



FASEB

Federation of American Societies
for Experimental Biology

Representing Over 110,000 Researchers

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November 7, 2023

Office of Science Policy
National Institutes of Health
ATTN: Tyrone Spady, PhD
6705 Rockledge Drive, Suite #750
Bethesda, MD 20817

RE: Request for Information (RFI) on the Draft Scientific Integrity Policy of the National Institutes of Health

Submitted electronically via [comment form](#)

Dear Dr. Spady,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to comment on proposed updates to the NIH Scientific Integrity Policy. As indicated in the *Federal Register* announcing availability of the draft policy for comment, NIH has a long-standing commitment to ensuring that scientific findings are objective, credible, and readily available to the public. The intent of the proposed updates is to bolster existing policies by defining individuals and parties responsible for developing, evaluating, and upholding scientific integrity policies. The proposed updates also align NIH's existing scientific integrity policy with that of the *Framework for Federal Scientific Integrity Policy and Practice* issued by the White House Office of Science and Technology Policy earlier this year, the goal of which is to establish uniform framework for fostering and enforcing scientific integrity across federal science agencies.

- 1. Role and Responsibilities of the NIH Scientific Integrity Officer** – Per the draft policy, the Scientific Integrity Officer (SIO) is the primary official responsible for directing scientific integrity matters within the agency. The designation of the Associate Director of Science Policy as the SIO for NIH is appropriate and aligned with the existing responsibilities for this role as well as the reporting line to the Principal Deputy Director, who is defined within the policy as the Chief Scientist. Specifically, the Associate Director of Science Policy is already responsible for coordinating policy development and implementation across divisions within the NIH Office of the Director (e.g., Office of Extramural Research, Office of Intramural Research, Office of Management Analysis), within the Department of Health and Human Services, the White House Office of Science and Technology Policy, and interagency committees. Designation of the Associate Director for Science Policy as the SIO also reinforces existing practice within NIH.
- 2. Role and Responsibilities of the Chief Scientist** – The draft policy defines the Chief Scientist (CS) as providing oversight of all NIH scientific integrity policies and procedures and designates

the NIH Principal Deputy for this role. As noted in our comments regarding the SIO role, this designation is appropriate and aligned with existing responsibilities and reporting lines.

- 3. Responsibilities of the NIH Scientific Integrity Council** – As outlined in the draft policy, the role of the Scientific Integrity Council is to assist the SIO in ensuring that the agency’s scientific integrity policies are rigorous, responsive to scientific integrity concerns, and uniformly applied. Although the responsibilities of the NIH Scientific Integrity Council are well outlined in the draft policy (pages 11 – 12 of the comment draft), FASEB recommends incorporating more context regarding the desired attributes of the individuals recruited to serve on the Council, including topical expertise, role(s) within an Institute/Center, and career stage. This would complement the justifications for designation of the SIO and CS and reiterate the agency’s commitment to fostering a culture of integrity across all scientific activities.

Since the intent of the proposed policy updates is to provide a scientific framework that restores trust in government science, FASEB recommends consideration of including a small number of external scientists to serve as *ad hoc* members of the NIH Scientific Integrity Council. This strategy could help reduce potential concerns about the stringency of Council actions while also expanding the collective expertise of Council members. For instance, Research Integrity Officers serving at research institutions could offer important external perspective to scientific integrity policy development and implementation.

- 4. Prohibitions Against Political Interference** – The draft policy outlines seven specific areas through which NIH aims to cultivate a culture of scientific integrity, with several including explicit callouts prohibiting political interference. For example, the first item within Section I, *Protecting Scientific Processes*, “prohibits political interference or other inappropriate influence on the design, proposal, conduct, management, evaluation, communication of, and use of scientific activities conducted by covered individuals.” FASEB also appreciated the explicit linkage of timely and accurate release of research findings to furthering public trust in science.
- 5. Other Comments** – FASEB commends NIH on these proposed updates to align its existing Scientific Integrity Policy with the January 2023 guidance from the Scientific Integrity Framework Interagency Working Group of the National Science and Technology Council. As NIH finalizes this policy, FASEB encourages incorporation of feedback received on related Requests for Information and/or Notices of Proposed Rulemaking open for comment at the same time (e.g., the Request for Information seeking input on proposed updates to the NIH mission statement open August 25 – November 24, 2023 and the Notice of Proposed Rulemaking on Public Health Service Policies on Research Misconduct open October 6 – December 6, 2023).

FASEB also recommends updating the definition of “covered individuals” to ensure readers understand for whom the policy applies. For instance, the policy includes, “...clinical, research, and postdoctoral fellows; doctoral trainees; interns;...” (page 5). While it is implied that this is referring to individuals holding those roles within the NIH intramural program, an explicit statement could minimize confusion. We also suggest clarifying whether “all levels of employees who manage or supervise scientific activities and use scientific information in policymaking” includes employees engaged in program administration roles. FASEB also recommends explicitly denoting peer reviewers as a role not defined as “covered individuals,” but for whom their efforts on behalf of NIH require upholding the principles of scientific integrity as described in the policy as part of the terms of their engagement with NIH.

Finally, FASEB appreciates the expansion the subsection on “Promoting a Culture of Scientific Integrity” within “Policy Requirements” (pages 13 – 14 of the comment draft) to acknowledge the interdependence between work environments that are equitable, inclusive, safe, and free from harassment, discrimination, and exploitation in fostering a strong culture of scientific integrity. Ongoing efforts from the Office of Scientific Workforce Diversity and the UNITE initiative have resulted in measurable progress, and FASEB looks forward to future NIH initiatives to achieve this goal more fully.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary-Ann Bjornsti". The signature is written in a cursive, slightly slanted style.

Mary-Ann Bjornsti, PhD
FASEB President