impact.

NIH could help address equity concerns for investigators and/or institutions to deposit research data by creating an agency-wide repository for data, especially for data without a current NIH-supported disciplinary repository. Such a repository or repositories would ensure that research data adheres to the FAIR principles of findability, accessibility, interoperability, and reusability of data. NIH could support both the technical infrastructure and the human infrastructure required to ensure quality data curation. This would increase standardization across the NIH directorates for research data produced in NIH-funded projects. This would also reduce the burden on any single researcher or institution on selecting an appropriate repository. An NIH-supported research data repository with expert staff (e.g. research librarians who could provide curatorial support) would reduce the cost to the investigator and/or institution, which would address many of the equity concerns related to publishing research data. The investigator community would be further helped if NIH led a coordinated effort with Other research agencies to support a common platform with common requirements. If there was such infrastructure,

investigators would only need to navigate one platform. Through this portal, NIH could also provide the aforementioned expert support services coupled with guidance and training for investigators on how to share their data so that it is FAIR and maximizes impact.

Creating critical infrastructure is only one concern of researchers and research institutions. Another concern that investigators have is that the publication of research may happen after the end of an award period due to the often-delayed peer review and revision process. How will NIH address cases where research outputs exceed the funding allocated in the grant or contract, or in which publications come out after the grant period has ended? A lack of funds may significantly impede the researcher's ability to publish their results in their discipline's preferred journal or deposit their research data in the discipline's preferred repository. This could, subsequently, affect the visibility and impact of the research, resulting in the marginalization of the career of researchers at emerging research institutions or less-resourced institutions. To help ensure that all researchers have the funds to appropriately and with greater impact share their findings, we encourage NIH to consider 1) allowing institutions to pre-pay publication costs; 2) allowing institutions to hold designated publication funds after the end of the award to pay for these publication costs; or 3) make supplemental funding available to cover these publication costs.

Additionally, the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research could help enable equity in sharing scientific data by harmonizing its requirements with the guidance given in the OSTP 2022 memo on "scientific data". The memo directs the agencies to ensure that "Scientific data underlying peer-reviewed scholarly publications [emphasis added] resulting from federally funded research should be made freely available and publicly accessible by default at the time of publication..." Currently, 'research findings' as defined by federal regulations (CFR 200.315 (e) and 45 CFR 75.322 (e)) are required to be published in a peer-reviewed scientific or technical journal. However, NIH's proposed expansion of the definition of 'scientific data' in its plan goes beyond the requirements of the OSTP memo and current regulations, potentially encompassing research data that has not necessarily been peer-reviewed. This could create uncertainty for researchers in determining when and what data needs to be shared "to validate and replicate research findings". Such a new standard for 'scientific data' may pose additional burdens on researchers, and the implications of this expansion need further clarification to ensure effective implementation of the NIH Plan while considering existing regulations and scholarly practices.

NIH could provide additional guidance to help researchers and institutions understand the impact of this plan on legal protections, retention of rights and intellectual property, and impacts on human subject protections and national security. As one concern, less resourced institutions may not have the technology transfer expertise to adequately determine whether a non-peer-reviewed data set falls under export control concerns. Who then ultimately decides which data that do not support a peer-reviewed publication is appropriate to share with the international community? Once research findings and research data enter the public domain it may be impossible to protect economically valuable information or protect against other unintended consequences. Who then becomes liable for any adverse outcomes that could not be reasonably anticipated?

Most importantly, there is not a clear mechanism for peer review to ensure the quality of the shared data - data that the general public might access and on which draw erroneous or even harmful conclusions. That it has been funded by NIH and shared with the public will signal that it is of a certain

quality and reliability, which may not be accurate. Who becomes liable for adverse events based on sharing this non-peer-reviewed data?

Further, we are concerned that there is no reasonable estimate for the cost to share this expanded scope of data that does not underlie peer-reviewed publications. The cost to the compliance system and the burden on researchers will be great since there is no clear way to track this data and currently little benefit to the researcher to share this data.

Given these concerns, we recommend that NIH's Plan to Enhance Public Access to the Results of NIH-Supported Research and related guidance follow the OSTP guidance to ensure scientific data underlying peer-reviewed publications be made accessible.

We recognize that in our current system some valuable data is not regularly peer-reviewed and shared (i.e. negative results data). To address this challenge, APLU would be happy to work with NIH and the broader research community to address how we might increase the incentives for publishing negative results by supporting venues where the data can be peer-reviewed and ensuring such publications are valued in grant reviews and performance/promotion.

2. Steps for improving equity in access and accessibility of publications.

To increase the discoverability of NIH-supported research data, NIH should support infrastructure that would enable searching all NIH-supported research data repositories via a common portal as NIH has done for peer-reviewed publications in NIH's PubMed Central.

3. Methods for monitoring evolving costs and impacts on affected communities.

We are pleased to see that NIH plans to actively monitor trends in publication fees and policies. We encourage NIH to also monitor publication outcomes that assess whether less resourced institutions, disciplines, and/or labs are increasingly locked out of publishing in the most accessed journals.

We are concerned that costs to publish will increase as publishers shift their business practices from collecting revenue from readers to collecting revenue from research awards. We encourage NIH to engage in an analysis of current article processing charges (APCs) within different disciplines and base "reasonable publishing costs" on current market rates for publications and depositing research data. This could be an annual analysis to ensure guidance on "reasonable publishing costs" is current and that publishing costs are not increasing at an excessive rate due to publishers shifting costs to investigators due to these new policies. The NIH could also engage in periodic dialogs with researchers, institutions, repositories, and publishers, especially from professional societies, to discuss what are "reasonable publishing costs".

4. Early input on considerations to increase findability and transparency of research.

APLU joined the Association of Research Libraries, the California Digital Library, and the Association of American Universities in convening an NSF-supported conference in 2019 (NSF #1945938) and released a report with recommendations for data practices supporting an open research ecosystem. Through those discussions, we came to a consensus on five persistent identifiers (PIDs) that would help ensure that research data is FAIR. These were:

1. Digital object identifiers (DOIs) to identify research data, as well as publications and Other outputs

2. Open Researcher and Contributor (ORCID) IDs to identify researchers
3. Research Organization Registry (ROR) IDs to identify research organization affiliations
4. Crossref Funder Registry IDs to identifier research funders
5. Crossref Grant IDs to identify grants and Other types of research awards

We also identified recommendations that would help support this necessary PID infrastructure. NIH could lead the following to advance the sharing of research and research data.

- NIH, in coordination and harmonization with Other federal agencies, could fund the design and development of tools and services to support the use of PIDs. NIH could fund investigators developing research-related workflows and systems that enable the collection of PIDs, storage of PID metadata, and connections to PIDs in Other systems.
- NIH, in coordination and harmonization with Other federal agencies, could invest in infrastructure and initiatives that support the use of PIDs by supporting member organizations that promote open scholarly infrastructure, such as Crossref, DataCite, and ORCID; funding organizations and data repositories that follow best practices for FAIR data; supporting community-led initiatives such as the Research Organization Registry and EZDMP.
- NIH, in coordination and harmonization with Other federal agencies, could minimize the burden on researchers by making it easy and seamless for researchers to use PIDs by designing workflows and systems to assign and collect them automatically and by supporting PID services or data repositories within the PubMed Central platform. This will be especially necessary for less-resourced institutions that may not have a research librarian to provide these services.

Email: kredd@aplu.org

Submit date: 4/24/2023

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

Name: Krystal Toups

Name of Organization: COGR

Type of Organization: Professional org association

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

To best ensure equity in publication opportunities for NIH-supported investigators, we offer the following comments and recommendations.

Costs:

As stated previously* , ensuring public access to publications and research data resulting from federally funded research requires financial investments across the research enterprise. The 2022 OSTP Memorandum notably removes the 12-month embargo period, and while we understand and support the benefits of this policy change, we share in the community's expressed concerns about the potential for shifts in publishing models and increased costs with varying impacts depending on institutional characteristics. It is important that agencies plan accordingly to prevent any inequities.

Publication Cost - While NIH policy allows supported researchers to charge reasonable publishing costs against their awards, it is important to recognize that "reasonable costs" may not account for all costs or account for increased costs due to a shift in the publishing models. We share the community's concerns about the shift in the publishing model towards Article Processing Charges (APC), which is a significant fiscal and cultural change from subscription-based cost models. This shifting model forces universities to bear an ever-increasing proportion of the costs associated with publishing, including APC, subscription costs, and provision of uncompensated scholarly reviewers. Budgetary constraints may force institutions to make difficult choices about which faculty members to fund, and early career researchers, researchers from institutions with limited resources, and/or under-represented groups may be disproportionately disadvantaged. Although NIH states in the RFI that APC may be charged to NIH grants, unless supplemental funds are provided, these charges will have a significant impact on the overall project budget. We hope that agencies and OSTP will directly address these concerns, and NIH should clearly state all APC, and Other publishing costs should be budgeted accordingly in NIH grants and contracts.

Modular Budget Caps - We would like to direct NIH to COGR's recent letter** that addresses the limitations of modular budget caps. COGR's December 8, 2022 letter provided support and analysis for raising the current modular cap (\$250,000) or eliminating the direct costs cap altogether (thereby allowing for all NIH-funded research to utilize the modular budget format). There has been a significant decline in the number of applications covered by modular budgets since implementation (90% in 1998 compared to 29% in 2021), and the modular cap has limited the ability to support fully all research activities in today's research environment. This is of particular concern within the context of Other recommendations being considered by NIH. Modular budgets are steadily squeezed in absorbing

increased activities, including activities for Data Management and Sharing*** and publishing costs. Increasing the modular budget cap or eliminating it together would allow researchers and institutions to account for the true costs of the project without hesitation or a need for tradeoffs to cover public access costs****.

Costs Beyond the Award Period/Post-Grant Funding - One area of NIH's Plan to Enhance Public Access that requires additional clarification is recovery of scholarly publication costs that will occur after the close of a project. These costs include fees associated with storing data and costs for manuscripts published after the grant has ended. We recommend that NIH address how these costs will be covered to meet policy expectations, such as providing supplements to cover costs, including those that occur during a no-cost extension.

Repositories :

Reduce Burdens Associated with Scholarly Publication Deposits - The OSTP memo requires that scholarly publications are made available in agency-designated repositories. The NIH Public Access policy requires that scholarly publications be made available in PubMed Central. Some universities additionally require that publications be deposited into University repositories (i.e., eScholarship), and the best practices of some fields recommend discipline-specific repositories. Depending on the situation, a researcher may be required to deposit the same publication in four different places to comply with various policy requirements. Considering the associated administrative burden with meeting various requirements, efforts to centralize and automate deposits into a single point for researchers will reduce the burden. Further, there is a concern that publishers may shift their approach away from automatic deposits to charging fees to deposit. This will increase the associated costs and researcher burden and potentially cause noncompliance with NIH's public access policy. To help reduce this burden, NIH should consider the following: 1) assume a larger role in creating a single central federal repository for public access, and 2) clarify whether PubMed Central meets the OSTP requirement.

* May 6, 2020 Joint Association Letter to OSTP on Public Access RFI -

<https://www.cogr.edu/sites/default/files/OSTP-RFI-Public-Access-AAU-APLU-COGR-formatted.pdf>

**December 2022 NIH Modular Grant Application and Award Process Letter

https://www.cogr.edu/sites/default/files/FINAL%20COGR_Modular%20Tabak%20Letter%20November%202022%20%28002%29.pdf

***December 19, 2022

https://www.cogr.edu/sites/default/files/DMS_COGR_Policy_Review_Dec19_final.pdf

****<https://www.aaas.org/sites/default/files/2022->

[10/OpenAccessSurveyReport_Oct2022_FINAL.pdf?utm_label=&utm_medium=twitter&utm_source=social&utm_campaign=AAAS](https://www.aaas.org/sites/default/files/2022-10/OpenAccessSurveyReport_Oct2022_FINAL.pdf?utm_label=&utm_medium=twitter&utm_source=social&utm_campaign=AAAS)

2. Steps for improving equity in access and accessibility of publications.

We are encouraged by NIH's plan to continue making articles available in human and machine-readable forms to support automated text processing to improve the accessibility of publications. NIH should work with the community to develop procedural improvements to ensure that articles are broadly available through assistive devices.

3. Methods for monitoring evolving costs and impacts on affected communities.

We appreciate NIH acknowledging the importance of monitoring trends in publication fees and associated policies to ensure that they remain reasonable and equitable. As described above, we are concerned about an adverse shift in publication models that may increase costs and impact early-career researchers, researchers from institutions with limited resources, under-represented groups, and researchers without federally funded research. As such, it is important for NIH to monitor trends and act, if publishing fees increase to ensure that researchers do not face undue burdens to publish. In this regard, we recommend coordination across NIH units, including OSP and OPERA, to ensure efficient practices are developed that reduce burden. To monitor costs, we recommend that NIH perform an assessment to identify equitable funding models. We are particularly concerned that increased costs and burden may disincentivize researchers to publish, leading to a decreased number of publication outputs.

4. Early input on considerations to increase findability and transparency of research.

COGR supports NIH's efforts to increase the findability and transparency of research by engaging through community dialogue for proposed policies related to PIDs and metadata. A particular area of importance is promoting cross-agency coordination to ensure consistency of agency plans and minimize compliance burden. We look forward to engaging with NIH further on this topic.

NIH should create template language, leveraging existing author addenda created by stakeholders and best practice organizations that may be utilized by researchers and institutions during the publication process to retain not only the right to publicly share an accepted manuscript but to create derivative works and to distribute the peer-reviewed manuscript under an open license even when publishing in a subscription journal (III.C.1). One example of this is the SPARC***** addendum. NIH should also consider encouraging licenses to permit sharing and reuse (i.e., Creative Commons and Other similar protocols) that enable broad circulation of scholarly publications. To maximize the impact of the above, NIH should consider what mechanisms and processes could be put in place to encourage researchers to use the provided template language and select less restrictive licenses. Finding ways to give researchers cause to use such resources would go a long way toward equitable compliance and ensuring the impact of funded research results is maximized.

*****<https://sparcopen.org/our-work/author-rights/brochure-html/>

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/COGR-Response-to-NOT-OD-23-091.pdf>

Description: Please see the attached letter for additional comments. We greatly appreciate the opportunity to comment and NIH's efforts.

Email: ktoups@cogr.edu

Submit date: 4/24/2023

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

Name: Christine Marie Battle

Name of Organization: American Association for Cancer Research

Type of Organization: Nonprofit research organization

Role: Institutional official

- 1. How to best ensure equity in publication opportunities for NIH-supported investigators.**
- 2. Steps for improving equity in access and accessibility of publications.**
- 3. Methods for monitoring evolving costs and impacts on affected communities.**
- 4. Early input on considerations to increase findability and transparency of research.**

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/NIH-RFI-NOT-OD-23-091.docx>

Submit date: 4/24/2023

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

Name: Agnes Balla

Name of Organization: University of California Office of the President

Type of Organization: University

Role: Institutional official

1. **How to best ensure equity in publication opportunities for NIH-supported investigators.**
2. **Steps for improving equity in access and accessibility of publications.**
3. **Methods for monitoring evolving costs and impacts on affected communities.**
4. **Early input on considerations to increase findability and transparency of research.**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/UC-Comment-Letter-on-NIH-Public-Access-Plan_final.pdf

Description: University of California system comment letter

Email: agnes.balla@ucop.edu

Submit date: 4/24/2023

I am responding to this RFI: On behalf of myself

Name: Carrie Nelson and Cameron Cook

Name of Organization: University of Wisconsin-Madison

Type of Organization: University

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

We encourage NIH to recognize that its policies are part of the global ecosystem of research and publishing. While NIH researchers are likely to comfortably be able to cover APCs or Other publishing charges with their funding, Other researchers with funding from Other agencies or without funding do not have the same advantage. While this is a great step in supporting all NIH researchers in making their work publicly accessible, it will continue to add to or potentially widen the gap with researchers without such funding. These discrepancies in resources affect where those researchers can publish, who will then read and cite them, and then subsequently their job, promotion, and funding prospects. This will continue to disadvantage early career researchers, historically excluded researchers, and researchers from Other countries across the globe.

NIH should consider working with publishers to negotiate a cap for, or Other model for managing and justifying, APC charges. While the NIH policy doesn't require a researcher to publish via gold or green OA, without any oversight publishers may take advantage of an unchecked market, those with a lack of literacy in publishing and public access policy terminology/processes, or identify ways to monetize reducing burden on the researchers via offering deposit in PMC. We are already seeing movements that suggest this is a real possibility - Springer Nature has already announced that only articles published openly will be deposited into PMC automatically.

An unchecked market could also add further stress to library budgets at research institutions. Library budgets are pressured to maintain existing purchases and subscriptions but are also beginning to be pressured to become a major mechanism for supporting publishing costs with read/write agreements, and subvention funds. This is especially challenging as library budgets serve and are set by their institutions, making it hard for libraries to both forecast and anticipate major changes or absorb extra costs. While libraries generally want to be a partner in shifting the mechanisms of open publishing, these costs continue to increase and compete with collection budgets, electronic resource budgets that continue to climb yearly, and Other staffing and resource costs. Researchers and libraries should not bear the brunt of the impact from this policy change.

There also continue to be concerns on costs -

If researchers do not publish until after close of project, they won't have funding for their publications

If costs for publishing continue to come out of the same budget as their Other research requests, they will continue to have to make unnecessary choices between their work and their options for publishing.

2. Steps for improving equity in access and accessibility of publications.

We encourage NIH to create standard language that authors are required to use when signing with publishers that allows them to retain their copyrights. SPARC and Other stakeholder and best practice organizations have existing author addenda language that is built in collaboration with Creative Commons and Other community members. Adapting SPARCs existing language would be best and encouraging use of it would enable easier compliance with this policy as this language requires that publishers provide a PDF final copy to the researcher who can then deposit the work. It also allows them to retain rights to make derivative works which would maximize the impact of federally funded research results. We also recommend NIH to consider encouraging researchers to use the least restrictive creative commons license possible and work with publishers to discourage use of the non-derivative (ND) clause of Creative Commons licenses.

3. Methods for monitoring evolving costs and impacts on affected communities.

High and unrestrained growing costs of publication fees negatively impact institutional and library spending on Other research resources.

NIH should identify opportunities for supporting early-career and historically excluded researchers. They should identify ways to work with associations or societies to connect with these populations and provide listening opportunities for feedback from those communities.

4. Early input on considerations to increase findability and transparency of research.

NIH should require researchers to both have and then use their ORCID ID when depositing in PMC. Encouraging the use and interoperability of standard and widely-adopted persistent identifiers will be beneficial for all stakeholders.

Email: carrie.nelson@wisc.edu

Submit date: 4/24/2023

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

Name: Anali Maughan Perry

Name of Organization: Arizona State University -ASU Library

Type of Organization: University

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Researchers and authors have come to associate paying publishers an article processing charge with making their research open or publicly accessible, despite this being only one business model. We recommend the NIH make explicit that the NIH does not require authors to pay any fee in order to comply with the NIH policy. The manuscript submission option for publications is the most affordable and equitable compliance mechanism, since there is no additional cost for the investigator to deposit in PubMed Central. Rather, institutions and libraries can build in support for workflows to assist researchers with the deposit process across federal agencies.

The NIH could provide a service to researchers by providing clear language and processes that researchers could use when working with publishers, to ensure they retain the rights they need to make their final, peer-reviewed manuscript freely and openly available in PMC without an embargo period.

Additionally, incentives and rewards for researchers need to be adjusted to better reflect desired changes in behavior and practice. For example, continuing to reward and privilege publications in high impact journals will serve to reinforce the status quo. This presents a conflicting message to researchers, when they are faced with competing demands to make their work publicly available by their funder, but evaluated on publication in certain outlets at their institutions. The Higher Education Leadership Initiative for Open Scholarship (HELIOS) working groups are developing new paths to address this at the institution level, and the NIH should collaborate with HELIOS to harmonize these efforts to reward public access compliance.

2. Steps for improving equity in access and accessibility of publications.

As stated above, the NIH could greatly assist researchers by providing clear language and processes that researchers could use when working with publishers, to ensure they retain the rights they need to make their final, peer-reviewed manuscript freely and openly available in PMC and specifically addressing the rights needed to support automated text processing and improving accessibility. All publications resulting from NIH-funded research should carry open licenses to fully enable future use and reuse. A CC-BY license, or functional equivalent, is the best way to ensure equity in access and accessibility, not only through less-restrictive dissemination, but also by explicitly enabling adjustments to format to allow for computational analysis, text and data mining, and adapting to assistive technologies both now and in the future.

Without explicit licenses giving permission to modify and redistribute research, libraries must rely on copyright exceptions to fully remediate content to support universal design principles. Many

institutions do not have the copyright expertise to feel confident making these evaluative, and often ambiguous, decisions, resulting in risk-avoidant behavior.

Finally, at ASU Library, we are required to make case-by-case consultations with researchers on whether computational analysis can be used for any given database or vendor platform, which is time-consuming and inefficient. Policies and practices around permissions for text and data mining vary widely and are inconsistent, resulting in significant barriers to enabling twenty-first century research practices. Our efforts to advocate for changes in license terms to support our researchers results in small steps forward. The NIH could make a significant advance in this area by requiring open licenses that enable computational research and discovery.

3. Methods for monitoring evolving costs and impacts on affected communities.

Publishing models that require authors to pay an APC for journal publication present significant publication barriers for many researchers. The rising cost of APCs prove prohibitive to individuals and their institutions, resulting in fewer opportunities for publications. APC costs disproportionately affect younger researchers, female researchers, and those at less well-funded institutions, who are less likely to have secured research funding. APCs also require a diversion of funds away from the research process; investigators often must use money originally intended for materials and equipment, supporting postdocs, and for professional development opportunities.

We recommend that the NIH monitor costs associated with APCs to ensure that federal research dollars are being spent as intended on research and that the costs of publishing are not creating arbitrary barriers to entry for researchers. As previously stated, the NIH should be explicit that authors are not required nor expected to pay any publication fee in order to comply with the NIH policy.

4. Early input on considerations to increase findability and transparency of research.

Where possible, NIH should require the use of existing external identifiers (DOIs for data sets and DMPs, ORCIDs for publications, RORs for institutions, etc.) along with continued requirements for internal identifiers (PMCID, GeneBank Accession numbers, etc.). Having consistent and standard identifiers promotes adoption and interoperability, which makes workflows and systems less complicated for all stakeholders.

Email: anali.perry@asu.edu

Submit date: 4/24/2023

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

Name: Makyba Charles-Ayinde

Name of Organization: American Association for Dental, Oral, and Craniofacial Research

Type of Organization: Professional org association

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The American Association for Dental, Oral, and Craniofacial Research (AADOCR) is the leading professional community for multidisciplinary scientists who advance dental, oral, and craniofacial research. We appreciate the opportunity to share our thoughts on the request for information on the National Institutes of Health (NIH) plan to enhance public access to the results of NIH-supported research. AADOCR recognizes and applauds the NIH's efforts toward providing public access to scholarly publications and data resulting from the research it supports. Further, the AADOCR commends the White House's Office of Science and Technology Policy (OSTP) efforts to ensure free, immediate, and equitable access to federally funded research in a manner that maintains scientific integrity and reproducibility of research. To respond to this request for comments, AADOCR engaged its Science Information Committee and its Board of Directors.

Increasing access to publications and data resulting from federally funded research offers many benefits to the scientific community and the public. However, there are costs associated with reviewing, editing, and publishing manuscripts that will need to be financed¹. There are concerns that the publication costs from longstanding print journals may rise quickly and significantly for open-access articles. Publishing open access articles involves an open access publication fee (APC) which varies per journal². Over the past few years, the cost for this option has increased rapidly. Significant fees for publication are now becoming normalized (apart from COVID-related articles). Several journals, such as Cell, eLife, Anatomical Record, and Nature Neuroscience, have notably increased their APC with costs reaching up to ~\$12,000 USD per manuscript³. Budgeting \$12-15,000 per year within a grant would be a substantial cost for investigators and may potentially affect the output of a researcher if they quickly exceed their publication allotment.

These high publication costs are especially challenging for early-career researchers who may feel greater pressure to publish their research more frequently, researchers within smaller institutions or organizations with limited resources, Historically Black Colleges and Universities, researchers who do not qualify or are not selected for grants to assist with APCs, and those utilizing micro or seed grants. Researchers at institutions with a student body < 10,000 students were three times as likely to find it very difficult to obtain funds for APCs as their counterparts at larger institutions, adjusting for gender, race, and length of time conducting research⁴. These prohibitive financial barriers may result in meaningful research going unpublished. Therefore, AADOCR supports a subsidized approach to the publication of open access articles where the funding institutions absorb a larger percentage of the APCs required to increase access to the articles. This will ensure that the NIH's Public Access Plan does not

result in scientists bearing the brunt of publishing costs through substantially higher fees passed on to them by journals.

AADOCR also supports a federally managed public registry for NIH funded studies to provide access to the results/data from these studies. The format of this registry may be similar to clinicaltrials.gov, and accessible to the general public. The public registry should provide a platform for all NIH funded researchers to deposit their results including unpublished negative data. Researchers will be required to include all experimental details and will be helpful to increase findability and transparency of research. It will also be helpful to include progress reports on available grants to ensure that analyses of studies without publications are publicly available. Although there is currently a Grantome interface, there are several challenges associated with that platform including difficulty navigating the interface (large number of unrelated or unwanted results), difficulty updating the result/publication section, and inability to include the researchers' website or data sharing links.

2. Steps for improving equity in access and accessibility of publications.

AADOCR supports reducing the knowledge gaps that exist with researchers and publication availability and access. Sharing information about publication availability with researchers/universities, organizations, and schools to increase awareness that these resources are available freely to them is critical to improving equity. Additionally, streamlining the NIH grant process and better publicizing mechanisms to access NIH funding that can substantially support APCs or waive publishing fees will benefit smaller institutions or early-career researchers without large grants.

Researchers from underserved populations, including early career researchers, those from historically excluded backgrounds, and those at less research-intensive institutions, do not have assured access to open access publication funds. Research has also shown gender disparities in funding for APCs as females were three times as likely to use grant funds to pay for APCs when compared to their male counterparts⁴. This diversion of funds comes at the expense of Other career advancement options such as professional development, equipment, and materials. This continues to further perpetuate disparity gaps in the biomedical workforce. Therefore, AADOCR supports NIH dedicating publishing resources for researchers from underrepresented populations and providing guidance to program officers on addressing equity in publication opportunities.

3. Methods for monitoring evolving costs and impacts on affected communities.

4. Early input on considerations to increase findability and transparency of research.

AADOCR supports providing an option to filter the search by grant funding / IC / mechanism. This provides a utility to search by researcher and identify which publications are from the funded grants in PubMed or Other biomedical literature search engines.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/AADOCR-Comments_NIH-Plan-to-Enhance-Public-Access.pdf

Email: mcayinde@iadr.org

Submit date: 4/24/2023

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

Name: Dan Valen

Name of Organization: Figshare (Digital Science)

Type of Organization: Other

Type of Organization-Other: Research Software

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

At Figshare, we believe equity in publishing begins with openness and transparency. One way to strengthen the NIH Public Access policy and create more equity in publication opportunities could be to require or encourage NIH-supported investigators to submit their pre-peer reviewed publications to a preprint server (such as the ones listed by ASAPbio: <https://asapbio.org/preprint-servers>).

Posting preprints to a preprint server increases the visibility of research more quickly than publishing in traditional journals and also provides broader exposure. Preprints have the added benefit of reaching those with and without access to expensive journals or journal databases and removes the need for researchers to wait for a peer reviewed publication.

The NIH Plan for Scientific Data addresses many of the requirements needed to not only encourage investigators and NIH-supported researchers to make data underlying a publication available, but also to treat research data as a 'first-class' research object, in turn allowing researchers to build on pre-existing research. As part of this effort, it would be beneficial to index scientific data published in repositories in PubMed as well as to ensure links between publications and datasets in PubMed metadata.

One final aspect of the new Public Access Policy would be to consider developing criteria that ensure transparency and fairness in the selection and review of articles for publication in NIH-supported journals, regardless of the authors' affiliations or backgrounds.

2. Steps for improving equity in access and accessibility of publications.

One of the biggest barriers to access of articles across PubMed is the majority of content on the platform is in English. The language barrier can be limiting or seen as a limitation to research from non-English-speaking countries or researchers and users in the US whose first language is not English. With the removal of the 12-month embargo for all NIH-supported publications, content will be available early and as full text. It would be fantastic to explore ways to not only provide access to articles in human and machine-readable forms but also to provide multilingual support. In addition, continuing to refine the user interface so PubMed can be easily searched by non-experts, such as patients and members of the public, would facilitate greater access to this publicly funded content.

3. Methods for monitoring evolving costs and impacts on affected communities.

There are a few ways to monitor evolving costs and the subsequent impacts on affected communities. Namely, the NIH could conduct regular surveys or questions around publication fees from publishers to

ensure they remain reasonable and equitable. Similarly, the NIH can consult with stakeholders and community members to help identify emerging issues related to publication fees from publishers.

The NIH can also look to analyze trends and data related to publication fees of NIH-sponsored research and publications to help inform future policies and provide a benchmark for the impact of making research openly available.

The benefits of open science are widely seen as a positive contribution to both the research process and wider society as a whole. One topic that is often not addressed is the economics of open data -- namely, how can we ensure that sustainable data sharing practices are accessible and equitable for researchers across diverse fields, institutions, and geographic regions? Tracking the compliance and costs not only of the publication but also of the accompanying data should be under consideration. Researchers are now encouraged to plan and budget for “fundamentals for data management and sharing activities” and institutions are also increasingly providing resources for these efforts. NIH programs could track how funds are budgeted and spent on these activities and also survey academic institutions that receive NIH funding on the resources they are providing to meet these needs.

4. Early input on considerations to increase findability and transparency of research.

To increase findability and transparency of research outputs, the NIH may consider adopting a standardized system of PIDs, metadata, and specific ontologies across research objects to make content more discoverable and linkable across platforms and repositories outside of the NIH. The Generalist Repository Ecosystem Initiative (GREI) is currently addressing this among generalist data repositories, but it would be helpful to reinforce this work and promote the adoption of PIDs and standard metadata by researchers, institutions, discipline-specific repositories, and publishers to increase the interoperability and accessibility of research content. PIDs and metadata should also leverage existing community standards and initiatives to increase standardization such as the DataCite metadata schema, ORCID and ROR identifiers, and Make Data Count metrics. PIDs and metadata that allow for easy tracking and linkage with specific NIH funding sources (grants, awards, contracts) would be especially valuable for the research output community to incorporate as a common standard and support linking research outputs to funding sources, which would also facilitate tracking of data sharing and public access at the NIH and institutional levels.

The NIH should continue to consult with stakeholders and community members to identify any specific issues or use cases related to PIDs and metadata that may need to be addressed to improve the use and adoption of these tools.

Email: dan@figshare.com

Submit date: 4/24/2023

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

Role: Medical provider

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

ASCO and the NIH-funded researchers within our membership are concerned that if a zero-embargo green open access model (whereby manuscripts accepted for publication in journals that report on NIH funded research are made available on PubMed Central immediately upon

publication) is no longer available due to journals having to convert to author-pays gold open access models, underfunded researchers will be shut out of publishing their research in journals. This will create more disparities in the research pipeline and in evidence-based care that puts all patients at risk.

Looking ahead, we are concerned that in an environment where the majority of publications require fees for publishing, manuscript output (the main driver used by researchers to show the impact of the funding) will decline. Grant awards, already often insufficient for the intended research, will also be unlikely to fully cover publication expenses, putting the funds needed to conduct research in direct competition with funds needed to publish research.

This unintended, though highly likely, scenario will have a disproportionate adverse impact on early career researchers, whose grants typically are smaller and have less room to accommodate expenses not directly applied to the research itself. These predictable impacts are the reason that ASCO urges the NIH to fully consider and account for the ramifications this proposed plan will have on all levels of grantees. (Please see full letter attached.)

2. Steps for improving equity in access and accessibility of publications.

ASCO's journals provide value to clinicians, researchers, institutions, and funders by facilitating high-quality peer-review and integrity checks on all published materials. We request that the NIH refrain from applying broad re-use licenses to the PubMed Central deposited papers as it will have the unanticipated, undesired, and paradoxical effect of diminishing the quality of content made available to the profession and the public.

Instead, to preserve equity in publishing opportunities across our journals, we are committed to providing a green open access model for as long as financially sustainable. However, if a zero-embargo green policy is coupled with broad re-use rights, we will not be able to afford to maintain a green route for author compliance. (Please see full letter attached.)

3. Methods for monitoring evolving costs and impacts on affected communities.

Certain grants do not permit use of funds for publication fees. Therefore, ASCO recommends that NIH exempt certain types of infrastructure-related grants (e.g., cancer center support grants, TSAs, NCORPs) and teaching grants (K awards, T awards) from reporting funding to journals and thus requiring deposit.

The broad reach and impact of this proposed plan will be a challenge to implement and enforce if compliance is mandated for all NIH funded authors regardless of how much funding they received or how small a role any given individual plays in a research project or manuscript. The NIH should instead apply a minimum threshold of funding and/or level of participation by authors and researchers before subjecting the papers to the proposed mandate.

We encourage the NIH to publish clear guidance, on which circumstances qualify submitted papers to claim NIH funding, and on the conditions that invoke a requirement to comply with the public access mandate. More and better communication to grantees and Other stakeholders regarding expected compliance is essential with the planned zero embargo policy. (Please see full letter attached.)

4. Early input on considerations to increase findability and transparency of research.

Please see full letter attached.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/ASCO-Comments-NIHopenaccRFI04242023-signed4-24-2023revised.pdf>

Description: ASCO NIH RFI Comments

Email: angela.cochran@asco.org

Submit date: 4/24/2023

I am responding to this RFI: On behalf of myself

Name: Jonathan Saunders

Name of Organization: UCLA, Department of Neurology

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The steps towards openness in the 2022 OSTP Memorandum and subsequent notices like NOT-OD-23-091 are admirable steps to use the power of the NIH as a funding body to set standards for equity in public research. The proposals as written seem to be “fighting the last war,” however, focused on closed-access publication without considering the significant shift in market structure as traditional scientific publishers have transformed into data brokers.

It is impossible to ignore the role of for-profit academic publishers as a primary source of inequity when considering these policies -- without their prior model of subscription-based access, there would be no need for these policies at all. We cannot play coy and pretend to be market neutral when considering how scientific publishing should work: for-profit scientific publishing, now largely an oligopoly owned by a handful of information conglomerates, is an ethical catastrophe, and if we intend to grasp at the root of the problem we need to contend with the ways their business models distort the practice of science at every stage.

The publishing oligopoly has had ample time to prepare for the shoe of universal open access to drop, and if their shareholder-facing communications are any indication, they have already fully accounted for it and adapted their business models accordingly. They have been focused heavily on shifting their default strategy from subscription-based publication to author-pays APC-driven open access, as this proposal tacitly endorses. This model is **intrinsically inequitable,** as it is explicitly designed to shift the burden of payment from libraries to individual researchers, and more closely align the cost of publication with the benefits accrued through the prestige associated with a journal brand. At the point when (1) there is **any** gradient of APCs such that high-prestige journals like Nature and Cell have a higher cost, and (2) publications in high-prestige journals are a necessity for grant funding and promotion, the system is fundamentally inequitable. Worse, by atomizing the ability to negotiate with publishers, shifting from libraries and library consortia to individual researchers, we neutralize the power of some of the few organizations capable of pushing back against the for-profit publishers by embracing a positive feedback loop where researchers have every incentive to slide the slippery slope of rising APCs in order to retain their employment.

If this proposal leaves the for-profit publishing apparatus largely intact, it will enter the history of half-measures made in deference to the publishing oligopoly that leave the problem perpetually unsolved. One can only imagine the state of every field of research from pharmaceuticals to astrophysics if we had the courage in 1999 to implement the full version of Harold Varmus’ vision for PubMed Central, displacing for-profit publishing entirely with free to publish, free to read research as the norm. What could the world be like if we had 20 years of experimenting with open research dissemination, rather

than spending the dawn of the information era hobbled by broken systems accessible to a vanishingly small and privileged few? Will we be looking back in another 20 years wishing we had the courage to end for-profit publishing now?

The very framing of this RFI as being focused on open access publication rather than the infrastructure of our communication demonstrates that we are missing the implications of the shift in the business models of the major for-profit publishers towards “surveillance publishing.” The next era of scholarly communication battles will be about *infrastructure.* Profit models are consolidating around collecting user data and repackaging it into bibliometrics and informatics platforms like so-called “research intelligence” tools like RELX’s SciVal. With the requirement for open data, we will face another period of enclosure where there is a less clear distinction between publishing, data sharing, and computation. As written, the NIH would directly create a new triple-pay system in the very policy that is intended to address the prior one: if NIH’s STRIDES project is the intended model, NIH pays cloud providers for discounts so that researchers can pay to archive their data as well as pay to export it.

The infrastructure of scientific communication is a fraction of the complexity of that which will be required for universal open data: it is trivial to start a new journal-like website, it is not so trivial to create a new server farm for storing bulk data. The inequity from APCs will be orders of magnitude greater as the process of science congeals into a series of pay-to-use platforms that skim public funding at every stage from grant proposal through data collection, analysis, and publication. The NIH discusses monitoring funding inequity for publication, but is it prepared to handle the broader inequities from the capture of research information infrastructure by a handful of cloud platform giants? Who, exactly, will have the funding necessary to pay for tools that produce clean data, to hire the data scientists to manage it, and to pay the costs of cloud storage and computation? Plainly, the NIH stands to slice off an increasing fraction of its budget to orbiting information rentiers rather than directly funding research, and the dream of universal information access will always be out of reach beyond some exorbitant hosting bill.

The landscape of options that would truly make a more equitable and robust scientific process is wide open, and all of them mean taking a meaningful stand in favor of a public information commons and against for-profit private ownership of information infrastructure. Rather than a single recommendation, I urge the NIH to reorient this and future proposals towards a nonprofit, publicly-owned informational commons. Requiring that all publishers must be operated as nonprofits is one first step. A fixed and decreasing cap on APCs to sunset pay-to-publish models in favor of so-called “diamond” open access is another. Publishing venue-agnostic grant decisions are another. Addressing the next generation of infrastructure needs equitably requires that we look beyond the “Platform as a Service” model articulated in NIH’s 2018 strategic plan for data science where public research bodies outsource and rent basic infrastructure from cloud providers. A full technical evaluation is of course out of scope of this RFI, but a system of peer to peer infrastructure that can leverage resources from individual computers through institutional and federal systems without dependence on cloud providers would be capable of addressing inequity as well as realizing the ambitions of information access articulated in these proposals.

I and Others have written elsewhere and are working on these systems.

2. Steps for improving equity in access and accessibility of publications.

The greatest hindrance to accessibility of scientific publications is not technical (though the ailing infrastructure of the traditional publications is some decades behind the rest of the web), but the socio-economic construct of traditional journals themselves. The form of the scientific journal article is entirely unlike how the vast majority of non-scientists interact with information, and is structured by an industry that maintains its profit by strategically suppressing semantic organization in favor of using journal brands as the primary organization principle to maintain the effect of their prestige. It is prestigious to publish in Nature because people will read it. People read Nature papers because there are no effective means of finding research based on its content, leaving scientists to organize dissemination in ad-hoc media like Twitter or be dependent on downstream patches like Google Scholar.

If the NIH is serious about making scientific research more accessible to non-scientists, it must address the ways that research incentives uniformly encourage publication of impenetrable prose in domain- or prestige-limited venues in favor of promoting alternative means of organizing scientific communication, including peer review and publication. We need to not only make it easier for everyone to make sense of the scientific record, we must also reckon with how our incentive structures cause the scientific record to be so difficult to make sense of in the first place.

Accessibility for people that need assistive technologies can *only be helped* by taking more direct control over our infrastructures of communication. Rather than being beholden to the structure imposed by journals, we should directly address the technologies and social systems that structure scientific communication as part of a holistic project of information accessibility.

3. Methods for monitoring evolving costs and impacts on affected communities.

If the NIH agrees to step in and offset exorbitant APCs in prestige journals in the name of equity, particularly without clear language about what counts as a “reasonable” cost, it sends the message that it is willing to pay any price that the publishers demand. The framing of monitoring evolving costs indicates that the NIH is aware that this policy will increase publication costs, and those increases will inequitably affect researchers outside of the highest echelons of funding and prestige. We do not need to accept this as an inevitability --- there are multiple routes towards explicitly avoiding an APC-driven publishing market, and towards creating a peer to peer data infrastructure that avoids outsized cost burdens for marginalized researchers.

4. Early input on considerations to increase findability and transparency of research.

It is critical to understand the history of PIDs and how they structure and reinforce the for-profit publishing system, advantaging larger players and disadvantaging independent alternatives. The DOI system itself was created in response to NIH’s 1999 push for PubMed Central in order to preserve the publishing industry’s dominance in assigning identifiers --- and thus what can be counted as research. The decades of research on persistent identifiers show that decentralized alternatives like the ARK or IPFS’s CID work, and we should prioritize identifiers that can be created and structured by any researcher, rather than controlled by a centralized authority. Critical research on ontologies and metadata also show their intrinsically political nature, which also points towards tooling to express metadata rather than the current approach taken by NIH’s Biomedical Translator project of creating quasi-universal ontologies to be mapped onto.

I am available for further comment on this and the rest of the responses to this RFI, and I appreciate any time taken to read this.

Description: The NIH should directly oppose a for-profit APC-driven publication system and cloud research infrastructure, and instead focus efforts on building truly public information infrastructures.

Email: j@nny.fyi

Submit date: 4/24/2023

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

Name: Cable Green

Name of Organization: Creative Commons

Type of Organization: Nonprofit research organization

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

- We note that the manuscript submission option for publications is the most affordable and equitable compliance mechanism as it is free for the investigator to deposit in PubMed Central (PMC).
- We recommend that NIH state explicitly that there is no charge for complying with NIH's policy.
- Depositing a final peer reviewed manuscript in PMC is free of charge, legal, and ensures that the researcher is in full compliance with the NIH Public Access policy.
- Any fees charged by a publisher are for publication in that particular journal — not for compliance with NIH's Public Access Policy.
- NIH should offer clear language and processes that investigators can use to retain rights to make their peer reviewed manuscript freely available and fully reusable post-publication in PMC without an embargo period. Specific instructions for doing this effectively and emphasizing that it is compliant with copyright and journal policies will help authors comply with the policies, make federally-funded research reusable, and further support NIH's goal to ensure equity in publishing.
- NIH should encourage the use of publication channels that do not present financial (or Other) barriers to researchers, including non-Article Processing Charge (APC) supported open access journals, preprint servers, and Other emerging community-driven options. Journal business models requiring authors to pay a fee for journal publication present significant publication barriers for many researchers.
- The NIH should work with the higher education community to align research assessment and career advancement incentives (e.g., promotion and tenure) to support scientific publication models that actively promote equity in publication opportunities.

2. Steps for improving equity in access and accessibility of publications.

- The OSTP Nelson memorandum asks agencies to "make federally funded publications, data, and Other such research outputs and their metadata...findable, accessible, interoperable, and reusable, to the American public and the scientific community in an equitable and secure manner." To fulfill the reusability requirement, all publications resulting from NIH-funded research should carry standard international open licenses, and NIH or authors should explicitly retain the rights needed to authorize those open licenses.
 - Placing the most current version of the CC BY license or its functional equivalent on a publication is the best way to ensure that publications can be freely accessed and fully reused.

- Open licensing advances research, enables text and data mining to foster further scientific investigation, educational reuse, translations into Other languages, and computational uses, as well as use of content on assistive devices.
- NIH should offer clear language that investigators can use to specifically retain rights to make their final peer-reviewed manuscript freely available and fully reusable (under the CC BY license or its functional equivalent) post-publication in PMC without an embargo period.

3. Methods for monitoring evolving costs and impacts on affected communities.

- We note once again there is no cost for complying with the NIH Public Access Policy when using the manuscript submission option.
- However, NIH should be aware that models requiring authors to pay an Article Processing Charge (APC) fee for journal publication present significant publication barriers for many researchers.
 - The rising cost of APCs often prove prohibitive to individuals and their institutions, resulting in fewer opportunities for publications. Studies have documented that APC costs disproportionately affect younger researchers, female researchers and those at less well-funded institutions.
 - APCs also require a diversion of funds away from the research process; investigators often must use money originally intended for materials and equipment, supporting postdocs, and for professional development opportunities including presenting research results at conferences.
- We recommend that the NIH monitor costs associated with APCs with special attention to how costs are distributed along disaggregated data variables for different marginalized groups to ensure federal research dollars are being spent as intended on research and that the costs of publishing are not creating arbitrary barriers to entry for researchers, and the ultimate availability of publishing opportunities for researchers at traditionally underrepresented institutions and in less-well-resourced disciplines.
- The NIH should monitor the cost of APCs levied on its investigators. Data collection on the amount spent to publish NIH-funded research regardless of the source would increase transparency and insight into how these fees affect various communities — including the potential impacts of publishing opportunities — on traditionally underrepresented institutions and in less-well-resourced disciplines.

4. Early input on considerations to increase findability and transparency of research.

- Ensuring that the results of NIH-funded research along with metadata containing information about who conducted the research, where it was done, and with what resources is an important component of the NIH Public Access Plan. This requires NIH to articulate clear expectations about the use of Persistent Identifiers (PIDs) throughout the research process.
- Where possible, NIH should require the use of existing external identifiers (DOIs for publications, data sets, and DMPs, ORCIDs for researchers, RORs for institutions, etc.) along with continued requirements for internal identifiers (PMCLDs, GeneBank Accession numbers, etc.)
- Because similar identifiers will be required to be used by all federal agencies as a result of the OSTP Memorandum, NIH should coordinate its efforts with Other participants in interagency working groups,

including the National Science and Technology Council's (NSTC) Subcommittee on Open Science, to identify best practices and potential standards.

- NIH should also consider collaboration with a standards body, such as the National Information Standards Organization (NISO), to help develop a set of standards and framework for a national PIDs strategy to facilitate smooth implementation.

Creative Commons thanks the NIH for updating its policy to eliminate embargoes, improve data sharing and enhance reuse rights to publicly funded research outputs. Openly-licensed research accelerates the pace of discovery, reduces information sharing gaps, encourages innovation, and promotes reproducibility. We appreciate the opportunity to comment on this draft plan, and we are eager to assist in its eventual rollout.

Email: cable@creativecommons.org

Submit date: 4/24/2023

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

Name: James C. Appleby

Name of Organization: The Gerontological Society of America

Type of Organization: Professional org association

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

As a critical component of its public access plan, we urge the NIH to focus on creating an environment that balances reader access to published work with researchers' ability to publish. This will require transparency and recognition of the costs borne by researchers and research funders. We must strive to create a system wherein scientists are not required to pay additional fees to publish and where grants are not required to bear the brunt of publishing costs. Otherwise, we risk creating heavy cost burdens not only for researchers and their institutions, but also for funders of research, including taxpayers.

Rigorous peer review and expert editorial efforts ensure GSA continues to be a trusted, reliable, and credible source for scientific publications in gerontology and geriatrics. Through a publishing agreement with a scholarly publisher, GSA can reinvest the revenue from the GSA journals to ensure the quality of the publications.

2. Steps for improving equity in access and accessibility of publications.

Scientists' ability to communicate their scientific results through publication is critical to the incorporation of their expertise into the scientific enterprise and the progression of their careers. Monitoring implementation of changes to the public access policy, and how researchers and institutions pay publishing costs, will be critical to ensuring that public access plans do not create new systemic inequities or reinforce existing ones. Careful and continued study will be essential for understanding the near- and long-term effects of related changes. Study of cost effects at the researcher, institution, and enterprise levels is needed. It may also be valuable for NIH to survey researchers and institutions about publishing costs and about tradeoffs made to pay such costs.

3. Methods for monitoring evolving costs and impacts on affected communities.

Adaptation of federal grant agreements to require reporting on the payment of publication fees and reliance on transformative agreements (in instances where authors avoid payment of a fee because their institution has a transformative agreement with their journal of choice) represents one logical approach to monitoring fees. All 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.

4. Early input on considerations to increase findability and transparency of research.

We are pleased that through our current publisher, GSA provides some or all metadata for all authors. GSA appreciates efforts underway such as the requirement for individuals supported by research training, fellowship, research, education, and career development awards to have Open Research and

Contributor Identifiers and exploring the use of the digital object identifier system. GSA looks forward to the opportunity to provide continued input as systems to increase findability and transparency of research are developed.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/230424-RFI-NOT-OD-23-091-NIH-Public-Access-GSA.pdf>

Description: RFI Response

Email: pdantonio@geron.org

Submit date: 4/24/2023

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

Name: Katie Grady

Name of Organization: American College of Radiology

Type of Organization: Professional org association

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

NIH and NIH-funded researchers have a duality of interest in publication of research project results, but may have a different interest in how, when, and where those results should be published. While the NIH would likely prefer earlier reporting for transparency and access to data, researchers funded through NIH may prefer later reporting to allow for greater time and ability to complete and evaluate primary and secondary endpoints, and toxicity. To address this duality of interests, the NIH would be best served to encourage (or require) early reporting of select findings, using a templated reporting process to ensure consistency. Peer-reviewed journals are unlikely to accept these preliminary reports, so consideration could be given to an internal NIH-developed outlet, similar to the www.clinicaltrials.gov product. Reporting to/through the new product could be required, but the data provided would not preclude subsequent submission to peer-reviewed journals or meetings. Time of submission could be following completion of the initial Data Safety Monitoring Board (DSMB) review. Templated required data, to provide sufficient information for the public and providers/researchers, could include a brief outline of the trial (phase, study, control arms, inclusion and exclusion criteria, statement regarding generalizability of findings, statement of DSMB findings, statement as to meaning (or lack of meaning) of the data at this juncture, analysis of the current findings, and a statement regarding next steps. Journals are unlikely to willingly give up editorial control or consider reducing their peer-review processes or quality criteria, so novel approaches are necessary to ensure ultimate access to study results, especially for negative or discontinued trials, which journals have historically been unwilling to publish. The NIH could launch a publication for manuscripts reporting only NIH-funded research or could consider supplement(s) to existing NIH journals limited to manuscripts reporting NIH-funded research. This could be done through various Institutes and Centers (ICs). The NIH could consider support through its ICs for publication of supplements limited to NIH-funded research manuscripts. Finally, the cost of submitting articles for publication creates inequity based upon the resources available to researchers. Evaluation of this cost process should be considered to improve equity for investigators.

2. Steps for improving equity in access and accessibility of publications.

Except for final manuscripts at study completion, all interim reports should be open access and in a process that not only allows but requires interim reporting of NIH-funded research.

3. Methods for monitoring evolving costs and impacts on affected communities.

Providing a source for interim reporting directly through the NIH will allow for significant cost reduction/control.

4. Early input on considerations to increase findability and transparency of research.

Reporting of interim reports could be available through hot links on www.clinicaltrials.gov, and Other sites listing NIH-funded research.

Email: kgrady@acr.org

Submit date: 4/24/2023

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

Name: Katie Steen-James

Name of Organization: SPARC

Type of Organization: Professional org association

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

SPARC strongly supports the OSTP Memorandum's emphasis on ensuring equity in contributing to, accessing, and benefitting from the results of federally funded research, and we appreciate NIH's specific attention on how to ensure equity in publication opportunities for its funded investigators. As the research process has shifted to the digital environment, a wide variety of channels designed to support more rapid, frequent, and iterative communication of research findings have emerged.

It is vital that researchers have compliance options that do not present them with financial barriers. To that end, NIH should make it clear that investigators can fully comply with its public access policy by depositing their author's accepted manuscripts into PubMed Central (PMC) or any Other agency-approved repository—and that there is no charge to do so.

In its guidance, it is important for NIH to make clear that any fee that investigators may be asked to pay is a publication fee, and not a fee required by NIH to comply with its policy. It is critical that investigators do not conflate compliance with article processing charges (APCs), which create significant barriers for less-well-resourced investigators and institutions to make their research available.

There are a growing number of communications options that provide free, immediate access to research outputs that do not rely on unnecessary and unsustainable author-side charges for investigators. NIH should actively encourage the use of publication channels that do not present financial barriers, including non-APC supported open access journals, publications from non-profit University presses, and scholarly society publishers that allow repository deposit and full reuse of author manuscripts, preprint servers, and Other emerging community-driven options.

We also note that institutional repositories run by libraries and Other research institutions generally do not charge authors to deposit articles or manuscripts, and could play an important role in easing compliance burdens on investigators, improving discoverability of research outputs, and providing long term preservation support. We recommend that NIH engage with the U. S. Repository Network (which recently released the "Desirable Characteristics of Digital Publication Repositories" document) to identify additional repositories that meet NIH's criteria for depositing publications.

To accelerate and sustain equitable research communication practices in the long term, it is critical that research assessment and career advancement incentives be updated to actively promote equity in publication opportunities. NIH should look for opportunities to better align its awards process with equitable research communication practices, such as avoiding journal-based metrics and recognizing preprints. It would also be useful for NIH to engage with ongoing efforts designed to address this important area, including The NASEM Roundtable on Aligning Incentives for Open Science and the Higher Education Leadership Initiative for Open Scholarship (HELIOS).

NIH's efforts to ensure equity in publication opportunities for its investigators naturally align with the critical work of the National Science & Technology Committee's (NSTC) Subcommittee on Equitable Data. SPARC strongly supports the Subcommittee's work to "Build Capacity for Robust Equity Assessment for Policymaking and Program Implementation" and recommends NIH coordinate the implementation of its public access plan with the NSTC Subcommittee and the Department of Health and Human Services' (HHS) Equity Action Plan. Additionally, the public access plan should be included in HHS' equity assessments and disparity impact strategies.

2. Steps for improving equity in access and accessibility of publications.

The early stages of the COVID-19 pandemic demonstrated the importance of full reuse rights when, after prompting by global leaders, publishers made COVID-related articles immediately available in PMC under article-level licenses that allowed for full reuse and secondary analysis. Within the first two weeks, these articles had been accessed or downloaded over 2 million times—greatly accelerating the rate of discovery, speeding the translation of science, and increasing the community's understanding of the virus. This temporary shift in practice highlights the need for a permanent change making federally funded research publications both immediately available and fully reusable in order to provide much broader, real-time returns on taxpayer investments in scientific research.

The OSTP Memorandum asks agencies to "make federally funded publications, data, and Other such research outputs and their metadata...findable, accessible, interoperable, and reusable, to the American public and the scientific community in an equitable and secure manner." To fulfill the reusability requirement, NIH should ensure that all publications resulting from NIH-funded research carry open licenses and that NIH authors can explicitly retain the rights needed to authorize those open licenses, regardless of whether authors deposit an author accepted manuscript or a final published article. To this end, placing a CC BY license or its functional equivalent on a publication is the best way to ensure that publications can be freely accessed and fully reused.

NIH should ensure that it obtains sufficient rights to provide the public with the full benefits of the research that it funds. In particular, as the OSTP Memorandum directs, the public should be able to access final peer-reviewed accepted manuscripts freely, without embargo or delay, and under terms that make them fully reusable. The agency should seek to achieve this result in a manner that minimizes complexity and burden in compliance by grantee institutions and individual researchers.

3. Methods for monitoring evolving costs and impacts on affected communities.

At SPARC, we are deeply concerned about the financial barriers that author-side fees, particularly Article Processing Charges (APCs), present to authors and the significant additional negative effects these have on the research ecosystem. APCs are rising very rapidly in price, driving an overall increase in the cost of research communication that presents a growing risk of tradeoffs in diverting funds away from the research process itself. The diversion could negatively affect the budget needed for materials and equipment, supporting postdocs, and professional development opportunities including presenting research results at conferences.

APCs create prohibitive barriers to publication that negatively impact many researchers, especially in instances where publishing in particular APC-based journals is viewed as important for career advancement. This results in fewer opportunities for individual researchers to share their results with

the scientific community and the public. This is extremely troubling from an equity perspective, as studies have documented that APC costs disproportionately affect younger researchers, female researchers, and those at less well-funded institutions.

It is important for NIH to be aware of these impacts, and to actively monitor the impacts of any publication charges across demographic groups in the research ecosystem. For example, NIH should establish a baseline understanding of the environment by collecting data on the number and makeup of its current funding recipients who are charging publication fees as direct costs to their research grants and analyzing that data across different demographics (e.g., minority-serving institutions (MSIs), EPSCoR-eligible institutions, IDeA-eligible institutions, researchers in less-well-resourced disciplines, etc.)

Data collection on the amount spent to publish NIH-funded research regardless of the source would increase transparency and insight into how these fees affect various communities - including the potential impacts on publishing opportunities.

4. Early input on considerations to increase findability and transparency of research.

Ensuring that the results of NIH-funded research along with metadata containing information about who conducted the research, where it was done, and with what resources is an important component of the NIH Public Access Plan.

To complement continued requirements for internal identifiers (PMcIDs, GenBank accession numbers, etc), NIH should require the use of external persistent identifiers (PIDs). Specifically, NIH should adopt DOIs for publications, data sets, and DMPs, ORCIDs for researchers, and RORs for institutional affiliations, all of which are nonproprietary community standards for each identifier type. NIH should also explore the use of the DOI system to overlay NIH's current unique identifiers for awards.

Because similar identifiers will be required to be used by all federal agencies as a result of the OSTP Memorandum, NIH should coordinate its efforts with Other participants in interagency working groups, including the National Science and Technology Council's (NSTC) Subcommittee on Open Science, to identify best practices and potential standards. NIH also should consider collaboration with standards bodies, such as the National Information Standards Organization (NISO), to develop a framework and set of standards for a national PIDs strategy to facilitate smooth implementation.

Given the growing centrality of PIDs in research infrastructure, it is essential that the NIH and Other federal agencies only adopt nonproprietary identifier types that enable the broadest possible use and allow anyone to leverage this information in new and innovative ways.

Uploaded File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/NIH-RFI-SPARC-Response.pdf>

Description: Answers to the four questions and additional comments in letter format with hyperlinks

Email: katie@sparcopen.org

Submit date: 4/24/2023

Name: Juliane Baron

Name of Organization: Federation of Associations in Behavioral and Brain Sciences

Type of Organization: Nonprofit research organization

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

FABBS appreciates the NIH's commitment to equity in publication opportunities. We share these concerns. FABBS joins the broad scientific community (see the American Academy of Arts and Sciences' statement, which FABBS has signed onto) in pointing out the limitations of current publication models and encouraging NIH to continue to explore alternatives to subscription models and pay to publish fees.

The Behavioral Medicine Research Council issued a statement on Open Science (<https://psycnet.apa.org/fulltext/2023-60199-001.html>) in Health Psychology and Behavioral Medicine, establishing a commitment to open science, identifying challenges and providing guidance on open science practices.

2. Steps for improving equity in access and accessibility of publications.

FABBS cautions that public access will not automatically translate directly to equitable access. Beyond the ability to download a particular article, numerous other barriers - scientific training, time and ability to translate research to policy or practice - prevent the public from fully understanding academic language and methodology. In addition to a range of scientific training.

3. Methods for monitoring evolving costs and impacts on affected communities.

4. Early input on considerations to increase findability and transparency of research.

FABBS strongly supports the goals of increasing findability and transparency of research. Maximizing the potential of data sharing will require significant planning and effort to standardize terms, methods, and measures in the behavioral and cognitive sciences.

FABBS applauds the Office of Behavioral and Social Sciences Research for issuing a Notice of Intent to Publish a Funding Opportunity Announcement for Accelerating Behavioral and Social Science through Ontology Development and Use (U01) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-089.html>). This critical effort builds upon guidance from the National Academies of Science, Engineering, and Medicine's (NAEM) report on Ontologies in the Behavioral Sciences, of which FABBS is a sponsor. (<https://nap.nationalacademies.org/catalog/26464/ontologies-in-the-behavioral-sciences-accelerating-research-and-the-spread>)

By way of illustration, please see 'Limitations of the Sum-and-Alpha Approach to Measurement in Behavioral Research' (McNeish, 2022) (<https://journals.sagepub.com/doi/10.1177/23727322221117144>).

Description: The Federation of Associations in Behavioral and Brain Sciences (FABBS) is a coalition of 29 scientific societies and 60 academic departments that share an interest in equitably advancing the rigor, impact, and accessibility of our disciplines. FABBS scie

Email: jbaron@fabbs.org

Submit date: 4/24/2023

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

Name: Michael Keller

Name of Organization: Booz Allen Hamilton, Inc.

Type of Organization: Other

Type of Organization-Other: Consulting Firm

Role: Institutional official

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Booz Allen has prior experience in reviewing, planning, and implementing equitable access plans and advising on the benefits and drawbacks of not considering equity at each phase of research, including publication. For example, we assessed potential or perceived impacts of disclosure of protected health information (PHI) for research purposes on access to healthcare services by HIPAA-covered entities and real and perceived barriers to use of PHI in research in underrepresented populations. Based on such experience, we reviewed NIH's proposed Public Access Policy and provide the following recommendations relevant to equitable access to publication.

NIH should encourage grantees to share research results with the broader community and demonstrate how these studies impact the community and how communities could use NIH studies to improve health. Communities need demonstrations to access NIH search databases and the developers of these NIH resources should be utilized to make the findings accessible to all levels of understanding. Community engagement involves various participants in the publication process. Understanding the role of faith-based entities and educational institutions in community-wide activities is critical to monitoring the impact of research on communities of color (CoCs). Issues of national importance, such as COVID-19, intimate partner violence, opioid misuse, school shootings, police brutality, and Other socio-political and economic topics that NIH grants support, should be prioritized for CoCs to monitor the impact.

Supplementary to the above, there is no mention of a communication strategy for the new policy and subsequent method of implementation in the documentation. To ensure equity, communicating the new policy in its entirety and relevant impacts to all researchers at NIH will be necessary. In addition, external communication that NIH is revising its Public Access Policy to ensure equitable access to NIH-funded research would be beneficial to informing all possible users. The external communication can extend to underrepresented populations, Historically Black Colleges and Universities (HBCUs), small research organizations, and Others, increasing the accessibility to information.

2. Steps for improving equity in access and accessibility of publications.

To maximize equity in access to publications by diverse communities of users, Booz Allen recommends that NIH promote adaptive technologies and strategies centered around usability and accessibility, navigation, and content. Broad-based adoption of these assistive techniques by authors and publications will increase inclusivity among diverse communities of users by promoting equal access to, and engagement around, critical research and practice in the health and life sciences. The following

recommendations are not exhaustive; however, our team understands the added importance of addressing accessible format design elements including page layout, graphics, and charts.

Based on industry best practices, Booz Allen recommends that NIH should promote and fund user-centered studies to deepen the research on how to best use technology to make scholarly publications accessible to people with different learning styles and disabilities. These studies could evaluate methods of improving search systems such as PubMed with usability evaluations tools, submission accessibility guidelines, and document navigation tools to make results more findable to broader communities.

Booz Allen further recommends that NIH should engage with journal publications to establish guidelines promoting maximum accessibility so that authors may reach the largest community of users for their discipline, such as writing broadly to reach a mix of early graduate students and early careerists, and to employ descriptors and expressions to engage non-visual users who are highly reliant on descriptive text. NIH should also engage with journal publications to employ industry-accepted adaptive technology that will support users with visual, auditory, and perceptual disabilities.

3. Methods for monitoring evolving costs and impacts on affected communities.

NIH's research agenda requires monitoring costs and how those costs impact communities affected by NIH research and recipients of NIH awards. To effectively monitor publication costs (e.g., fees, increases, actual cost, and profit margins), there will need to be an ongoing monitoring and evaluation plan accessible to the general public. Since transparency and equity are related, the monitoring and evaluation plan for NIH should have several components/steps in place to ensure that equity planning is sustainable - these steps include surveying the current publication data that is available, identifying what is unknown, creating scales, metrics, and performance outcomes. After setting up processes to collect this data, NIH will be able to effectively monitor the evolving cost and impacts.

Biomedical and life science research scientific journals have a wide range in scope, collection size, and acceptance criteria. As a result, the publication process has a range of costs that must be understood before monitoring begins. Before costs can be monitored, expenses must first be tracked, understood, and then agreed upon. Booz Allen recommends that NIH perform an inventory or surveying of journals that publish studies with NIH funding followed by designing a metric to comprehensively evaluate publication costs and assign a score to journals based on this metric. Finally, continuous data quality audits should be implemented to ensure data are accurate and accessible.

Every level of the publication process is associated with policies related to who is allowed to peer review articles to the revised and resubmit process, procedures, and policies directly related to cost. All NIH publications need to review the question of who benefits and have a clear understanding and definition of what is "fair" and "equitable". NIH policies involving funding for publication costs should be reviewed, and every instance that demonstrates inherent disadvantages for less privileged populations should be tracked and flagged for future updates. In addition to this policy review, Booz Allen recommends that NIH should bucket the types of policies and evaluate them based on their impact.

To monitor the impact of NIH research and publication access on communities of color, NIH should develop indicators of impact/success to determine the effect of publication policies and NIH-funded research on communities of color, train the relevant practitioners on these metrics, and then revisit the

results to understand if improved access to publication opportunities and scientific results have impacted the relevant communities.

4. Early input on considerations to increase findability and transparency of research.

Recently, a Booz Allen team of researchers and analysts completed an NIH-funded initiative for the Office of Data Science Strategy (ODSS) in which the team developed a competency framework to guide biomedical and behavioral researchers through how to prepare their data to adhere to the metadata-driven Findable, Accessible, Interoperable, and Reusable (FAIR) principles and AI-readiness criteria. As part of this effort, Booz Allen interviewed professors and researchers from leading universities and minority serving institutions across various research areas to identify gaps in knowledge about data sharing standards. The following recommendations outline opportunities based on Booz Allen's discoveries from these interviews that would aid NIH in its efforts to strengthen research findability and transparency through knowledge sharing and expansion of new metadata standards and resources.

Booz Allen recognizes that NIH seeks to collect and make publicly available appropriate metadata associated with scholarly publications and data at the time of deposit in a public access repository. This has been challenging because researchers often do not know which metadata or metadata ontology standards they should use. To bridge these gaps, Booz Allen recommends developing a metadata ontology dictionary that would guide interested parties to terminologies that PubMed Central (PMC) officially recognizes.

Booz Allen also recognizes that NIH is interested in discovering innovative ways to instruct federally funded researchers to obtain digital persistent identifiers (PIDs) to maximize the findability of the research they share on PMC. From an instructional standpoint, Booz Allen recommends that NIH develops trainings for FAIR and TRUST principles, as many professors and researchers have a general lack of awareness of these principles, which are closely tied to the NIH Data Management and Sharing (DMS) Policy.

In accordance with the 2022 OSTP Memorandum, NIH seeks to elevate transparency about integrity of scientific research that was paid for with taxpayer dollars. Booz Allen recommends that PMC expand its taxonomy of PIDs to include metadata that would indicate the reproducibility of findings in publications. Currently, PIDs include information about authorship, funding, affiliation, and development status of federally funded research. However, there is no easily searchable indication of how many, and which researchers, labs, and institutions have reproduced the findings of publications. Booz Allen recommends that NIH develop PID requirements for reproducibility of findings and integrate them into a PMC such that publications with stronger reproducibility rankings would appear higher in search results. This would generate incentive for researchers to promote collaborative science by seeking opportunities with Other labs because it would contribute to them gaining more exposure on PMC.

Email: black_rebecca@bah.com

Submit date: 4/24/2023

I am responding to this RFI: On behalf of myself

Name: Robin Puett

Type of Organization: University

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

Multiple steps toward ensuring equity are needed, such as addressing publication bias, providing equal opportunities for null or negative findings to be published. The burden of high costs for open access journal publications, as well as publication costs in general should also be considered to ensure equity, particularly as results may continue to be reported after grants have ended. In addition, novel venues for free and low cost dissemination of research results would allow for more funding to go directly to conducting the research. These venues should include a rigorous peer-review process and should be structured to provide measurable impact for tenure and promotion reviews.

2. Steps for improving equity in access and accessibility of publications.

Given that distinguishing between rigorous peer-reviewed journals and disinformation outlets is challenging for individuals who are outside the field of interest, more resources should be directed toward the translation of scientific journal articles into digestible messages for a lay audience and requiring the inclusion of limitations and uncertainties. More resources should also be directed toward educating the public on how to find rigorous peer-reviewed science, distinguishing it from disinformation and critiquing it based on scientific methods. One effort toward communicating science that is commendable is the Frontiers for Kids translation of rigorous scientific articles for kids with editing by kids. The education is for scientists to translate results and for kids to be empowered and education in the scientific method.

An important related topic - is to consider how Chatgpt and AI are going to impact scientific research reporting - distinguishing disinformation will become more difficult and rigorous scientific processes may be shortcut.

3. Methods for monitoring evolving costs and impacts on affected communities.

One hidden cost is the inordinate amount of time required for submitting manuscripts (entering each first and each last name of each co-author in separate fields, followed by each affiliation, etc with large teams of scientists). The time required seems mundane but often several hours may go toward entering these data which could be spent more directly on teaching/research/engaging with the community. The technology for submission seems very antiquated.

Also publication costs are not easy to find - and an increase may also be a surprise after the manuscript has been accepted if open access is required. Any monitoring system will be challenged to find the real costs for all journals- perhaps requiring journals to be more up front with costs would be a starting point.

4. Early input on considerations to increase findability and transparency of research.

Most researchers that I am aware of do this work with the ultimate goal of serving the public (which includes us our families and friends), providing them info and improving their health. However researchers also have to treat the generosity of study participants with the upmost privacy, respect and confidentiality. This ensures that future health research will happen. With the everchanging tech environment, chatgpt, AI, high performance computing providing easier ways to search for datasets, combine them and reverse engineer variables that are not technically PHI or considered identifiers - the potential for identifying study participants is an increasing and evolving risk. Researchers do not have the appropriate tools/background and universities do not have the personnel/resources to ensure that all potential identifiers are scrubbed for use of the data in perpetuity. If all identifiers are scrubbed, this often makes the data useless. For example several GIS layers which contain specific timed information can be combined and reverse engineered to isolate fairly small geographic locations - when combined with Other data, study participant identification becomes much riskier. Datasets that are publicly available via digital format will never be ensured of destruction, however tech is ensured to advance exponentially. How can confidentiality and anonymity be ensured forever? Greater consideration of risks, resources, current and future tech, limitations, and requirements for informing study participants of these changes should occur before data sharing requirements. For example, Other agencies have provided a substantial funding increase in recognition of the amount of resources required to ensure data are safely made publicly available and are archived in time limited fashion and with different levels of restriction based on types of data. Even basic DUAs require monitoring and often require the names, positions and human subjects certifications of anyone accessing the data. Findability and transparency of research is an admirable goal but also is maintaining the confidentiality and anonymity of study participants who are generously sharing their lives to help improve everyone's.

Submit date: 4/24/2023

I am responding to this RFI: On behalf of myself

Name: Gary McDowell

Name of Organization: Lightoller LLC

Type of Organization: Other

Type of Organization-Other: Academic Consulting

Role: Member of the public

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

I would like to encourage NIH to reconsider the use of the word “maintain” when describing the “broad discretion for researchers and authors to choose how and where to publish their results”. I have the perspective that the current situation is somewhat restrictive, and could be expanded by NIH.

I think, in response to this, many will be thinking of the “right” of a researcher to publish in whatever magazine they wish; that right has always existed, and will continue to exist under the proposed changes. The question is who will pay for it. I am a taxpayer who currently is not guaranteed access to federally-funded research, that I need for my work, at the point of publication. I would therefore suggest to NIH that the burden can be removed, with a simultaneous introduction of more choices of how and what to publish, through greater incentives for using preprints. I would like to suggest greater recognition of preprints as a method for NIH to ensure compliance, to allow authors a choice of where to publish that extends beyond simply the requirement to publish in magazines.

One could make the argument that we could make an ecosystem for sharing research and data using preprints, perhaps on a federal server, which would serve perfectly well as a medium for evaluating researchers and remove the currently flawed reliance on Impact Factors and prestige, which have been shown to be biased and subjective. In such a world, academics could then pay to publish their research in magazines from their own pocket, if they so wished. Given that researchers already carry out peer review as voluntary labor, it’s not clear to me why the taxpayer needs to be paying so much money to publish a certain kind of research in magazines, just because that is what academics at universities and research institutions have decided is their preferred method for evaluation and promotion.

I believe that NIH is motivated to maximize the opportunities for communication of results by its grantees, and grantees should be motivated to ensure that as much data as possible can be shared with the wider community. The current system for communicating research outputs, relying on magazine articles to publish work, restricts what can be communicated. The use of these articles by the academic community, including by funders such as NIH, to evaluate a scientist and thus determine their career path, then incentivizes publishing only in a certain manner.

Much of the work that is carried out by researchers will, by its very nature, not be in the form of novel, positive data that can be formed into the narrative structure favored by magazine publishers. There is negative data that is collected; small experiments that don’t fit into a larger narrative; and of course large datasets that may not easily be evaluated by a single team. Publishing this kind of work is not currently incentivized in the traditional academic environment and it means that much of the data

funded by the taxpayer may remain within individual laboratories for the simple reason that the academic community has decided not to value this, even though it may be perfectly valid research. This may have effects, such as reducing the efficiency of biomedical research. For example, numerous labs across the country may be e.g. attempting to purify exactly the same troublesome protein, leading to potentially many laboratories trying out the same technique or experiment over and over again with no success - or, perhaps, simply taking longer to get to a successful outcome. All this is due to a lack of prior knowledge and information being published. The knowledge exists, maybe across multiple labs, but for some reason is not being shared despite the obvious efficiency it could produce for scientist and taxpayer alike. In addition, this system of only rewarding positive novel results also selects for (at best) luck, and (at worst) cherry-picking (or even outright falsifying) data, because a career is dependent not on the actual result, but a positive one. It is not designed to select for merit, as scientists cannot possibly predict whether their hypotheses will be correct all the time, and only a lucky few will chance upon the right problem to work on. Many very thorough and brilliant scientists may have been lost to academic research simply because they have not produced the particular kind of research being selected for in magazine article publishing.

I would like to provide some insights from my own experience of moving from the traditional academic environment to my consulting role. The work of a consultant is extremely similar to the work of an academic: I carry out research to solve a particular problem and am paid money by stakeholders to carry out that research (including for the taxpayer, on federally-funded research grants). The transition to this kind of work has been very simple given my previous academic experience.

There is one striking difference. When I communicate my results, my priority is to communicate all of my data and findings in a clear and concise manner to the stakeholders who paid for my work in order to help them solve a problem. This is in contrast to my previous experience as an NIH-funded postdoc.

If, as a consultant, I were to behave in the manner of a University academic, I would not write-up all of my analyses, but only those that I chose based on a narrative story of positive results. I would then publish this in a magazine, in the form of an article written in a esoteric style according to the desires of the magazine. I would then tell the people who paid me that they have to pay to read that work in the magazine, and would complain loudly about my "academic freedom" if there were moves to make me do Otherwise.

Obviously, I would not last long in the consulting business if I followed this model. This is, in part, why it is such a relief to have left the University environment and be able to do what I originally intended in science - work with people to solve challenging problems using research methods and data analysis. I am confident that there are many NIH-funded academics who feel the same way about their ability to communicate research.

The nature of my work is very similar to my time at universities; it is the incentives that are different. As a contractor I am not expected to publish magazine articles, as this is not a practice that is part of a consultant's work. In this way, I should note, publishing magazine articles is not an activity of all scientists - just a cultural practice followed by academics. However, I am also an academic, and as such I do see great value in sharing work through scholarly communication formats such as preprints, to allow for evaluation and improvement of the work as part of scholarly discourse. I am a firm believer in the principle of peer review, and in improvement of work through communicating knowledge through successive versions of analysis and interpretation, with updates as and when I receive feedback. The

change of incentive structures, by operating in a slightly different system but performing very similar work, has allowed me to think in different ways about how to communicate ALL of our data and work.

It was always my goal through my academic training to make sure as much of my data that had been gathered and analyzed appropriately and methodically was released for someone else to use; but this was harder to do when I worked in an academic University environment because of the publication structure and incentives. It is easier now to release data and analyses freed from this restrictive structure, and I enjoy research and review processes more because of this freedom.

I believe it is in NIH's interest to prioritize incentivizing taxpayer-funded researchers to similarly communicate as much of the data and work that they achieved with NIH support as possible - even if it does not have a clear "big story" to go with it. I have always maintained that any small or strange result that doesn't fit into my story could be of use to someone else, my ignorance about the problems Others work on should not determine what I think is fit, or not, to publish, if it is an experiment done well. It is not for me to determine what of my publicly-funded work could, or should, be of use to someone else.

As an academic consultant, I would love to see more public sharing of work by Others in my community of contractors. But the current magazine publishing process is long and tedious and takes up valuable time that could be spent on Other more important work, and it has little reward for those of us who are not assessed on our magazine-article publishing. Impact factor does not matter in my line of work; neither do tedious conversations about who needs what authorship where for their next career step, nor trying to fit your work into the restrictive structure of a particular magazine. When working with my academic colleagues, it is always disappointing when we move from talking about our science, to talking about the magazine publishing process and the careerist motives and strategies needed.

I also want to add that in my line of research, there is a lot of focus on trying to involve more students in scholarly communication as a way of educating them about the scientific process, but also to work on increasing their sense of identity as scientists, and sense of belonging in the process - important factors in encouraging students to follow biomedical and scientific research pathways. But there is an active conversation about how it is hard to engage students in writing articles for magazines, because they (in my view, correctly) see the current form of magazine articles as esoteric and only for future career goals. They are not viewing magazine articles as a way to actually communicate science with Others; and in many cases it seems that they are forming this impression not least because academics are reinforcing the idea that these magazine articles are credential-enhancing products, not a means for sharing results and advancing knowledge.

In all, I would urge NIH to incentivize and promote more innovative ways of sharing work, not least because the system with preprints is not without its difficulties. Carrying out peer review, or being part of peer review communities and providing feedback that will be incorporated into a work in development, still need work, support and innovation. I think there is great value to the general principles of scholarly communication, and of peer review, that need adapting and revising away from the focus of curation of magazine articles, and back towards ensuring validity and constant improvement of research.

2. Steps for improving equity in access and accessibility of publications.

As an American taxpayer and small business owner, the work I carry out supporting training and education of future generations of scientists, some of it federally-funded, is affected by my current inability to access newly-published federally-funded research legally. I am therefore extremely grateful for the removal of the current embargo.

I rely on federally-funded research to carry out my work. My work itself covers issues related to early career researchers, including their participation in and education about the communication of scientific research.

Tax dollars contributed by myself and Other Americans are used by NIH-supported researchers to publish their work, and to fund institutional library subscriptions to access the work of Others - at institutions that can afford to pay these subscriptions. Therefore the taxpayer currently pays for academics to publish their work, and then a privileged subset are able to gain access to the work of Others. Meanwhile the taxpayer is left out in the cold.

I would encourage continued use of the system on PMC to allow access to articles. I do want to make clear that there are academics who have insisted that members of the public can always email corresponding authors for a copy of the manuscript; this is clearly not an appropriate recommendation as response rates are very poor, and of course there should be effort to ensure that the public can access the work they fund as easily as possible. I thank NIH for their work on this as a priority.

Under the current system, anyone who is not in one of the institutions that can afford subscriptions to journals currently faces barriers to timely access to this work. Access to federally-funded research is not extended to all who support its development. Patients, patient advocates, small-business owners - we are all excluded from reading and using this important work. In addition, access isn't even granted to all academic researchers and students. Access to specific magazines, in which scientists publish their articles, is dependent on the ability of a University to be able to pay the subscriptions. Not all institutions are able to afford subscriptions. There are therefore thousands of students and researchers at American institutions of higher education who cannot access work needed to carry out their research and education. Shockingly, the Nelson memo is a great win for education and research at American universities themselves, and will allow greater access to those students, some of whom I have had occasion to work with.

I would ask NIH to require researchers to publish using a CC BY or less restrictive license. It is most useful for educational purposes if articles are not just free to read, but are truly open access. Free to read articles restrict the ability to work with the material in an authentic way, and is restrictive. For students and educators alike to make full use of research articles, it is important to ensure free and open licensing for articles and images.

3. Methods for monitoring evolving costs and impacts on affected communities.

I would encourage NIH to look into the DocMaps Framework (<https://docmaps.knowledgefutures.org>), which I once worked on but am no longer affiliated with. This is a project by the Knowledge Futures Group to develop a community-endorsed framework for capturing valuable context about the processes used to create documents in a machine-readable way. Please see "The DocMaps Framework for representing assertions on research products in an extensible, machine-readable, and discoverable

format (<https://www.biorxiv.org/content/10.1101/2021.07.13.452204v1>)". Policies and fees associated with articles could be examples of metrics mapped onto articles.

Peer review and preprint policies are unclear at most major journals (<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0239518>), and many of these policies affect equity in the magazine publishing world, which is an opaque and subjective process rife with bias. The Royal Society of Chemistry, for example, released a report demonstrating that the process of publishing magazine articles is rife with bias against women, at every step of the process (<https://www.chemistryworld.com/news/rsc-report-finds-publishing-pipeline-hinders-women/4010608.article>).

There are a number of reasons NIH should be keeping a close eye, or supporting efforts to do so, on magazine publishers. For example, consider the role of early career researchers in peer review. In biomedicine it is common practice for a PI, as an invited reviewer, to pass a manuscript from a magazine on to graduate students and postdocs to carry out the review, sometimes under the guise of training, but often not reported to the magazine. We gathered data and published an analysis "Co-reviewing and ghostwriting by early-career researchers in the peer review of manuscripts" (<https://elifesciences.org/articles/48425>), showing that it was indeed common that ECRs would undertake review with no credit, and receiving no feedback, hence negating the claim that this is a "training exercise". I will note that when my colleagues and I have been presenting or communicating about this work, a very common request from NIH-funded postdocs is that we move on to looking at the same phenomenon with NIH grants.

Ghostwriting is a form of plagiarism, and we have provided recommendations to multiple stakeholders, including magazines, about how to fix this problem, in "How to bring peer review ghostwriters out of the dark" (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8101444/>). However, I am disappointed to report that some magazines have doubled down against taking action to deal with this. In particular, there are efforts to require graduate students and postdocs to undertake training before being "allowed" to review, whereas someone with a faculty appointment does not have to undertake training. This very clear gatekeeping is likely to be affected by the fact that the faculty population is much less diverse than the graduate student and postdoc populations, and it is sending a harmful message that reinforces that graduate students and postdocs are incompetent. The notion of "expertise" is highly subjective, and as such is likely to be affected by the typical biases we have come to know within academia.

This is just one example of a policy that I would encourage NIH to engage in tracking. As a taxpayer, I am very concerned about how effectively tax dollars are being spent at magazines to publish articles, not least because of the evidence for biased pools of peer reviewers, and subjective decisions by editors, that are gatekeeping the very resources used to help - or hinder - the career progress of early career researchers. For example, eLife found that interventions were needed to ensure that early career reviewers in the reviewer database were actually being used and selected by editors; even when we see ECRs being added to a reviewer database, it isn't enough, because editors can pick reviewers using subjective assessments (<https://elifesciences.org/inside-elife/958c61d1/early-career-reviewers-reflections-on-focused-inclusion-in-reviews-at-elife>). This isn't restricted to career stage - faculty peer review frequency also appears to vary with perceived institutional prestige. Just last week, I attended a national conference where a journal editor stated publicly that they do not "need" to check the

reviewer database when receiving a submission - they “already have the names in their head”. Clearly such a limited and subjective pool of reviewers will give a limited perspective on academic works, and it’s not a system that I’m very pleased to see the taxpayer supporting. I encourage NIH to signal that magazines need to have very good justifications for their high costs to the taxpayer. After attending the Peer Review Congress in 2022, I managed to come away with a lower opinion - and a much more evidence-based one - of magazines and their peer review processes than before. Their claims that they are providing value for money do not seem to stand up to much scrutiny - not least when one views their activities through the lens of equity.

I want to highlight that the NIH also has a working group on postdocs, and a key reason that researchers are stagnating in postdoctoral roles, and therefore a possible factor in why increasingly graduate students are choosing not to undertake an academic postdoc, is time taken for magazines to publish their articles. At this precise moment I myself am working on the second request for revisions, for a paper submitted 7 months ago. The major motivation for our group publishing this article in a magazine is because we need to support our graduate student author in their academic career aspirations. I mention this not only because this is actually a very normal timeline for the review process, that is somehow acceptable to the academic community. It is plainly ridiculous that people’s careers are being held up not because of any training needs, but because of the inability of magazines to fulfill their role. This is costing the taxpayer money not only in the lengthy publishing process, but also because a significant number of these researchers are themselves supported by taxpayer funding, and are now stagnating longer than needed at the taxpayer’s expense. This is a clear opportunity for NIH to recognize preprints from graduate students and postdocs for use in evaluation of productivity, as the length of time a magazine takes to publish its articles is out of the control of any individual early career researcher, and should not be a deciding factor in selection of future faculty.

With respect to preprints, I would encourage NIH to consider federal funding for a community preprint infrastructure. I would also like to take the opportunity to point out that as academic researchers already review each Other’s work for free, they could publish preprints on a federal government server and then review each Other’s work all for free, and this would save the taxpayer a lot of money. It would also come with the benefit of being able to publish various kinds of research, experiments, figures, data and metadata. It could therefore be less restrictive, and much cheaper, than the current magazine publishing model.

4. Early input on considerations to increase findability and transparency of research.

NIH should require everyone to have an ORCID. I would like to point out that many foundations and Other funders already require ORCIDs, and it is my understanding that ORCIDs provide the only feasible means of satisfying upcoming federal policies, and will likely be required of all agencies anyway. NIH should also require the use of ORCIDs by its funded institutions, to allow connection of institutional data with their researchers, funding and publications for NIH-funded research.

NIH should assign DOIs to grants to allow them to be citable products.

NIH should index all preprints, and not just those supported by NIH investigators.

I would encourage NIH to participate in, and ensure interoperability with, global initiatives and efforts in Other countries.

Again, I would encourage NIH to look into the DocMaps Framework (<https://docmaps.knowledgefutures.org>). This is a project by the Knowledge Futures Group to develop a community-endorsed framework for capturing valuable context about the processes used to create documents in a machine-readable way. Please see “The DocMaps Framework for representing assertions on research products in an extensible, machine-readable, and discoverable format (<https://www.biorxiv.org/content/10.1101/2021.07.13.452204v1>)”.

Email: info@lightoller.org

Submit date: 4/27/2023

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

Name: Douglas White

Name of Organization: American College of Rheumatology

Type of Organization: Professional org association

Role: Scientific researcher

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

See attached

2. Steps for improving equity in access and accessibility of publications.

See attached

3. Methods for monitoring evolving costs and impacts on affected communities.

See attached

4. Early input on considerations to increase findability and transparency of research.

See attached

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/6/FINAL_ACR_Comments_on_RFI_NIH_Roadmap_Open_Access_04.24.23.pdf

Submit date: 4/27/2023

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

Name of Organization: Fully OA Publishers

Type of Organization: Not applicable

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

On public repositories, we believe the NIH Public Access Plan rightly encourages and prioritises the widest possible choices for researchers as they relate to publishing venue, as well as the principles of academic freedom. We think the Plan strikes the right balance by making PubMed Central (PMC) a convenient and compliant repository for research without privileging or mandating it.

On the fairness of the article processing charge (APC), it is worth noting this charge is not an inevitable component of Gold Open Access (OA) publishing. Indeed, we recognize that in some cases, it is not the preferred or most sustainable price structure for researchers, funders, libraries, and research institutions. And while we, like others in the publishing industry, think the APC model is a good one, we are not in principle wedded to it. We are continually in touch with institutional partners to find solutions that meet their needs.

For APCs to remain affordable, there must be fair competition on a level playing field between legacy publishers and pure open access publishers or other innovative platforms, and researchers should be rewarded to use publication funds responsibly. So called “transformative agreements” or Read&Publish agreements, where legacy publishers sell journals to libraries with subscription fees that bundle access to back-articles with coverage of APCs to publish in their journals, are in our view anticompetitive as they encourage researchers to publish in legacy titles regardless of the APC-level. Full OA publishers have nothing to “transform” so they are not included in such agreements. Instead of enabling a true competition between pure OA publishers and legacy publishers, transformative agreements subsidise publication in legacy titles and contribute to a oligopolistic publishing ecosystem by ignoring the fact that researchers may disseminate their work with other publishers (including pure open access publishers) or platforms more cost-effectively.

Frameworks such as Plan P (planp.science) address the APC problem with creating a

transparent market place for publication opportunities for researchers after they made their preprint available to the public, and also support a multipayer environment, where the APC is ultimately covered by both the institution and funders.

On the additional steps the NIH might take to ensure new inequities are not created, or existing ones reinforced, we believe the NIH should

- Implement policies that make sure that institutions and libraries offer equitable publication opportunities by creating, supporting, or mandating institutional open access funds that support cost-effective peer-review and publication in all accredited open access venues, outlawing transformative agreements without the presence of a generic institutional open access fund that supports open access publication in any accredited OA journal. "Accreditation" could use existing "white-lists" such as DOAJ or OASPA membership, or be the results of an institutional/federal procurement/RFI process to create an institutional list of "accredited" OA journals that receive a APC subsidy
- encourage researchers to publish in the Gold OA model - on the basis that the public funding of public access is efficient, scalable, and delivers value for money.
- Encourage researchers to make their publications available as preprints first
- Find mechanisms that support a multipayer model, where the costs APCs are shared between institutions and funders, and to make billing processes as frictionless as possible for researchers.

In our view, Gold OA publishing is one of the most effective ways of securing that outcome. It offers a simple, transparent, and competitive way to unlock the benefits of fully accessible science; and it enables researchers, agencies, universities, libraries, and repositories to fulfil both the NIH Public Access Policy and the OSTP guidance. Publishing in a Gold OA journal immediately facilitates the transfer of articles to a repository, with metadata in machine-readable formats. In this model, there are no embargoes and no superfluous or costly bundled services that are common in "hybrid" or "transformative" subscription options offered by legacy commercial publishers.

On public value for money, new federal guidelines seek public access but do not specify

delivery models. We agree that openly accessible science can - and should - be delivered by more than one publishing model. We welcome competition if it spurs innovation and the amount of rigorous science accessible to all.

But in judging those delivery models, federal agencies must make a robust and transparent assessment and comparison for efficiency, scalability, and public value for money - guided by the objective of discoverability that underpins public access.

For example, public access known as “Green Open Access (OA)” clearly removes some barriers and does not create or perpetuate inequity. But the mechanisms for finding, reading, and sharing Green OA files vary widely, and the level of peer-review is not always clear.

Substantial new funding will be required just to bring that variance down and lift standards for discoverability, with new investment in infrastructure for metadata enrichment. Those institutions unable to fund that investment are likely to face the continued cost pressure of paywall subscriptions that might only minimally ease search and discovery.

So, it is vital that the funding of public access is as efficient, scalable, and as good a value for money as possible, and in our view, Gold OA publishing is one of the most effective ways of securing that outcome. It offers a simple, transparent, and competitive way to unlock of the benefits of fully accessible science.

2. Steps for improving equity in access and accessibility of publications.

On the 12-month embargo, we strongly welcome the NIH’s decision to end it on publications. We believe that so-called Transformative Agreements (TAs) were worthwhile in their conception as a means of smoothing the transition to fully open access science, but in their execution have become a blunt instrument.

TAs lack transparency, have complex bundles of services making it all but impossible to judge value for money, and come with no contractual commitment to a move to full open access (Green, Gold, or otherwise) within a binding deadline.

Most of these agreements are large scale “read and publish” or hybrid deals. Publishers will often allow authors to appear in their hybrid journals without being charged, if their institutions pay, while at the same time they maintain the amount of science they publish behind paywalls.

We believe TAs help prop up the market dominance of legacy publishers by controlling the pace of transition to fully open access science. The worldwide scientific publishing oligopoly is a market estimated to be around US \$27 billion.¹ The five largest paywall publishing houses² have captured more than half of it.³

On the basis the NIH seeks equity in access as well as transparency in costs, backed by financial sustainability, we believe Gold OA publishers can deliver.

On automated text processing, assistive devices, and other inclusionary measures, we fully support the NIH's position. We consistently invest in measures that improve the accessibility of our publications. Many such requirements were mandated by the Coalition S initiative, which this group fully supports, and which saw wide-ranging and progressive open access policies adopted by funders in the US, in the United Kingdom and across Europe.

We firmly back public policies that promote equity of opportunity, the ability both to read and publish research, and the scientific rigor, academic freedom, institutional values, and personal and professional recognition that underpin success.

We are committed to increasing research access, knowledge resources, and educational opportunities for all, especially for those groups, nations, and individuals who are historically marginalized, underrepresented, or disadvantaged.

On institutional success, we work hard to build communities and tackle the inadequacies and inequities often characterizing research dissemination. The shift toward open access represents an opportunity to expand access to knowledge in a significant way across academic institutions of all stripes, as well as small businesses and the public.

We would urge the NIH to draw on its influence to see that library, research, and educational institutions commit to investing in open access so that all parties can source sufficient funding for publishing. Several equitable open publishing models are readily available. It cannot be right if colleges and universities are encouraged to maintain robust publications budgets for subscriptions and then asked to make cuts to open access. Many institutions initially supported open access with the hope that it will reduce library costs for subscriptions, and signed statements like the Compact for Open Access Equity (COPE, <http://www.oacompact.org/>), which vowed that there will always be institutional support to

help with APCs; unfortunately, in many cases such institutional funds are no longer available as libraries make deals with traditional publishers that fund only their APCs

(<https://scholarworks.duke.edu/open-access/cope/>).

We believe there is enough funding in the system to make the transition to open access complete. But that funding can only be unlocked with public sector, policymaker, and buyer leadership, on the basis we look beyond legacy publishing models that have been responsible for a decades-long cost explosion in scholarly publishing.⁴ With the right policies and incentives, agencies can help drive the value of taxpayer-funded investment and spur innovation.

3. Methods for monitoring evolving costs and impacts on affected communities.

On financial costs, we welcome the NIH's interest in the commercial drivers of scholarly publishing, particularly in matters of access or equity.

Since our inception as a born-digital publisher, we have sought to reduce or remove financial and operational burdens facing researchers. The governing principle of all scholarly publishing should be that the researchers have the most freedom possible to focus on their research. And so, all publishers compete to lower administrative and process-based burdens.

While the dissemination of research requires a complex ecosystem, we believe a wide-scale shift to open access would allow libraries and research institutions to free substantial resources now tied up in (paywall) subscriptions, and to apply those resources to researchers' publishing costs.

A strong signal or directive from the NIH that research institutions should commit these freed-up funds - as well as grant money ringfenced for publication - to the widespread and immediate sharing of research would have a profound and positive impact on the drive to fully open access science.

On the perceived relative fairness of pricing regimes, and as we say in response to Question 1, it is worth noting the APC is not an inevitable component of Gold OA publishing. While we think the APC model is a good one - not least because it brings greater costs transparency for monitoring purposes - we are not in principle wedded to it. We are continually in touch

with institutional partners to find solutions that meet their needs. We are seeking to shift the funding paradigm to help authors cover the fair and actual cost of publishing, to make scientific knowledge accessible to the widest possible audience.

Within an APC framework, we have expanded our portfolio of institutional models to meet the tailored needs of our customers (with, for example, institutional partnerships for research-intensive “publish” organizations as well as high consumption “read” institutions and societies). Our success indicates a range of pricing regimes can meet the needs of a range of customers and institutions.

The publishing industry at large is experimenting with pricing regimes and introducing new ones in its drive to innovate. Though the nomenclature varies - advance annual payment, fixed fee, flat fee, multi-payer, Subscribe 2 Open, waivers - all of these seek to offer more cost-efficient and sustainable alternatives to libraries’ subscription expenditure.

4. Early input on considerations to increase findability and transparency of research.

On data sharing, we fully back the NIH’s effort through its Public Access Plan to spur a better and more consistent use of PIDs and metadata. In driving this effort, the NIH is providing critical leadership in the scholarly publishing ecosystem.

Moreover, we welcome the NIH’s focus on the findability and transparency of research.

Open data drives scientific and technological innovation and spurs collaboration; is critical to driving efficiency and scaling innovation; and in uniform standards can be verified, reproduced, and built upon.

If data is transparent and open to scrutiny and evaluation, it follows that trust and confidence in science are more likely to be sustainable. The infrastructure for open data is readily available and an increasingly frequent resource; and many large-scale repositories already exist to make data open. Examples include Figshare, a commercial, field-agnostic repository; field-specific, non-profit databases like the society-supported FlowRepository for cytometry data and the commercial Protein Data Bank; and federally backed databases like NIH’s data repositories.

On data repositories, substantial funding will be required for operation and upgrades. And in the absence of funding committed to scaling up PMC, we would back a federated approach

that focuses on shared standards and access across multiple repositories. By way of illustration, we deposit the full text or metadata of our 230-plus journals in more than 20 repositories when we publish articles.

As a group of fully OA publishers, together we have made thousands of peer-reviewed articles available online immediately, without embargo. Our starting point - and end point - is ease of discovery.

In simple terms, an article that cannot be found, cannot be shared, and cannot be cited also cannot spur vital collaboration and breakthrough. Publishing in a Gold OA journal unlocks discoverability. The articles and underlying data are transferred to a repository such as PubMed Central or stored in commercial or other non-profit databases.

Moreover, the metadata from Gold OA journals come in XML files and other machine-readable formats to meet FAIR data standards of findability, accessibility, interoperability, and reuse. The metadata includes persistent identifiers such as that of ORCID for author identification, a Digital Object Identifier (DOI) for the article itself, and tags to the relevant grant funding or research institution. And compliance with JATS DTD for XML and other PMC-recommended tagging enables an even more efficient search and discovery experience.

Open science is all about transparency and the quality of science is expected to increase if transparency increases, e.g. by publishing protocols. While it is common to publish and register clinical trials, NIH could do more to make other forms of research more transparent. In terms of identifying protocols or grant proposals, some signatories of this letter have pioneered the use of a new persistent identifiers (PID) called IRRID (International Registered Report Identifier, <https://irridregistry.org/>), which uses the DOI system to link protocols and grant proposals (RR1) to results papers (RR2). If a protocol or grant proposal is published with a DOI, the IRRID in the results paper links back to the protocol. Together, RR1 and RR2 form “registered reports”, which is the idea that scientists should publish the protocol or proposal of their work first, and then the results paper, which should be published regardless of whether the findings are negative or positive. NIH as funding agency could encourage protocol and proposal publication by

- making peer-review reports from NIH review committees openly accessible under a Creative Commons licence if the principal investigator and reviewers agree
- encouraging NIH-funded researchers to formally publish their protocols and grant proposal if they are successful so they receive a DOI and a IRRID
- encourage or mandate to cite the protocol or grant proposal using a IRRID in the abstract of any results paper

The new federal guidelines seek public access without specifying delivery models, and we agree openly accessible science can - and should - be delivered by more than one publishing model. We welcome competition if it spurs innovation and the amount of rigorous science accessible to all.

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We think it is possible to achieve the fullest possible access to our collective knowledge - for fairer outcomes in all parts of society - in a business model that is cost-effective, commercially sustainable, and underpinned by private sector innovation.

We stand ready to support the NIH and its partners in the federal government. It is vital we back this effort for open science and meet the public appetite for accountability,

transparency, and trust.

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