Responding to Requests for Information: Perspectives from the General Public's Viewpoint

The Future of Research Integrity Conference
May 20, 2024

COGR

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COGR

- Nonprofit 501(c)(3) association of leading research-intensive universities and affiliated medical centers and nonprofit research institutes
- 219 member institutions in 48 states & D.C.
  - 83 Privates | 136 Publics | 20 Affiliate Academic Hospitals and Research Institutes
  - 135 Carnegie Research I Institutions
  - 32 Carnegie Research II Institutions
  - 30+ Hispanic Serving Institutions (HSI)
  - $49 Billion+ in combined federal expenditures (2022 NSF HERD Survey)

COGR's responds to many requests for information and proposed regulations!

COGR Submits Comments to ORI on Public Health Service Policies on Research Misconduct Notice of Proposed Rulemaking

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COGR Responds to Request for Information (RFI) on an Update to the Current OLAW Guidance Disclaimer

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COGR Responds to RFI on Flexibilities for Streamlining IACUC Review of Protocols and Significant Changes (NOT-OD-23-152)

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COGR Responds to Proposed Amendments to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) (88 FR 54332)

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Purpose of RFIs

- Collect broad public input and comments on particular issues.
- May contain broad areas for comment or very specific questions
- Responses are voluntary – meant for information and planning purposes only
- Government may use the information solicited at its discretion, including posting information received on public websites.
- No payment for preparation of information submitted or for government's use of the information

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RFIs. v. Proposed Rules

Unified Agenda: Agency's Annual Regulatory Plan & Agenda of Regulatory and Deregulatory Actions

Advance Notice of Propose Rulemaking: Formal invitation to the public to participate in shaping the proposed rule.

Notice of Proposed Rulemaking: Official announcement in Federal Register that announces and explain proposed rule

Consideration of Submitted Comments

Publication in Federal Register of Final Rule

Source: Office of the Federal Register, A Guide to the Rulemaking Process

COGR's Commenting Process

- Review RFI – Is there enough time to respond? Who does the RFI seek information from (e.g., researchers, research administrators, institutional officials)? Does the RFI clearly specify what information is being requested?
- Decide who should comment – Associations? Associations + Institutions? Joint letters?
- Gather subject matter experts
- Consider issues/questions posed by RFI
- Compare with current regulations, guidance, policy
- Identify impact data – administrative burden, costs
- Identify alternative approaches
- Develop and circulate draft response
- File final comments

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Example

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An Association of Research Institutions

ARIO
ASSOCIATION OF RESEARCH INTEGRITY OFFICERS

October 30, 2022

Submitted electronically to: OASH-ORI-Public-Comments@hhs.gov

Dr. Wanda K. Jones, Acting Director
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct

Dear Dr. Jones:

COGR (Council on Governmental Relations) and ARIO (Association of Research Integrity Officers) submit this letter in response to the Office for Research Integrity's Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct published in the September 1, 2022, Federal Register. [87 FR 53750] (the "RFI"). COGR is an association of over 200 public and private United States research universities and affiliated academic medical centers and research institutes. ARIO is an association of research integrity officers (RIOs) and general counsel that shares best practices and strategies for handling research misconduct allegations and promoting ethical research. Both COGR and ARIO are concerned with the impact of federal regulations, policies, and practices on the performance of research conducted at their member institutions, and research integrity is one area of significant interest and expertise among COGR member institutions and ARIO members.

Our specific comments are organized below under each question posed in the RFI, and they are presented in order of the regulations at 42 CFR Part 93 to which they pertain. At the beginning of each response, we have included a bulleted list of the main points addressed. Note, that our comments do not encompass every section or aspect of the regulations at 42 CFR Part 93, but rather focus on our primary concerns.

QUESTION 1: WHICH SECTION(S) SHOULD BE CHANGED OR AUGMENTED WHEN REVISING 42 CFR PART 93? WHY? HOW SHOULD THE SECTION(S) BE CHANGED OR AUGMENTED?

a. ***42 CFR §93.105, Time limitations, including the interplay of this section with §93.310(h), Pursue leads and §93.316, Completing the research misconduct process***

Major Topics Addressed in this Response:

- Provide institutions with more discretion to terminate proceedings at assessment or inquiry
- Retain health or safety of public exception at §93.105(b)(2)
- Delete or substantively revise the subsequent use exception at §93.105(b)(1)
- Set clear limitations on the phrases "pursue diligently all significant issues and leads discovered" in §93.310(h) and "pursue diligently all significant issues" in §93.316(a)

One of the most important recommendations that we offer in this letter is for ORI to rethink the provisions of §93.105, §93.310(h) and §93.316 as they pertain to the scope of inquiries/investigations and the circumstances under which an inquiry or investigation may be

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It’s a lot of work!
Is commenting worth the effort?

YES!!

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The Results

"You can't always get what you want
But if you try sometimes, well, you just might find
You get what you need"

The Rolling Stones

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