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Weighing in on Policy Development: It's easier than you think!

Yvette R. Seger, PhD

Director of Science Policy

Session Goals

- Enhance awareness of opportunities for stakeholders to provide input on the regulatory and policy making processes
- Share best practices for developing and submitting feedback to requests for public comment
- Highlight current opportunities seeking stakeholder feedback

FASEB: 27 societies representing over 115,000 scientists

Key Definitions

- **Law:** products of written statutes, passed by the U.S. Congress and signed by the President
- **Regulations:** Standards and rules adopted by administrative agencies that govern how laws will be enforced
  - Have the force of law
- **Policies:** Implemented by agencies to establish uniform processes and reporting expectations
  - Not law, but non-compliance can lead to negative consequences
- **Guidance Documents:** Issued by agencies to assist in the interpretation of regulations

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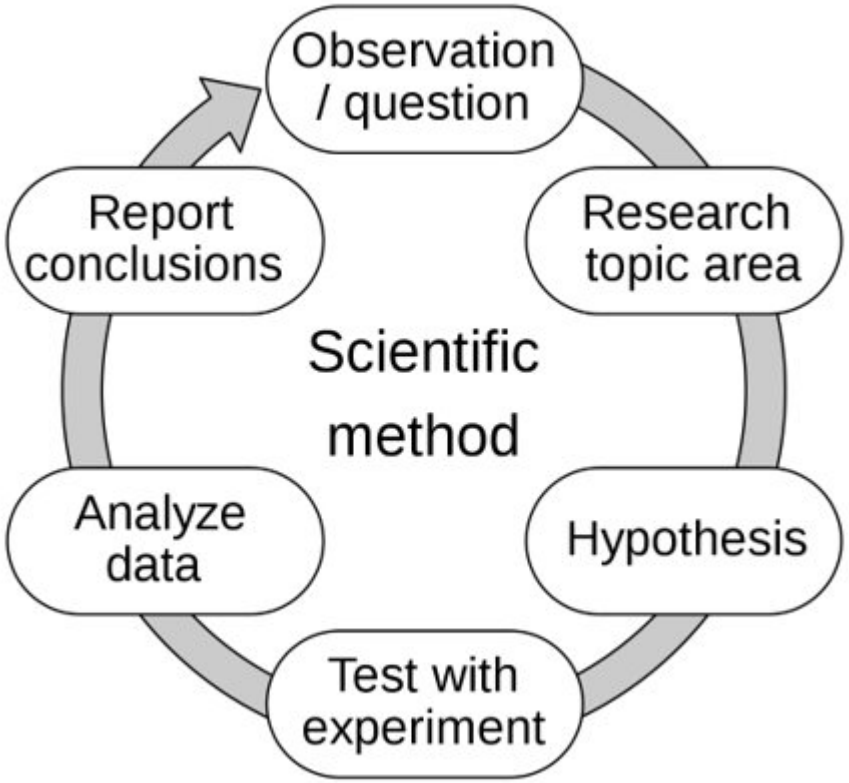
A somewhat familiar process?



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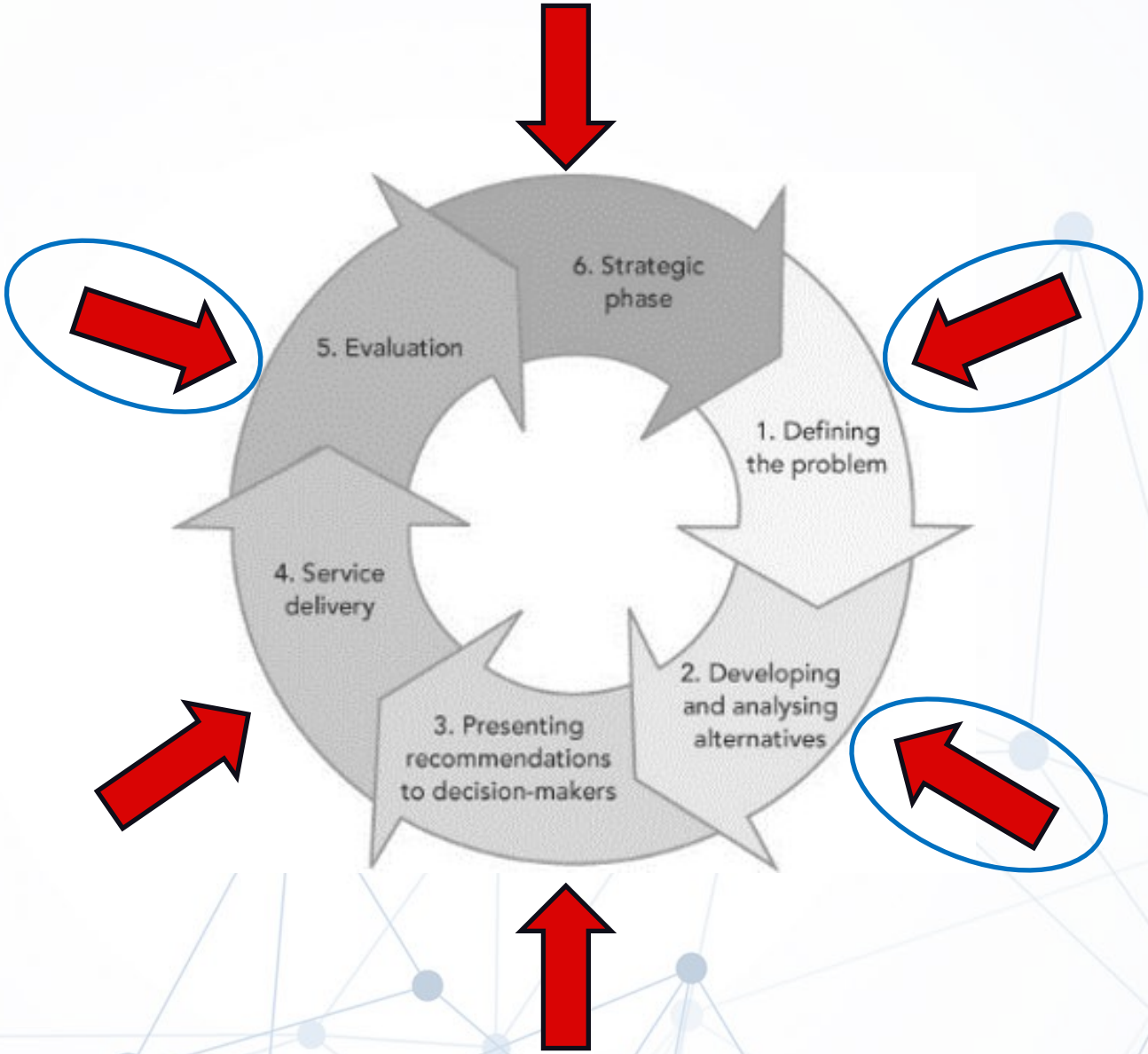
When is Stakeholder Input Collected?



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How is Input Collected?

- Responses to Requests for Information / Calls for Comments
  - Policy Acronym: RFI
  - Regulatory Acronym: ANPRM or NPRM
- Testimony / Public Comments
- Expert Interviews
- Data Analysis
- Literature Searches

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Where to Find Comment Opportunities?

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Where to Find Comment Opportunities (2)

BROADENING PUBLIC ENGAGEMENT IN THE FEDERAL REGULATORY PROCESS

ACD Working Group on Re-envisioning NIH-Su
Postdoctoral Training

The working group has posted a Request for Information (RFI) for the community to share insights on i
solutions to the recent decline in postdoctoral trainees. Responses will be used to help develop recomn
problem which impacts U.S. competitiveness in biomedical research and innovation. Please consider sharing and responding to the RFI, which closes on April 14, 2023.

In addition to the RFI, the working group welcomes community input through four public virtual listening sessions between March 8 — March 20, 2023. Register to attend and share your input here!

Review Matters

Strengthening Fellowship Review

Bruce Reed
Deputy Director

Lystranne Maynard Smith
Scientific Review Officer

Cibu Thomas
Scientific Review Officer

January 6, 2022

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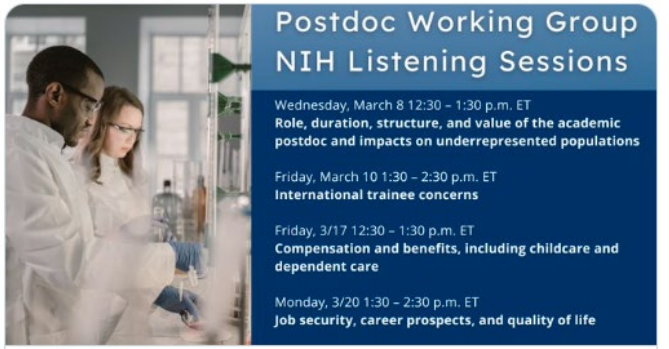
to hear your thoughts on what works, what

aining that will enhance pre- and post-

Extramural Research @NIHgrants · Feb 24
Make your voice heard, postdocs! NIH wants to hear from you on challenges to postdoc progression. Submit your thoughts by 4/14: bit.ly/NIHpostdocRFI

5 1 1,331

Extramural Research @NIHgrants · Feb 27
NIH welcomes community input on the status of the postdoctoral training system through four public virtual listening sessions between March 8 – March 20, 2023. Register today!



nexus.od.nih.gov
You Are Invited: NIH Listening Sessions on the Postdoc Training Syst...
NIH welcomes community input on the status of the postdoctoral training system through four public virtual listening sessions betwee...

1 51 39 21.2K

Interested in Commenting?

Now What?

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Who Are You Representing?

- Self?
- Your Employer?
- Other Organization?

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Is There an Existing Process for Developing Comments?

- Who needs to be engaged in development and review of comments?
- Do comments require governance votes?
- Who is the signatory / submitter of comments?

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What makes a good response?

- Clearly states who you are or the constituents represented
- Personalized – even if you are building upon uniform content
- Identifies unintended consequences of proposed change(s)
- Suggests solutions rather than just reiterating the problem
- Provides data/references to justify rationale
- Offers to make additional information, as requested

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Other Tips & Tricks

- Start with the deadline
- Follow instructions for submission
  - Most RFIs require electronic submission
  - Many must be submitted through web forms
- Adhere to word limits
- Comments are frequently made public and can be subject to FOIA
  - Don’t submit proprietary information
  - Comments posted to Regulations.gov are publicly available shortly after submission
  - Full comments or excerpts of comments may be included in final reports

Example: NIH Postdoc RFI

Request for Information (RFI): Re-envisioning U.S. Postdoctoral Research Training and Career Progression within the Biomedical Research Enterprise

Notice Number:

NOT-OD-23-084

Key Dates

Release Date:	February 14, 2023
Response Date:	April 14, 2023

How to Submit a Response

All comments must be submitted electronically on the submission website.

Responses must be received by 11:59:59 pm (ET) on April 14, 2023.

Responses to this RFI are voluntary and may be submitted anonymously. Please do not include any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your response. The Government will use the information submitted in response to this RFI at its discretion. **The Government reserves the right to use any submitted information on public websites, in reports, in summaries of the state of the science, in any possible resultant solicitation(s), grant(s), or cooperative agreement(s), or in the development of future funding opportunity announcements.** This RFI is for informational and planning purposes only and is not a solicitation for applications or an obligation on the part of the Government to provide support for any ideas identified in response to it. Please note that the Government will not pay for the preparation of any information submitted or for use of that information.

We look forward to your input and hope that you will share this RFI opportunity with your colleagues.

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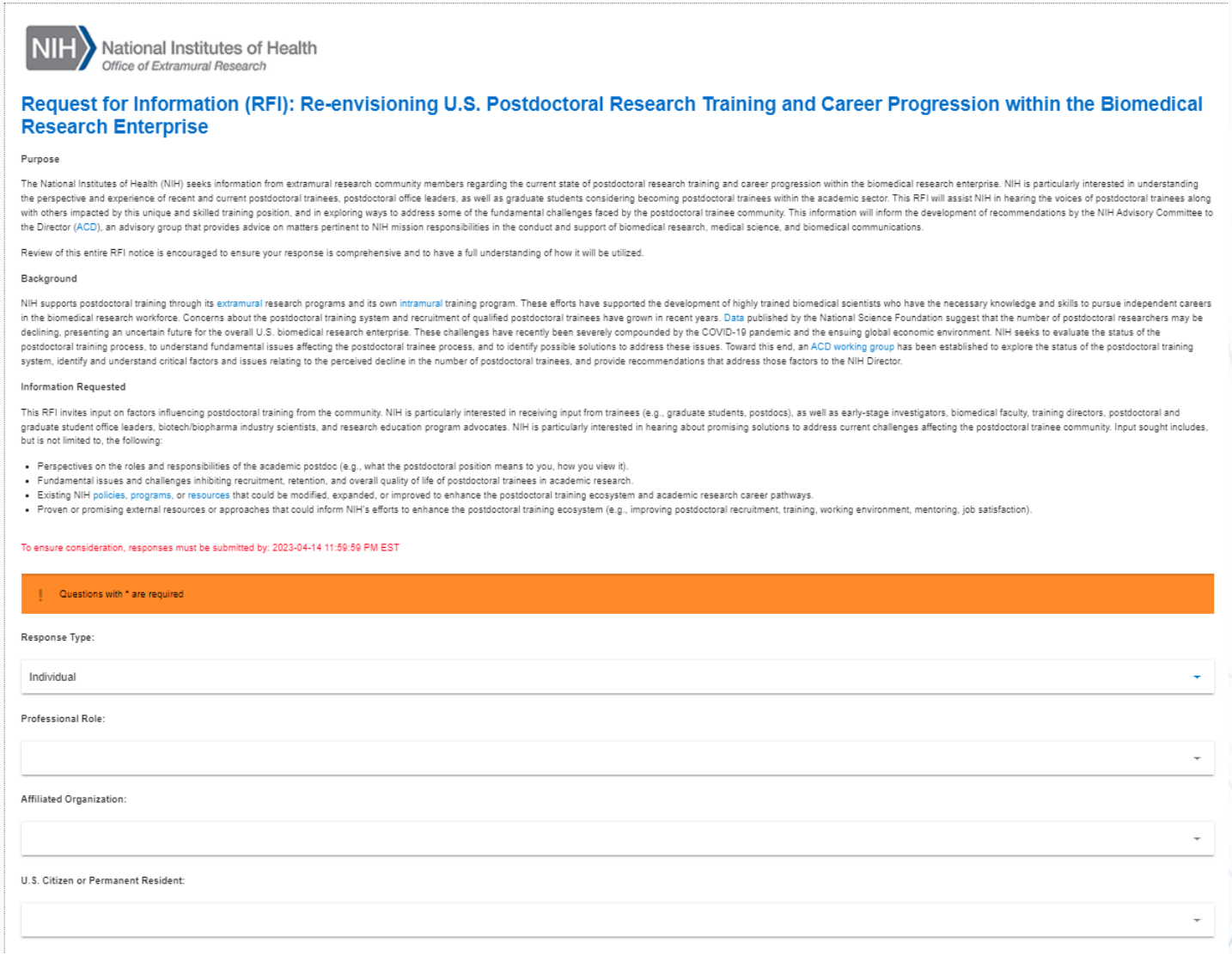
Example: NIH Postdoc RFI (2)



National Institutes of Health
Office of Extramural Research

Request for Information (RFI): Re-envisioning U.S. Postdoctoral Research Training and Career Progression within the Biomedical Research Enterprise

Purpose

The National Institutes of Health (NIH) seeks information from extramural research community members regarding the current state of postdoctoral research training and career progression within the biomedical research enterprise. NIH is particularly interested in understanding the perspective and experience of recent and current postdoctoral trainees, postdoctoral office leaders, as well as graduate students considering becoming postdoctoral trainees within the academic sector. This RFI will assist NIH in hearing the voices of postdoctoral trainees along with others impacted by this unique and skilled training position, and in exploring ways to address some of the fundamental challenges faced by the postdoctoral trainee community. This information will inform the development of recommendations by the NIH Advisory Committee to the Director (ACD), an advisory group that provides advice on matters pertinent to NIH mission responsibilities in the conduct and support of biomedical research, medical science, and biomedical communications.

Review of this entire RFI notice is encouraged to ensure your response is comprehensive and to have a full understanding of how it will be utilized.

Background

NIH supports postdoctoral training through its extramural research programs and its own intramural training program. These efforts have supported the development of highly trained biomedical scientists who have the necessary knowledge and skills to pursue independent careers in the biomedical research workforce. Concerns about the postdoctoral training system and recruitment of qualified postdoctoral trainees have grown in recent years. Data published by the National Science Foundation suggest that the number of postdoctoral researchers may be declining, presenting an uncertain future for the overall U.S. biomedical research enterprise. These challenges have recently been severely compounded by the COVID-19 pandemic and the ensuing global economic environment. NIH seeks to evaluate the status of the postdoctoral training process, to understand fundamental issues affecting the postdoctoral trainee process, and to identify possible solutions to address these issues. Toward this end, an ACD working group has been established to explore the status of the postdoctoral training system, identify and understand critical factors and issues relating to the perceived decline in the number of postdoctoral trainees, and provide recommendations that address those factors to the NIH Director.

Information Requested

This RFI invites input on factors influencing postdoctoral training from the community. NIH is particularly interested in receiving input from trainees (e.g., graduate students, postdocs), as well as early-stage investigators, biomedical faculty, training directors, postdoctoral and graduate student office leaders, biotech/biopharma industry scientists, and research education program advocates. NIH is particularly interested in hearing about promising solutions to address current challenges affecting the postdoctoral trainee community. Input sought includes, but is not limited to, the following:

- Perspectives on the roles and responsibilities of the academic postdoc (e.g., what the postdoctoral position means to you, how you view it).
- Fundamental issues and challenges inhibiting recruitment, retention, and overall quality of life of postdoctoral trainees in academic research.
- Existing NIH policies, programs, or resources that could be modified, expanded, or improved to enhance the postdoctoral training ecosystem and academic research career pathways.
- Proven or promising external resources or approaches that could inform NIH's efforts to enhance the postdoctoral training ecosystem (e.g., improving postdoctoral recruitment, training, working environment, mentoring, job satisfaction).

To ensure consideration, responses must be submitted by: 2023-04-14 11:59:59 PM EST

! Questions with * are required

* Response Type:

Individual

* Professional Role:

* Affiliated Organization:

* U.S. Citizen or Permanent Resident:

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Example: NIH Postdoc RFI (3)

Perspectives on the roles and responsibilities of the academic postdoc (e.g., what the postdoctoral position means to you, how you view it).

Peep that word limit (300 words per question)

0 typed / 300 words allowed

0

Fundamental issues and challenges inhibiting recruitment, retention, and overall quality of life of postdoctoral trainees in academic research.

0

Existing NIH policies, programs, or resources that could be modified, expanded, or improved to enhance the postdoctoral training ecosystem and academic research career pathways.

0

Proven or promising external resources or approaches that could inform NIH's efforts to enhance the postdoctoral training ecosystem (e.g., improving postdoctoral recruitment, training, working environment, mentoring, job satisfaction).

0

Example: NIH Public Access Policy RFI

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

Notice Number:
NOT-OD-23-091

Key Dates

Release Date:	February 21 2023
Response Date:	April 24, 2023

How to Submit a Response

Comments must be submitted at https://osp.od.nih.gov/nih-plan-to-enhance-public-access-to-the-results-of-nih-supported-research Responses will be accepted through April 24, 2023.

Responses to this RFI are voluntary and may be submitted anonymously. You may also voluntarily include your name and contact information with your response. Other than your name and contact information, please do not include in the response any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your response. After the Office of Science Policy (OSP) has finished reviewing the responses, the responses may be posted to the OSP website without redaction.

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Example: NIH Public Access Policy RFI (2)

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

NIH seeks public input on the *NIH Plan to Enhance Public Access to the Results of NIH-Supported Research* (NIH Public Access Plan). In 2022, the White House Office of Science and Technology Policy (OSTP) released a memo on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research that establishes new guidance for improving public access to scholarly publications and data resulting from Federally supported research. The NIH Public Access Plan outlines the proposed approach NIH will take to implement the new guidance, consistent with its longstanding commitment to public access.

The Public Access Plan can be viewed at: NOT-OD-23-091. The comment period will close on April 24, 2023.

How to Submit a Response

Comments must be submitted electronically using this form. Responses will be accepted through April 24, 2023. You may provide comments to one or more of the topics in the comment boxes below.

Responses to this RFI are voluntary and may be submitted anonymously. You may also voluntarily include your name and contact information with your response. Other than your name and contact information, please do not include in the response any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your response. After OSP has finished reviewing the responses, the responses may be posted to the OSP website without redaction.

To ensure consideration, responses must be submitted by: April 24, 2023, 11:59:59 EDT.

I am responding to this RFI:

- ○ On behalf of myself
- ○ On behalf of an organization

**If submitting comments on behalf of another individual, please submit the name and function of that other individual.*

Name

Name of Organization

Type of Organization

Not Applicable

Role

Select One

NIH seeks information regarding the NIH Public Access Plan, from all interested individuals and communities, including, but not limited to, authors, investigators, research institutions, libraries, scholarly publishers, scientific societies, healthcare providers, patients, students, educators, research participants, and other members of the public. While comments are welcome on all elements of the NIH Public Access Plan, input would be most welcome on Section III related to scholarly publications and on the particular issues identified below. Comments may be entered below or attached in the next section.

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

The NIH Public Access Plan aims to maintain the existing broad discretion for researchers and authors to choose how and where to publish their results. Consistent with current practice, the NIH Public Access Plan allows the submission of final published articles to PubMed Central (PMC) (in cases where a formal agreement is in place) to minimize the compliance burden on NIH-supported researchers and also maintains the flexibility of NIH-supported researchers to submit the final peer reviewed manuscript. NIH seeks information on additional steps it might consider taking to ensure that proposed changes to implementation of the NIH Public Access Policy do not create new inequities in publishing opportunities or reinforce existing ones.

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.

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.

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.

Attachment:

The following file extensions are accepted: PDF, XLS, XLSX, DOC, DOCX

File Upload

Select Files

Description

Option for File Upload

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Don’t Forget…

Be sure to thank the agency for the opportunity to offer input. Your comments could lead to future dialogue on related topics.

Good Luck!

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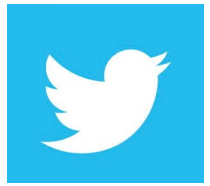
Thank You!

yseger@faseb.org



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