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
A somewhat familiar process?
When is Stakeholder Input Collected?
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
Where to Find Comment Opportunities?

Initial Proposals For Updating OMB's Race and Ethnicity Statistical Standards

A Notice by the Management and Budget Office on 01/27/2023

Make a difference. Submit your comments and let your voice be heard.

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
The working group has posted a Request for Information (RFI) for the community to share insights on key factors and possible solutions to the recent decline in postdoctoral trainees. Responses will be used to help develop recommendations to address this problem which impacts U.S. competitiveness in biomedical research and innovation. Please consider sharing your thoughts 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.
Interested in Commenting?

Now What?
Who Are You Representing?

• Self?

• Your Employer?

• Other Organization?
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?
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
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.
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, 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 Postdoc Advisory Committee to the Director (PACD), an advisory group that provides advice on matters pertaining to NIH mission responsibilities in the conduct and support of biomedical research, medical sciences, and biomedical communications.

Nature of this entire RFI notice is enunciated 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 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 associates may be declining, prompting an神州ton for the overall U.S. biomedical research enterprise. These challenges have recently been accentuated by the COVID-19 pandemic and the ongoing 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 ACS working group has been established to explore the state of the postdoctoral training system, identify and understand critical factors and issues relating to the varied decline in the number of postdoctoral trainees, and provide recommendations that address those factors to the NIH Director.

Information Requested

The NIH is interested in factors influencing postdoctoral training from the community that are particularly relevant in receiving input from various stakeholders, such as graduate students, postdoctoral trainees, early career investigators, biomedical faculty, training directors, postdoctoral and graduate student leaders, research program leaders, and research education program advisors. 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 is the postdoc position worth to you, how do you see it?);
- Fundamental issues and challenges involving recruitment, retention, and overall quality of life for postdoctoral trainees in academic research;
- Existing NIH policies, programs, or resources that could be modified, expanded, or improved to enhance the postdoctoral training association and academic research career pathways;
- Promising new 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 2023-03-14 11:59 EST.
Example: NIH Postdoc RFI (3)

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

2. Peep that word limit (300 words per question)

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

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

5. 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).
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.
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 2023, 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 NIH Public Access Plan can be viewed at [NITP 02-23-23]. 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 on one or more of the topics listed below. To submit a comment, please complete the form below. Your comments will be published on the NIH website. 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 you are submitting comments on behalf of another individual, please submit the name and function of that 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 on all aspects of the NIH Public Access Plan are welcome, comments are especially welcome on Section II related to scholarly publications and the particular issues identified below. Comments may be entered below or attached in the next section.

Option for File Upload

File Upload

Select File
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!
Thank You!

yseger@faseb.org

@FASEBorg
@YvetteSeger

https://www.linkedin.com/in/yvettersegerphd/