Comment Form: Draft NIH Scientific Integrity Policy Preview

September 22, 2023 – November 9, 2023

Table of Contents

Submit date: 9/25/2023

I am responding to this RFI: On behalf of myself

Name: JEAN PUBLIE

Type of Organization: Other

Type of Organization-Other: american citizen

Role: Member of the public

Comment:

THIS AGENCY IS NOT OPEN AND TRANSPARENT. NOT WHEN IT TRIES TO HOLD DOCUMENTS FOR 76 YEARS. CERTAINLY YEARS AND YEARS 36 ON ANOTHER OPRA REQUEST IS WHEN YOU WANT TO GIVE DOCUMENTS TO THE PUBLIC. 99% OF YOUR MEETINGS ARE CLOSED SO THAT THEPUBLIC CANT FIND OUT WHAT YOU ARE UP TO. THE ENTIRE AGENCY IS SNEAKY, SUBSTANDARD, AND HARMS THE US CITIZENRY. THEre is no scientificintegrity shown ever. to say you do that is a bold faced lie. criminality goes on at this agency.entire agency is a big pharma puppet. health of americans has gone down down down under dicta of this agency for last 3-5 years. using 8 mice to deamand vaccine is shot into the worlds arms shows the corruption of this agency. the mice were sick from the vaccine. this agency is the opposite of science. it is a propaganda agency.this agency has never been fair, just, impartial honest or accessible - never. the free flow of science does not exist into your agency but you spend taxpayer dollars to flow crap out to the usa citizenry. and your outflow is dishonest and corrupt. this proplsa shoudl prohibit the hiring of attack journalists. the conflict of interest in every employee in this agency is suspect so that we dont get truthful research - we get proosals that will benefit their own pockets and big pharma solely.

Description: this agency lies with its current proposal. this agency has been guilty of criminal corruption for the last 3 years.

Email: jeanpublic1@gmail.com

Submit date: 9/26/2023

I am responding to this RFI: On behalf of myself

Name: Jacoby Davis

Name of Organization: Instrumentality LLC

Type of Organization: Other

Type of Organization-Other: Cybersecurity Compliance Consulting

Role: Member of the public

Comment:

In-document Comments added by Ghost_000(Jacoby Davis): Examples of changes that could be made that would draw attention to the seriousness with which NIH takes integrity. The additional responsibilities reflect a subjective “well-rounding” of these leadership positions.

Sections that were adjusted:

Page 2

1. Purpose

2. Scientific Integrity at NIH - 1st Paragraph Only.

Page 10

1. CS Role (Added more responsibilities + 10)

2. SIO Role (Added more responsibilities + 6)

Page 11

1. Intro paragraph for the council.

2. NIH Council Responsibilities (Added more responsibilities + 5)

If outside of NIH document scope or outside of this review scope, please disregard. Otherwise, the last item I would recommend is a change log at the top of the document. Name | Department | Date | Purpose.

I would be happy to draft SOPs for each as well. :)

Bon chance, fellow humans.

Uploaded File:

Draft_SI_Policy.pdf

Description: Draft_SI_Policy_edited_by_Jacoby_Davis

Email: jacoby.davis@protonmail.com

DRAFT
Scientific Integrity Policy of the National Institutes of Health

Table of Contents

Purpose

The purpose of this policy is to promote a continuing culture of scientific integrity at the National Institutes of Health (NIH). This policy aims to ensure the integrity of all aspects of NIH scientific activities, including proposing, conducting, reviewing, managing, and communicating about science and scientific activities, and using the results of science to inform policy and program decision-making.

Scientific Integrity at NIH

The mission of NIH is to seek fundamental knowledge about the nature and behavior of living systems and apply that knowledge to enhance health, lengthen life, and reduce illness and disability. NIH accomplishes this mission by funding extramural researchers throughout the country, conducting research within its intramural research program, and developing policies and programs to responsibly advance biomedical research. Embedding principles of scientific integrity throughout the NIH enterprise relies on two key elements. The first element is an all-hands-on-deck approach in which scientific rigor and research quality are prioritized. The second element is having inclusive, robust processes that safeguard scientific integrity.

In fostering scientific integrity, NIH aims to ensure that (1) scientific findings are objective, credible, and readily available to the public, and (2) the development and implementation of policies and programs is transparent, accountable, and evidence-based. NIH has numerous policies and procedures to ensure the Nation's investment in biomedical research is scientifically robust and rigorous and that our workforce maintains the highest standards of integrity.

Public input and accountability are woven throughout NIH processes to assure the public of the credibility of our science and our scientific findings. These activities range from presenting potential scientific solicitations at public meetings (e.g., concept clearance) to soliciting community feedback during policymaking activities. In supporting the NIH mission, all NIH researchers and staff are expected to:

- Foster an organizational culture of scientific integrity,
- Protect the integrity of the research process,
- Communicate science with integrity, and
- Safeguard scientific integrity.

NIH's long-standing commitment to fostering scientific integrity was summarized in its 2012 report NIH Policies and Procedures for Promoting Scientific Integrity at https://www.nih.gov/sites/default/files/about-nih/nih-director/testimonies/nih-policies-procedures-promoting-scientific-integrity-2012.pdf. This document was updated in 2022 at https://osp.od.nih.gov/wp-content/uploads/2023/09/SI_Compendium-2022Update.pdf, partly in response to the 2021 Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/ to reflect more than a decade of updates to agency policies and procedures that support scientific integrity. The NIH Scientific Integrity Policy articulates expectations to preserve scientific integrity throughout all NIH activities, establishes key roles and responsibilities for those who will lead the agency's scientific integrity program, and, as appropriate, establishes relevant reporting and evaluation mechanisms with a goal of ensuring scientific integrity is foundational to all NIH activities. The NIH Scientific

Integrity Policy is consistent with the U.S. Department of Health and Human Services (HHS) Scientific Integrity Policy. The majority of procedures regarding scientific integrity described herein are longstanding and foundational to NIH-supported research. This Scientific Integrity Policy integrates existing and new practices under a single harmonized framework.

Effective Date and Policy Amendments

This policy goes into effect 12 months after publication of the final policy in the Federal Register. This policy will be evaluated by NIH one year after its effective date and regularly thereafter. Proposals to amend this policy will be overseen by the NIH Scientific Integrity Officer (SIO), in collaboration with the NIH Scientific Integrity Council (Council) described below, and any such amendments will be communicated to HHS and the Director of the White House Office of Science and Technology Policy (OSTP) no later than 30 days after adoption.

Applicability & Scope

All NIH employees; Public Health Service Commissioned Corps members; political appointees; clinical, research, and postdoctoral fellows; doctoral trainees; interns; and advisory committee members in their capacity as special Government employees, and those managing scientific activities and using scientific information in policymaking, are expected to adhere to NIH's policies when in the course of their official duties they propose, conduct, review, or communicate about science and scientific activities on behalf of NIH. When relevant, NIH has also implemented separate policies for contractors, collaborators, awardees, and volunteers to uphold the principles of scientific integrity established by this policy.

Exceptions

This policy will be implemented consistent with applicable Federal law.

Definitions

Allegation refers to a disclosure of a suspected loss of scientific integrity.

Chief Scientist (CS) provides oversight of all NIH scientific integrity policies and procedures. NIH recognizes organizational culture starts with leadership at the highest levels. It has designated the NIH Principal Deputy Director as the NIH CS.

Corrective scientific action refers to actions taken to restore the accuracy of the scientific record after a loss of scientific integrity has been determined, consistent with this policy, such as correction or retraction of published materials. In addition to scientific actions, administrative actions may also be taken in response to substantiated violations of this policy.

Covered individuals include all NIH employees; Public Health Service Commissioned Corps members; political appointees; clinical, research, and postdoctoral fellows; doctoral trainees; interns; and advisory committee members in their capacity as special Government employees, when in the course of their official duties they propose, conduct, review, or communicate about science and scientific activities; and all levels of employees who manage or supervise scientific activities and use scientific information in policymaking. NIH contractors, partners, permittees, lessees, grantees, and volunteers who engage or assist in NIH scientific activities are not considered covered individuals but are expected to uphold the principles of scientific integrity described in this policy, as incorporated into the terms of their engagement with NIH.

Ethical behavior refers to activities that reflect norms for conduct that distinguish between acceptable and unacceptable behavior, such as honesty, lawfulness, equity, and professionalism, and to adherence to statutes, regulations, policies, and guidelines governing employee conduct.

Federal agency refers to an Executive department, a U.S. Government corporation, and an independent establishment.

Inclusivity refers to the practice of providing equal access to opportunities for full participation of all people and all groups, including marginalized, underserved, and underrepresented contributors, without bias or prejudice. Full participation is enabled through implementation of strategies that promote equitable access and fair treatment in the organization.

Inappropriate influence refers to the attempt to shape or interfere in scientific activities or the communication about or use of scientific activities, against well-accepted scientific methods and theories and without scientific, legal, programmatic management, or security justification.[1,2]

Interference refers to inappropriate, scientifically unjustified intervention in the conduct, management, communication, or use of science. It includes censorship, suppression, or distortion of scientific or technological findings, data, information, or conclusions; inhibiting scientific independence during clearance and review; scientifically unjustified intervention in research and data collection; and inappropriate engagement or participation in peer review processes or on Federal advisory committees (FACs).

[1] Examples may include 1) suppressing a decisionmaker's ability to offer the best judgment based on scientific information; 2) suppressing, altering or delaying the release of a scientific product for any reason other than technical merit or providing advance notification; 3) removing or reassigning scientific personnel for any reason other than performance, conduct or budgetary constraints; 4) using scientific products that are not representative of the current state of scientific knowledge and research (for example because of a lack of appropriate peer review, poor methodology, or flawed analyses) to inform decision making and policy formulation; or 5) misrepresenting the underlying assumptions, uncertainties, or probabilities of scientific products. This is not intended to be an exhaustive list.

[2] Differences of scientific opinion are not necessarily inappropriate influence. Additionally, NIH officials are regularly expected to provide agency perspectives when acting in their official capacity.

Loss of scientific integrity refers to the failure to comply with this Scientific Integrity Policy or to adhere to objectivity, transparency, and ethical behavior when conducting, managing, using the results of, and communicating about science and scientific activities. This loss may include research misconduct or inappropriate influence in the conduct, communication, management, and use of science.[3]

Policy refers to laws, regulations, procedures, administrative actions, incentives, or voluntary practices of Governments and other institutions.

Policymaking refers to the (1) development of policies or making determinations about policy or management; (2) making determinations about expenditures of Federal agency funds; (3) implementing or managing activities that involve, or rely on, scientific activities.

Political interference is inappropriately shaping or interfering in the conduct, management, communication, or use of science for inappropriate partisan advantage or such that it undermines impartiality, nonpartisanship, or professional judgement.

Research integrity refers to the use of honest and verifiable methods in proposing, performing, and evaluating research; reporting research results with particular attention to adherence to rules, regulations, and guidelines; and following commonly accepted professional codes or norms.

Research misconduct refers to fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.[4]

[3] A report by the Scientific Integrity Fast-Track Action Committee of the National Science and Technology Council. "Protecting the Integrity of Government Science." January 11, 2022. Available at: https://www.whitehouse.gov/wp-content/uploads/2022/01/01-22-Protecting_the_Integrity_of_Government_Science.pdf.

[4] Federal Research Misconduct Policy, 65 FR 76260, 76262 (Dec. 6, 2000) and https://www.ecfr.gov/current/title-42/chapter-I/subchapter-H/part-93/subpart-A/section-93.103.

Research security refers to safeguarding the research enterprise against the misappropriation of research and development to the detriment of national or economic security, related violations of research integrity, and foreign Government interference.

Science refers to the full spectrum of scientific endeavors, including basic science, applied science, evaluation, engineering, technology, economics, social sciences, and statistics, as well as the scientific and technical information derived from these endeavors.

Scientific activities refer to activities that involve the application of well-accepted scientific methods and theories in a systematic manner, and includes, but is not limited to, data collection, inventorying, monitoring, evaluation, statistical analysis, surveying, observations, experimentation, study, research, integration, economic analysis, forecasting, predictive analytics, modeling, technology development, and scientific assessment, as well as any findings derived from these activities.

Scientific data refers to recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data does not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens.[5]

Scientific integrity is the adherence to professional practices, ethical behavior, and the principles of honesty and objectivity when conducting, managing, using the results of, and communicating about science and scientific activities. Inclusivity, transparency, and protection

[5] NIH Data Management and Sharing Policy at: https://sharing.nih.gov/data-management-and-sharing-policy.

from inappropriate influence are hallmarks of scientific integrity. (Note: this is the Official Federal Definition of Scientific Integrity, consistent with OSTP and HHS definitions.[6])

Scientific Integrity Council will assist the NIH SIO in iterative review, policy development, and priority setting to ensure that the existing policies and procedures are responsive to issues that arise in the scientific integrity space.

Scientific Integrity Official (SIO) is the primary official for responsibilities over scientific integrity matters and reports to the NIH CS. This policy empowers the NIH SIO with the independence necessary to gather and protect information to support the review and assessment of scientific integrity concerns. The NIH SIO will also advocate for appropriate engagement of scientific leadership in policymaking. NIH recognizes organizational culture starts with leadership at the highest levels. NIH has designated the Associate Director of Science Policy as the NIH SIO.

Scientific record refers to published information resulting from scientific activities. NIH is responsible for ensuring the accuracy of elements of the scientific record that are published by NIH.

Scientist refers to an individual whose responsibilities include collection, generation, use, or evaluation of scientific and technical data, analyses, or products. NIH scientists are NIH employees and other covered individuals who conduct these activities. It does not refer to individuals with scientific and technical training whose primary job functions are in non-scientific roles (e.g., policymakers, communicators).

[6] A Framework for Federal Scientific Integrity Policy and Practice. Available at: https://www.whitehouse.gov/wp-content/uploads/2023/01/01-2023-Framework-for-Federal-Scientific-Integrity-Policy-and-Practice.pdf.

Roles and Responsibilities

Chief Scientist and Scientific Integrity Official

The CS shall:

1. Provide oversight of all NIH scientific integrity policies and procedures, including the periodic updates of those policies and procedures;
2. Engage agency efforts regarding diversity, equity, inclusion, and accessibility;
3. Provide for the resourcing and staffing needs of the NIH scientific integrity program;
4. Promote scientific integrity across the agency; and
5. Serve as an alternate in scientific integrity adjudication processes if the NIH SIO is alleged to have violated NIH or HHS Scientific Integrity Policies.

The SIO shall:

1. Report to the CS on all matters related to scientific integrity;
2. Periodically update the NIH Scientific Integrity Policy;
3. Provide regular reporting on NIH scientific integrity allegations and outcomes to OSTP and the public;
4. Determine the resourcing and staffing needs of the NIH scientific integrity program;
5. Promote scientific integrity across the agency;
6. Lead the NIH Scientific Integrity Council, participate on the HHS Council, and other interagency efforts regarding scientific integrity;
7. Serve as a focal point for the receipt of agency scientific integrity allegations (particularly related to political interference) that fall outside of existing processes managed by the Office

of Extramural Research (OER), the Office of Intramural Research (OIR), the Office of Management Analysis (OMA), and the HHS Office of the Inspector General (OIG);

8. Lead the review and adjudication of allegations of loss of NIH scientific integrity (particularly related to political interference) in cases where such allegations fall outside of existing processes managed by OER, OIR, OMA, and OIG; and
9. Promote agency efforts regarding diversity, equity, inclusion, and accessibility.

NIH Scientific Integrity Council

The NIH SIO shall establish an NIH Council comprising career employees from across the NIH and from relevant NIH offices. This committee will assist the SIO in iterative review, policy development, and priority setting to ensure that the existing policies and procedures are responsive to issues that arise in the scientific integrity space.

The primary responsibilities of the Council are to:

1. Ensure that a well-informed and high-level group of experts supports scientific integrity at NIH;
2. Ensure that the NIH Scientific Integrity Policy is implemented consistently across NIH;
3. Review, assess, and revise the NIH Scientific Integrity Policy as needed;
4. Engage NIH leadership in upholding the principles of scientific integrity, and maintaining leadership awareness of scientific integrity issues as necessary and appropriate;
5. As requested, assist the SIO in adjudicating allegations of losses of NIH scientific integrity (particularly related to political interference) in cases where such allegations fall outside of existing processes managed by OER, OIR, OMA, and OIG; and

6. Determine handling of investigation and adjudication proceedings from which the HHS SIO is recused.

Background on NIH Functions

Intramural Research

The Intramural Research Program (IRP) is the internal research program of NIH, known for its synergistic approach to biomedical science. The IRP is the largest biomedical research program on earth, and its unique environment means the IRP can facilitate opportunities to conduct both long-term and high-impact science that would otherwise be difficult to undertake. The NIH IRP conducts research and training within its laboratories and clinics, and when appropriate, collaborates with the private sector to develop technologies of importance to public health. To help ensure the high quality and integrity of its intramural programs, NIH has developed and implemented NIH-wide policies and review standards for research, training, and technology transfer. The NIH Policy Manual at https://policymanual.nih.gov/ is an official mechanism of issuing NIH-wide policy and all Manual Chapter issuances. More information about the NIH IRP can be found on the NIH OIR website at https://oir.nih.gov/.

Extramural Research

Approximately 80 percent of NIH's investment in biomedical and behavioral research supports extramural researchers at institutions in every state in the country. Given the size and breadth of this investment, NIH has a robust infrastructure to ensure scientific integrity is embedded throughout the extramural research continuum and its workforce. While the covered individuals for this policy consist primarily of NIH employees, the principles of scientific integrity are

foundational to NIH's role in funding extramural biomedical research, and the importance of scientific integrity is integrated throughout all NIH does as a funder of biomedical research. As such, existing policies to maintain scientific integrity of extramural research will continue. More information about the NIH extramural research program can be found on the NIH OER website at https://grants.nih.gov/aboutoer/intro2oer.htm.

NIH as a Policy Development Agency

NIH promotes progress in the biomedical research enterprise through the development of sound and comprehensive policies. To achieve this, NIH engages partners within and outside of NIH to develop policies on a wide range of issues including biosafety, biosecurity, genetic testing, genomic data sharing, human subjects protections, the organization and management of the NIH, and the outputs and value of NIH-funded research. This is accomplished through a wide range of analyses and reports, commentary on emerging policy proposals, and the development of policy proposals for consideration by NIH, the Federal Government, and the public. More information about NIH policy development can be found on the NIH Office of Science Policy (OSP) website at https://osp.od.nih.gov/.

Policy Requirements

Promoting a Culture of Scientific Integrity

NIH leadership at all levels recognizes, supports, and promotes this policy and its underlying principles, and models behavior consistent with a strong culture of scientific integrity.

NIH works to promote a culture of scientific integrity by creating an empowering environment for innovation and protecting scientists and the process of science from inappropriate interference. Scientific findings and products must not be suppressed, delayed, or altered for political purposes and must not be subjected to political interference or inappropriate influence.

A strong culture of scientific integrity begins with ensuring a professional environment that is safe, equitable, fair, just, impartial, honest, and inclusive. Diversity, equity, inclusion, and accessibility (DEIA) are integral components of the entire scientific process. Attention to DEIA can improve the success of the scientific workforce, foster innovation in the conduct and use of science, and provide for more equitable participation in science by diverse communities. The responsible and ethical conduct of research and other scientific activities requires an environment that is equitable, inclusive, safe, and free from harassment, discrimination, and exploitation.

NIH also works to apply scientific integrity practices in ways that are inclusive of non-traditional modes of science, such as citizen science, community-engaged research, participatory science, and crowdsourcing. This may include expanded scientific integrity practices and expectations, such as seeking greater input from communities and participants into the research questions and design, recognition of data and knowledge sovereignty, and inclusion of multiple forms of evidence, such as Indigenous Knowledge.

NIH has posted the NIH Scientific Integrity Policy prominently on its website and ensures education is available for all covered individuals, as well as contractors who perform scientific activities for the agency, on their rights and responsibilities related to scientific integrity. All

NIH employees will receive scientific integrity information or training as new employees and NIH, in concert with HHS, will make available training for covered individuals and others, as applicable.

To promote a culture of scientific integrity at NIH, this policy outlines seven specific areas:

I. Protecting Scientific Processes
II. Ensuring the Free Flow of Scientific Information
III. Supporting Policymaking Processes
IV. Ensuring Accountability
V. Protecting Scientists
VI. Professional Development for Government Scientists, and
VII. Federal Advisory Committees

I. Protecting Scientific Processes

NIH has implemented a suite of efforts to protect the integrity of research processes from bias and interference, which is essential to upholding public trust and confidence. These efforts rely on transparent processes, diverse community engagement, management of real or apparent conflicts of interest, and robust and open dialogue. NIH utilizes a variety of mechanisms to achieve these aims, such as holding policy discussions in open settings, soliciting public input on future research directions, and the use of Federal advisory committees (FACs) to advise the agency. In addition, for covered individuals, NIH explicitly prohibits political interference or inappropriately shaping or interfering in the conduct, management, communication, or use of science for inappropriate partisan advantage or such that it undermines impartiality,

nonpartisanship, or professional judgement. Further processes will be developed and documented to support this policy in an NIH manual chapter.

It is the policy of NIH to:

1. Prohibit political interference or other inappropriate influence in the design, proposal, conduct, management, evaluation, communication of, and use of scientific activities conducted by covered individuals.
2. Prohibit inappropriate restrictions on resources and capacity that limit and reduce the availability of science and scientific products outside of normal budgetary or priority-setting processes or without scientific, legal, or security justification.[7]
3. Require that leadership and management ensure that covered individuals engaged in scientific activities can conduct their work objectively and free from political interference or other inappropriate influence.
4. Require reasonable efforts by covered individuals to ensure the fidelity of the scientific record and to correct identified inaccuracies that pertain to their contribution to any scientific records.
5. Require that covered individuals represent their contributions to scientific work fairly and accurately and neither accept nor assume unauthorized and/or unwarranted credit for another's accomplishments. To be named as an author, contributors should have made a substantial contribution or provided editorial revisions that include critical intellectual content, approved the final version, and agreed to be accountable for all aspects of the work

[7] This provision is further outlined in the NIH Policy Manual Chapter 3005 on Review and Evaluation of Intramural Programs. Available at: https://policymanual.nih.gov/3005.

to which they contributed. Prior consent should be obtained from each author to be represented on a particular work. Obtaining prior consent for acknowledgements is also a good practice.[8]

6. Ensure independent review of scientific activities conducted by covered individuals as appropriate to ensure scientific integrity.[9]
7. Require that covered individuals comply with NIH policies and procedures for planning and conducting scientific activities and show appropriate diligence toward protecting and conserving Federal research resources, such as equipment and other property, and records of data and results that are entrusted to them.
8. Prohibit research misconduct, the deliberate or reckless use of improper or inappropriate research methods or processes, and noncompliance with practices that safeguard the quality of research and other scientific activities or enhance research security for covered individuals.[10]
9. Require that covered individuals design, conduct, manage, evaluate, and communicate about scientific research and other scientific activities honestly and thoroughly, and disclose any conflicts of interest to their supervisor or other appropriate NIH official(s) for their determination as to whether a recusal, disclaimer, or other action is appropriate, consistent with NIH ethics policies and procedures.[11]

[8] This provision is further outlined in the 2023 8th Edition of Guidelines and Policies for the Conduct of Research in the Intramural Research Program at NIH. Available at: https://oir.nih.gov/system/files/media/file/2023-08/guidelines-conduct_research.pdf.

[9] This provision is further outlined in the NIH Policy Manual Chapter 3005 on Review and Evaluation of Intramural Programs. Available at: https://policymanual.nih.gov/3005.

[10] This provision is further outlined in the NIH Policy Manual Chapter 3006 on NIH Intramural Research Program (IRP) Research Misconduct Proceedings. Available at: https://policymanual.nih.gov/3006.

[11] This provision is further outlined in the NIH Conflict of Interest and Confidentiality Certification for Individuals Evaluating all NIH Intramural Programs. Available at: https://oir.nih.gov/system/files/media/file/2021-08/conflict_of_interest-bsc_reviews.pdf.

10. Require that research conducted by covered individuals involving the participation of human subjects and the use of non-human animals is conducted in accordance with applicable, established laws, regulations, policies, and ethical considerations.[12]
11. Support and enhance scientific integrity with the understanding that violations of scientific integrity can have a disproportional impact on underrepresented groups or weaken the equitable delivery of Federal Government programs.
12. Consistent with OSTP guidance and relevant HHS and NIH policy, prohibit personnel of NIH engaged in intramural research from participation in foreign talent recruitment programs, unless the participation is in an international conference or other international exchange, partnership, or program for which such participation has been approved by the appropriate authority in NIH.[13]
13. Consistent with OSTP guidance and relevant HHS and NIH policy, require disclosure of participation in foreign talent recruitment programs, including the provision of copies of all grants, contracts, or other agreements related to such programs, and other supporting documentation related to such programs, as a condition of receipt of Federal extramural research funding awarded through NIH.[14]

[12] This provision is further outlined in the NIH Policy Manual Chapter 3014 on NIH Intramural Human Research Protection Program and the NIH Policy Manual Chapter 3040-2 on Animal Care and Use in the Intramural Research Program. Available at: https://policymanual.nih.gov/3014 and https://policymanual.nih.gov/3040-2 respectively.

[13] Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, Pub. L. 117-328, Division FF, Title II, Section 2321 (Jan 3, 2023) and Chips and Science Act, Pub. L. 117-167, Title VI, Subtitle D, Section 10631 (Aug 9, 2022). OSTP guidance and relevant HHS and NIH policies to implement this legislation are forthcoming at the time of publication of this policy.

[14] Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, Pub. L. 117-328, Division FF, Title II, Section 2321 (Jan 3, 2023) and Chips and Science Act, Pub. L. 117-167, Title VI, Subtitle D, Section 10631 (Aug 9, 2022). OSTP guidance and relevant HHS policies to implement this legislation are forthcoming at the time of publication of this policy.

II. Ensuring the Free Flow of Scientific Information

NIH is committed to the broad and equitable dissemination and promotion of rigorous and objective scientific information. The NIH Office of Communications and Public Liaison (OCPL) and communication offices within the NIH Institutes, Centers, and Offices (NIH ICOs) disseminate objective and evidence-based research findings to the public through websites, listservs, brochures, videos, social media, and other modes of communication as appropriate. NIH OCPL and the ICO communication offices also respond to public inquiries and engage with technical and non-technical audiences through media and online forums to ensure responsible communication regarding the research it funds.

At the foundation of the NIH mission is the generation of reliable, rigorous, research results, and their publication in reputable, peer-reviewed scientific journals. NIH's IRP researchers adhere to a NIH-wide Policy for Manuscript and Abstract Clearance Procedures at https://oir.nih.gov/sourcebook/submitting-research-publications/publication-abstract-clearance and follow established guidance to ensure transparency in research findings through Processes for Authorship Dispute Resolution at https://oir.nih.gov/sourcebook/ethical-conduct/authorship-guidelines-resources/nih-irp-authorship-conflict-resolution-process if the situation arises.

It is the policy of NIH to:

1. Facilitate the free flow of scientific and technological information, to the extent permissible by Federal laws and regulations. Consistent with open science expectations, NIH shall

expand and promote access to scientific and technological information by making it available freely and without embargo to the public in an online digital format.[15,16,17,18]

2. Ensure that scientific findings and products created by NIH scientists are not unduly suppressed, delayed, or altered for political purposes and are not subjected to inappropriate influence.
3. Encourage, but not require, NIH scientists to participate in their official capacities in communications with the media regarding their scientific activities and areas of expertise, subject to limitations of Government ethics rules. In communicating with the media, NIH scientists are encouraged to seek advice from career NIH communications experts.
4. Allow, subject to limitations of Government ethics rules, NIH scientists to express their personal views and opinions with appropriate written or oral disclaimers, including on social media.[19] NIH scientists may name NIH as their employer in the context of biographical information but shall refrain from making or publishing statements that could be construed as being judgments of, or recommendations on, NIH or any other Federal

[15] White House Office of Science and Technology Policy Memorandum for the Heads of Executive Departments and Agencies on Increasing Access to the Results of Federally Funded Scientific Research. February 22, 2013. Available at: https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf.

[16] White House Office of Science and Technology Policy Memorandum for the Heads of Executive Departments and Agencies on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research. August 25, 2022. Available at: https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf.

[17] This provision is further outlined in the NIH Policy Manual Chapter 1184 on Preparation and Clearance of Scientific, Technical, and Public Information Presented by NIH Employees or Produced for Distribution by NIH. Available at: https://policymanual.nih.gov/1184.

[18] This provision is further outlined in the NIH Data Management and Sharing Policy. Available at: https://sharing.nih.gov/data-management-and-sharing-policy.

[19] This provision is further outlined in the United States Office of Government Ethics Standards of Conduct and 18 U.S.C. § 208 as Applied to Official Social Media Use. Available at: https://oge.gov/web/oge.nsf/News+Releases/EAE37A7DA3C38BF38525894700775339/$FILE/LA-23-03%20The%20Standards%20of%20Conduct%20and%2018%20U.S.C.%20%C2%A7%20208%20as%20Applied%20to%20Official%20Social%20Media%20Use.pdf.

Government policy, including the use of NIH or other U.S. Government seals or logos, unless they have secured appropriate prior approval to do so.

5. Ensure that the work and conclusions of NIH scientists and the work and conclusions of scientists funded or supported by the Federal Government are accurately represented in NIH communications. If communication documents significantly rely on a scientist's research, identify them as an author, or represent their scientific opinion, the scientist shall be given the option to review the scientific content of proposed communication documents.
6. Ensure that NIH scientists may communicate their scientific activities objectively without political interference or other inappropriate influence. Scientific products (e.g., manuscripts for scientific journals, presentations for workshops, conferences, and symposia) shall adhere to relevant NIH technical review procedures.
7. Require that NIH officials, including communications officers, shall not alter, nor direct NIH scientists and technology experts to alter, scientific and technological research findings or presentation of research findings in a manner that may compromise the objectivity or accurate representation of those findings.
8. Require that technical review and clearance processes include provisions for timely clearance and expressly forbid censorship, unreasonable delay, and suppression of objective communication of data and results without scientific, legal, or security justification.
9. Ensure that scientific information is accurately represented in responses provided by NIH to Congressional inquiries, testimony, and other requests.

10. Accurately represent the work and conclusions of NIH scientists in NIH social media communications and provide appropriate guidance to NIH scientists on the use of NIH social media.
11. Violations of clearance policies that result in suppression, delay, or alteration of scientific and technological information produced by NIH scientists without scientific, legal, or security justification constitute violations of the NIH Scientific Integrity Policy and may be reported under the procedures for Addressing Scientific Integrity Concerns.

III. Supporting Policymaking Processes

NIH utilizes multiple mechanisms for ensuring transparency and accountability in developing policy. The development of science policy at NIH generally follows procedures set forth under the Administrative Procedure Act (5 USC Subchapter II) at https://www.archives.gov/federal-register/laws/administrative-procedure, where applicable, and draft policy proposals are routinely issued through the NIH Guide and the Federal Register, as appropriate, to obtain early feedback into policy proposals. Once a proposal has been issued for public comment, it is often supplemented with informational webinars, interactive discussion sessions, and a robust public engagement plan to promote broad dissemination and engagement in the policymaking process. NIH considers all comments submitted on draft polices and policy proposals to ensure final policy proposals are informed by the community and capable of responding to emerging opportunities and challenges. Final policies are also issued through the NIH Guide and the Federal Register, as appropriate, and incorporated into the NIH Grants Policy Statement and NIH Policy Manual, as appropriate. Policies are also posted to NIH websites with additional resources such as Frequently Asked Questions and other supplemental resources as needed.

It is the policy of NIH to:

1. Ensure the quality, accuracy, and transparency of scientific information used to support policy and decision making, including by:
    a. Using scientific information that is subject to well-established scientific processes.
    b. Ensuring that scientific data and research used to support policy decisions undergo review by qualified experts, where feasible and appropriate, and consistent with law.
    c. Adhering to the Office of Management and Budget Final Information Quality Bulletin for Peer Review.[20] For example, as described in the Bulletin, when independent peer reviews of scientific information products are conducted by contractors, a conflict-of-interest review shall be conducted.
    d. Reflecting scientific information appropriately and accurately and making scientific findings or conclusions considered or relied on in policy decisions publicly available online and in open formats, to the extent practicable.
2. Where legally permissible and appropriate, directly consult with scientists whose work is being used in policy and management decisions to ensure that the science is accurately represented and interpreted.
3. Ensure, to the extent possible, the accuracy of NIH communication of the science upon which a policy decision is based.
4. Ensure that covered individuals are free to express differing scientific opinions free from political interference or inappropriate influence.

[20] Office of Management and Budget. "Final Information Quality Bulletin for Peer Review." *Federal Register*. Doc. 05-769. Available at: https://www.federalregister.gov/documents/2005/01/14/05-769/final-information-quality-bulletin-for-peer-review.

IV. Ensuring Accountability

NIH is firmly committed to establishing and formalizing procedures to identify and adjudicate allegations regarding compromised scientific processes or technological information. NIH has established several adjudication processes with distinct offices (i.e., OER, OIR, and OMA), to address different ways in which scientific integrity may be violated. Each office handles allegations pertaining to its respective jurisdiction, but anyone may submit an oral or written allegation via email or hotline. When an allegation or complaint is received, the appropriate office determines if it is specific, credible, and meets the definition of misconduct or an integrity violation. The procedures each office takes for investigating allegations or complaints, adjudication, and appeals are further detailed in the 2022 update to the NIH Policies and Procedures for Promoting Scientific Integrity at https://osp.od.nih.gov/wp-content/uploads/2023/09/SI_Compendium-2022Update.pdf. The designation of an NIH SIO will allow for more centralized interagency communication and coordination concerning allegations to ensure effective oversight and promote scientific integrity within the Federal Government. Additionally, the NIH SIO will provide review and adjudication of allegations (particularly related to political interference) that do not fall under the purview of these existing offices.

It is the policy of NIH to:

1. Ensure correction of the scientific record and implementation of corrective scientific actions when allegations of a loss of scientific integrity are substantiated.
2. Encourage and facilitate early informal or formal consultation between NIH employees and scientific integrity officials to advise on preventing loss of scientific integrity, to determine

whether a loss of scientific integrity has potentially occurred, and to ascertain whether an allegation should be referred elsewhere for resolution.

3. Provide clear guidance on how to formally and confidentially report concerns and allegations of loss of scientific integrity. Those who report concerns and allegations need not be directly involved or witness a violation.
4. Ensure that the NIH SIO or other NIH entities draft procedures, as needed, to respond to allegations of loss of scientific integrity in a timely, objective, and thorough manner. These procedures shall include an initial assessment and review, a fact-finding process, an adjudication or determination including description of remedies and preventative measures to safeguard the science, and reporting.
5. These procedures shall document the necessary aspects for each step of the process as well as the roles of NIH SIO and other agency staff in the process.

V. Protections

NIH prioritizes safe and respectful work environments that are free from harassment, including sexual harassment, discrimination, or other forms of inappropriate conduct that can result in a hostile work environment. Additionally, it is unlawful for NIH to take or threaten to take a personnel action against an employee because he or she made a protected disclosure of wrongdoing. A protected disclosure is defined as a disclosure of information that the individual reasonably believes is evidence of a violation of law, rule, or regulation; gross mismanagement; gross waste of funds; and abuse of authority; or a substantial and specific danger to public health or safety. Personnel actions that are covered by this can include poor performance review, demotion, suspension, termination, or revocation or downgrade of a security clearance. If staff

members believe that whistleblower retaliation has occurred, they may get more information from the HHS OIG at https://oig.hhs.gov/about-oig/.

It is the policy of NIH to:

1. Select and retain candidates for NIH scientific and technical positions based on the candidate's scientific and technical knowledge, credentials, experience, and integrity, and hold them and their supervisors to the highest standards of professional and scientific ethics.[21]
2. Promote diversity, equity, inclusion, and accessibility in the scientific workforce and to create and support the creation of safe workspaces that are free from harassment, discrimination, and exploitation.[22]
3. Protect from reprisal those individuals who report allegations of loss of scientific integrity in good faith. Efforts will also be made to protect from inappropriate actions those covered individuals alleged to have compromised scientific integrity.
4. Prevent NIH employees from intimidating or coercing NIH scientists to alter scientific data, findings, or professional opinions or from inappropriately influencing scientific advisory boards.
5. Comply with whistleblower protections, specifically:

[21] This provision is further outlined in the NIH Sourcebook on Personnel. Available at: https://oir.nih.gov/sourcebook/personnel.

[22] This provision is further outlined in the NIH Sourcebook Addendum to BSC Policies and Procedures. Available at: https://oir.nih.gov/sourcebook/processes-reviewing-nih-intramural-science/boards-scientific-counselors/addendum-policies-procedures.

a. The requirements of the Whistleblower Protection Act of 1989, and its expanded protections enacted by Pub. L. 103-424 and the Whistleblower Protection Enhancement Act of 2012, 5 USC Part 2302(b)(8)-(9).
b. The National Defense Authorization Act's expansion of certain whistleblower protections to employees of Federal Government contractors, subcontractors, and grant recipients in 41 USC Part 4712.
c. Presidential Policy Directive 19, which prohibits supervisors from taking, failing to take, or threatening to take or fail to take any action affecting an employee's eligibility for access to classified information in reprisal for making a protected disclosure.
d. The Military Whistleblower Protection Act (codified at 10 USC 1034), which is made applicable to the Public Health Service Commissioned Corps officers through section 1129 of the Food and Drug Administration Safety and Innovation Act (Pub. L 112-144), and implemented by Commissioned Corps Directive 121.06.

6. Scientific integrity staff at NIH are protected by all applicable employee rights as required by law. Consistent with applicable law, an SIO or other scientific integrity staff may not be terminated or reassigned without good cause or legitimate organizational reason. Possible good cause reasons include, but are not limited to, consistent poor performance, inefficiency, neglect of duty, malfeasance, conviction of a felony, conduct involving moral turpitude, knowing violation of a law, rule, or regulation, gross mismanagement, gross waste of funds, and abuse of authority.

VI. Professional Development for Government Scientists

A key aspect of the NIH effort to advance scientific integrity is encouraging NIH IRP researchers to engage with the broader research community in maintaining the highest ethical

standards and scientific norms. Creating an inclusive environment for scientists from all backgrounds, including those from traditionally underrepresented groups, is essential to supporting scientific integrity. The IRP promotes professional development of all researchers from trainees at every level, to tenure-track and tenured investigators, and all other research staff. Scholarly writing, lecturing, editing, and publishing are essential parts of research and professional development. These activities are in the public interest and bring credit and distinction to both NIH and its employees. In encouraging researchers to share information about their official and professional activities, NIH seeks to advance scientific knowledge and contribute to its employees' professional education.

It is the policy of NIH to:

1. Encourage timely publication of research conducted by covered individuals such as in peer-reviewed, professional, scholarly journals, NIH technical reports and publications, or other appropriate outlets.[23]
2. Encourage the sharing of scientific activities, findings, and materials developed by covered individuals through appropriate avenues including digital repositories.[24]
3. Encourage covered individuals to participate in and present research at professional meetings including workshops, conferences, and symposia.[25]

[23] This provision is further outlined in the NIH Data Management and Sharing Policy. Available at: https://sharing.nih.gov/data-management-and-sharing-policy.
[24] This provision is further outlined in the NIH Data Management and Sharing Policy. Available at: https://sharing.nih.gov/data-management-and-sharing-policy.
[25] This provision is further outlined in the NIH Sourcebook on Tenure in the NIH Intramural Research Program. Available at: https://oir.nih.gov/sourcebook/tenure-nih-intramural-research-program.

4. When appropriate, permit covered individuals to serve on editorial boards, as peer reviewers, or as editors of professional or scholarly journals.
5. When appropriate, permit covered individuals to participate in professional societies, committees, task forces, and other specialized bodies of professional societies, including removing barriers to serving as officers or on governing boards of such societies, to the extent allowed by law.[26]
6. Permit NIH scientists to receive honors and awards for contributions to scientific activities and discoveries to the extent allowed by law, and to accrue the professional recognition of such honors or awards.
7. Permit NIH scientists to perform outreach and engagement activities, such as speaking to community and student groups, as part of their official duties as appropriate.

VII. Federal Advisory Committees

FACs, as defined by the Federal Advisory Committee Act (FACA) at https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/legislation-and-regulations/the-federal-advisory-committee-act, are an important tool within NIH for ensuring the credibility, quality, and transparency of NIH science. NIH shall adhere to FACA and develop policies in coordination with the General Services Administration and consistent with the guidance on lobbyists serving on FACs when convening FACs tasked with giving scientific advice.

[26] This provision is further outlined in the NIH Sourcebook on Activities with Outside Organizations and the NIH Official Duty Activities Chart. Available at: https://oir.nih.gov/sourcebook/ethical-conduct/research-ethics/nih-policies/intramural-extramural-collaborations/activities-outside-organizations and https://ethics.od.nih.gov/sites/default/files/topics/ODA/2-ODA-Chart.pdf, respectively.

Consistent with all applicable laws and guidance regarding FACs, it is the policy of NIH to:

1. Promote transparency in the recruitment of new FAC members, including, when practical and appropriate, announcing vacancies with a notification in the Federal Register.
2. Select members to serve on a scientific or technical FACs based on expertise, knowledge, and contribution to the relevant subject area.[27, 28] Additional factors that may be considered are availability of the member to serve, alignment with the relevant Federal Advisory Committee Membership Balance Plan, and the ability to work effectively on advisory committees. [29] Ensure committee membership is fairly balanced in terms of points of view represented with respect to the functions to be performed by the FAC.[30, 31]
3. Comply with current standards governing conflict of interest as defined in statutes and implementing regulations.[32, 33]
4. Except when prohibited by law and to the extent practical, agencies should appoint members of scientific and technical FACs as Special Government Employees.

[27] This provision is further outlined in How Scientists Are Selected to Be Members of a Chartered Review Group. Available at: https://public.csr.nih.gov/ForReviewers/BecomeAReviewer/CharteredReviewers.
[28] This provision refers to not only FACA Councils that have SGE members but also peer review FACA committees that have NIH peer review consultants as members.
[29]This provision is further outlined in the NIH Selection Criteria for NIH Advisory Committees. Available at: https://ofacp.nih.gov/sites/default/files/SelectionCriteria.pdf.
[30] 2010 Memorandum from the White House Office of Science and Technology Policy on Scientific Integrity. Available at: https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf.
[31] General Services Administration 41 CFR Parts 101-6 and 02-3 Federal Advisory Committee Management; Final Rule. Available at: https://www.gsa.gov/system/files/FACAFinalRule_R2E-cNZ_0Z5RDZ-i34K-pR.pdf.
[32] This provision is further outlined in the NIH Policy Manual Chapter 1810 on Procedures for Avoiding Conflict of Interest for Special and other Federal Employees Serving as Advisory Committee Members. Available at: https://policymanual.nih.gov/1810-1.
[33] The NIH Office of Federal Advisory Committee Policy maintains the Special Government Employee (SGE) Portal for those interested in serving on an NIH Federal advisory committee as an SGE. The Portal contains all the requirements expected of advisory committee members who serve on advisory committees as SGEs, including ethics training, Foreign Activities and Lobbyist Certification, and the Confidential Financial Disclosure Report (OGE 450) at: https://sgeportal.od.nih.gov/Pages/default.aspx.

5. Treat all reports, recommendations, and products produced by FACs solely as the reports, recommendations, and products of such committees rather than of the U.S. Government, and thus not subject to intra- or inter-agency revision. The role of the FACs is to provide advice or recommendations to the agency. The agency may then craft policy based on the FACs' advice or recommendations if it chooses to adopt those recommendations.

Addressing Scientific Integrity Concerns

The NIH SIO has primary responsibility for assessing scientific integrity concerns and will develop procedures for addressing allegations of loss of scientific integrity and concerns that span or fall outside existing NIH adjudication mechanisms under the purview of OER, OIR, OMA, or OIG.[34] In particular, the NIH SIO will manage scientific integrity concerns related to political interference, if they do not fall within existing processes. Procedures for handling scientific integrity concerns will be made available on the NIH website. For information about rights and remedies against retaliation, employees may contact the HHS OIG Whistleblower Protection Coordinator.[35] As noted above, existing procedures under the purview of OER, OIR,

[34] OER reviews and refers allegations of research misconduct involving extramural researchers and peer review of grant applications to the HHS Office of Research Integrity (ORI) and may take corrective action against a grantee or peer reviewer based on the conduct identified in ORI findings. OIR reviews allegations related to research integrity involving NIH IRP researchers. The NIH Division of Program Integrity within OMA manages the review of allegations involving misuse of NIH grant or contractor funds, grantee or contractor conflicts of interest, and other misconduct or misuses of NIH resources by NIH employees or others doing business with NIH. The HHS OIG investigates allegations of criminal fraud, waste, and abuse. Further information about these processes and offices will be provided in a manual chapter.

[35] As appropriate, employees can also contact the NIH Office of Equity, Diversity, and Inclusion for information regarding retaliation based on protected equal employment opportunity, or the Office of Special Counsel for information regarding retaliation based on whistleblowing. Further information can be found at: https://www.edi.nih.gov/resolutions/resources/faqs and https://oig.hhs.gov/fraud/whistleblower/. Additionally, although encouraged to use the process detailed herein, employees may also disclose wrongdoing to their supervisor or another individual higher up in management, the HHS OIG, the Office of Special Counsel, or to Congress.

OMA, and OIG should continue to be followed. When those existing mechanisms do not cover a scientific integrity concern:

1. Concerns about a potential loss of scientific integrity at NIH may be reported to the NIH SIO by any individual who has knowledge of the situation.
2. NIH employees are encouraged to seek an informal consultation with the NIH SIO or other relevant agency integrity officials to discuss whether a concern constitutes a potential loss of scientific integrity before submitting a formal complaint. Employees ultimately have the discretion to submit a formal complaint as they see fit.
3. The SIO will oversee an initial assessment of each reported concern and determine whether to request additional information from the complainant or others and to determine whether a formal investigation is warranted. Additionally, if any reported concern falls within the purview of existing OER, OIR, OMA, or OIG processes, those mechanisms will instead be utilized.
4. Should an investigation be opened, an investigation committee consisting of the NIH SIO and other agency integrity officials from the NIH Scientific Integrity Council will be convened to develop a factual record by exploring the allegation(s) in detail and consulting with subject matter experts, interviewing witnesses, and reviewing documentation as needed.
5. Once the investigation is complete, the NIH SIO will determine whether scientific integrity was lost and report findings to the appropriate management entity.
6. The complainant and respondent will be given the opportunity to appeal a finding or any corrective scientific actions taken.

Handling Differing Scientific Opinions

Science and decisions based on science are strengthened by vigorous discussion and debate and by considering all available evidence. The process of challenging and improving ideas helps to guard against inadequate science and flawed analysis. NIH encourages its scientists to respectfully express and engage with differing views as an integral part of the scientific process.[36] In some cases, such as when a scientific dispute has a significant impact on public health or policy, a formal scientific dispute resolution process may be necessary. The goal of scientific dispute resolution should be to ensure that all perspectives are heard and documented in an unbiased way. A satisfactory resolution may involve adopting one opinion over another, deciding to conduct additional studies, formulating an alternate theory reconciling the differing opinions, or documenting the disagreement for the benefit of policymakers and fellow scientists. These steps may be completed in any order and are not necessarily an exhaustive list of dispute resolution measures among NIH scientists. In general:

- A team member or group of team members with a differing opinion may engage with their colleagues to resolve the issue as soon as the difference of opinion is known. NIH recommends this type of internal discussion as a first step in most dispute resolution proceedings.
- A team may choose to consult a manager. First-level managers may defer to an appropriate higher-level manager if the first-level manager has a conflict of interest or cannot offer an impartial opinion for any reason.

[36] Further information on the NIH IRP Authorship Conflict Resolution Process can be found in the NIH Sourcebook. Available at: https://oir.nih.gov/sourcebook/ethical-conduct/authorship-guidelines-resources/nih-irp-authorship-conflict-resolution-process.

- If the matter cannot be satisfactorily resolved by other means, a team may request assistance from OIR. The NIH SIO may be consulted if their assistance is requested or if there is a conflict of interest or perceived conflict of interest with relevant OIR staff.

Monitoring, Evaluating, and Reporting Scientific Integrity Activities and Outcomes

NIH, working through HHS, will develop and implement an evaluation plan to regularly measure, monitor, and evaluate ongoing scientific integrity activities and outcomes. The plan will include a roadmap of activities, evaluation metrics, and methods of measurement for the purpose of ongoing improvement of scientific integrity processes, procedures, and policies. As part of the monitoring and evaluation plan, an annual report on the number and outcomes of investigations involving allegations of loss of scientific integrity will be published. To the extent possible, all descriptions of investigations will be anonymized.

Related Policies and Statutes

Violations of related and supporting policies may result in a loss of scientific integrity and it is appropriate for the SIO to coordinate across the agency in these matters. The following policies and programs intersect with the development of the culture of scientific integrity within the agency.

Research Misconduct

- Federal Research Misconduct Policy: https://www.federalregister.gov/documents/2000/12/06/00-30852/executive-office-of-the-president-federal-policy-on-research-misconduct-preamble-for-research

- Public Health Service Policies on Research Misconduct: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-H/part-93
- NIH Policy Manual Chapter 3006 – NIH Intramural Research Program (IRP) Research Misconduct Proceedings: https://policymanual.nih.gov/3006
- NIH IRP Policies and Procedures for Research Misconduct Proceedings: https://oir.nih.gov/system/files/media/file/2021-08/policy-nih_irp_research_misconduct_proceedings.pdf

Diversity, Equity, Inclusion, and Accessibility in Addressing and Strengthening Scientific Integrity and the Disproportional Impact of Scientific Integrity Policy Violations on Underrepresented Groups

- HHS Equal Employment Opportunity and Anti-Harassment Policy: https://www.hhs.gov/about/agencies/asa/eeo/policy/index.html
- Government-Wide Strategic Plan to Advance Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce: https://www.whitehouse.gov/wp-content/uploads/2021/11/Strategic-Plan-to-Advance-Diversity-Equity-Inclusion-and-Accessibility-in-the-Federal-Workforce-11.23.21.pdf
- HHS Diversity, Equity, Inclusion, and Accessibility Strategic Plan 2022: https://www.hhs.gov/sites/default/files/2022-hhs-deia-strategic-plan.pdf
- NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility Fiscal Years 2023-2027: https://www.nih.gov/sites/default/files/about-nih/nih-wide-strategic-plan-deia-fy23-27.pdf

Public Access

- NIH Public Access Policy: https://publicaccess.nih.gov/policy.htm

- OSTP Memorandum on Increasing Access to the Results of Federally Funded Research (2013): https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf
- OSTP Memorandum on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research (2022): https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf
- 5 USC Part 552 --- Freedom of Information Act: https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-5

Human and Animal Subject Protections

- Federal Policy for Protection of Human Research Subjects (the Common Rule): https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html
- Animal Welfare Act and Regulations: https://www.aphis.usda.gov/animal_welfare/downloads/AC_BlueBook_AWA_508_comp_version.pdf
- Public Health Service Policy on Humane Care and Use of Laboratory Animals: https://olaw.nih.gov/policies-laws/phs-policy.htm
- Guide for the Care and Use of Laboratory Animals: https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf
- U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training: https://olaw.nih.gov/policies-laws/gov-principles.htm
- NIH Policy Manual Chapter 3014 – NIH Intramural Human Research Protection Program: https://policymanual.nih.gov/3014

- NIH Policy Manual Chapter 3040-2 – Animal Care and Use in the Intramural Research Program: https://policymanual.nih.gov/3040-2

Research Security

- National Security Presidential Memorandum 33 (NSPM 33): https://trumpwhitehouse.archives.gov/presidential-actions/presidential-memorandum-united-states-government-supported-research-development-national-security-policy/
- Guidance for Implementing NSPM 33: https://www.whitehouse.gov/wp-content/uploads/2022/01/010422-NSPM-33-Implementation-Guidance.pdf

Whistleblower Protections

- 5 USC Part 2302 --- Prohibited personnel practices: https://uscode.house.gov/view.xhtml?req=29&f=treesort&num=125
- Pub. L. 101-12 --- Whistleblower Protection Act of 1989: https://www.govinfo.gov/content/pkg/STATUTE-103/pdf/STATUTE-103-Pg16.pdf
- Pub. L. 103-424 --- Expansion of Whistleblower Protection Act of 1989: https://www.govinfo.gov/content/pkg/STATUTE-108/pdf/STATUTE-108-Pg4361.pdf#page=3
- Pub. L. 112-199 --- Whistleblower Protection Enhancement Act of 2012: https://www.congress.gov/112/statute/STATUTE-126/STATUTE-126-Pg1465.pdf
- 41 USC Part 4712 --- Enhancement of contractor protection from reprisal for disclosure of certain information: https://uscode.house.gov/view.xhtml?req=(title:41%20section:4712%20edition:prelim)
- Presidential Policy Directive 19 --- Protecting Whistleblowers with Access to Classified Information: https://www.usda.gov/sites/default/files/documents/ppd.pdf

- U.S. Office of Special Counsel: https://osc.gov/
- 10 USC Part 1034, made applicable to the Public Health Service Commissioned Corps through section 1129 of the Food and Drug Administration Safety and Innovation Act, Pub. L 112-144, and implemented by Commissioned Corps Directive (CCD) 121.06: https://dcp.psc.gov/ccmis/ccis/documents/CCD121_06.pdf

Other Related Policies

- NIH Data Management and Sharing Policy: https://sharing.nih.gov/data-management-and-sharing-policy
- Pub. L. 115-435 --- Foundations for Evidence-Based Policymaking Act ("Evidence Act"): https://www.congress.gov/115/plaws/publ435/PLAW-115publ435.pdf
- Pub. L. 107-174 --- Notification and Federal Employee Antidiscrimination and Retaliation Act ("No FEAR Act"): https://uscode.house.gov/statutes/pl/107/174.pdf
- U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern: https://www.phe.gov/s3/dualuse/documents/durc-policy.pdf
- U.S. Government Policy for Oversight of Life Sciences Dual Use Research of Concern: https://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf
- Pub. L. 92-463 --- The Federal Advisory Committee Act: https://uscode.house.gov/statutes/pl/92/463.pdf
- Pub. L. 104-13 --- Paperwork Reduction Act: https://www.congress.gov/104/plaws/publ13/PLAW-104publ13.pdf

Authorities

Pursuant to the 2021 Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/, and consistent with the 2009 Presidential Memorandum on Scientific Integrity at https://obamawhitehouse.archives.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09 and the 2010 Memorandum from the White House Office of Science and Technology Policy on Scientific Integrity at https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf, all Federal agencies must establish a scientific integrity policy. The requirements of this policy are derived from the 2022 National Science and Technology Council (NSTC) Report of the Scientific Integrity Fast Track Action Committee, Protecting the Integrity of Government Science at https://www.whitehouse.gov/wp-content/uploads/2022/01/01-22-Protecting_the_Integrity_of_Government_Science.pdf, and align with the principles set forth in the NSTC guidance document A Framework for Federal Scientific Integrity Policy and Practice at https://www.whitehouse.gov/wp-content/uploads/2023/01/01-2023-Framework-for-Federal-Scientific-Integrity-Policy-and-Practice.pdf.

This policy is established in accordance with:

1. Pub. L. 111-358 --- The America COMPETES Reauthorization Act of 2010, Section 103, as amended
2. Pub. L. 115-435 --- The Foundations for Evidence-based Policymaking Act of 2018
3. Pub. L. 106-554 --- The Information Quality Act of 2000

4. 67 FR 8451 --- OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies
5. 70 FR 2664 --- OMB Final Information Quality Bulletin for Peer Review
6. 65 FR 76260-76264 --- Federal Policy on Research Misconduct
7. Pub. L. 101-12 --- The Whistleblower Protection Act (WPA) of 1989, as amended
8. 41 USC Part 4712 --- The National Defense Authorization Act, Enhancement of contractor protection from reprisal for disclosure of certain information
9. 5 USC Part 13103 *et seq.* --- The Ethics in Government Act of 1978, as amended, and 5 CFR Parts 2634 and 2635, Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture and Standards of Ethical Conduct for Employees of the Executive Branch.
10. 18 USC Parts 201-209 --- Statutes regarding Bribery, Graft and Conflicts of Interest
11. 5 CFR Parts 5501 and 5502 --- Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services
12. 5 USC Ch. 10 --- The Federal Advisory Committee Act of 1972
13. 45 CFR Part 73, Standards of Conduct
14. 5 CFR Part 735, Employee Responsibilities and Conduct
15. HHS Protection of Human Subjects Regulation (45 CFR Part 46).
16. PPD 19 --- Protecting Whistleblowers with Access to Classified Information, 2012
17. M-20-12 --- OMB Phase 4 Implementation of the Foundations for Evidence-Based Policymaking Act of 2018: Program Evaluation Standards and Practices
18. 42 CFR Part 93 --- Public Health Service Policies on Research Misconduct

19. 10 USC 1034, made applicable to the Public Health Service Commissioned Corps through section 1129 of the Food and Drug Administration Safety and Innovation Act, Pub. L 112-144, and implemented by Commissioned Corps Directive (CCD) 121.06
20. Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, Pub. L. 117-328, Division FF, Title II, Section 2321 (Jan 3, 2023).
21. Chips and Science Act, Pub. L. 117-167, Title VI, Subtitle D, Section 10631 (Aug 9, 2022).

Submit date: 10/17/2023

I am responding to this RFI: On behalf of myself

Name: Jean

Name of Organization: Public

Type of Organization: Other

Role: Member of the public

Comment:

Uploaded File:

SI-Jean-Public-508.pdf

[Federal Register Volume 88, Number 184 (Monday, September 25, 2023)]
[Notices]
[Pages 65696-65707]
From the Federal Register Online via the Government Publishing Office
[www.gpo.gov]
[FR Doc No: 2023-20733]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information on the DRAFT Scientific Integrity Policy of the National Institutes of Health

AGENCY: National Institutes of Health, HHS.

ACTION: Request for information.

SUMMARY: The National Institutes of Health (NIH) is soliciting comments and suggestions from the public on the DRAFT ``Scientific Integrity Policy of the National Institutes of Health'' (DRAFT NIH Scientific Integrity Policy). The DRAFT NIH Scientific Integrity Policy codifies NIH's long-standing expectations to preserve scientific integrity throughout all NIH activities, establishes key roles and responsibilities for those who will lead the agency's scientific integrity program, and, as appropriate, establishes relevant reporting and evaluation mechanisms.

DATES: The DRAFT ``Scientific Integrity Policy of the National Institutes of Health'' is open for public comment for a period of 45 days. To ensure consideration, comments must be submitted in writing by November 9, 2023.

ADDRESSES: Comments may be submitted electronically at https://osp.od.nih.gov/comment-form-draft-scientific-integrity-policy-for-the-national-institutes-of-health/.

[[Page 65697]]

Comments 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.

FOR FURTHER INFORMATION CONTACT: Tyrone Spady, Ph.D., Director of the Science Policy Coordination, Collaboration & Reporting Division, Office

of Science Policy, at (301) 496-9838 or SciencePolicy@od.nih.gov.

SUPPLEMENTARY INFORMATION:

Background

Scientific integrity aims to make sure that science is conducted, managed, communicated, and used in ways that preserve its accuracy and objectivity and protect it from suppression, manipulation, and inappropriate influence (https://www.whitehouse.gov/wp-content/uploads/2022/01/01-22-Protecting_the_Integrity_of_Government_Science.pdf). In its mission to seek fundamental knowledge about the nature and behavior of living systems and apply that knowledge to enhance health, lengthen life, and reduce illness and disability, NIH has always sought to incorporate robust scientific integrity principles and practices throughout every level of its scientific enterprise. In fostering scientific integrity, NIH aims to ensure that (1) scientific findings are objective, credible, and readily available to the public, and (2) the development and implementation of policies and programs is transparent, accountable, and evidence-based. NIH has numerous policies and procedures to ensure the Nation's investment in biomedical research is scientifically robust and rigorous and that our workforce maintains the highest standards of integrity. In supporting the NIH mission, all NIH researchers and staff are expected to:

Foster an organizational culture of scientific integrity,
Protect the integrity of the research process,
Communicate science with integrity, and
Safeguard scientific integrity.

In 2012, NIH summarized the key components of its commitment to fostering scientific integrity in its NIH Policies and Procedures for Promoting Scientific Integrity Report (www.nih.gov/sites/default/files/about-nih/nih-director/testimonies/nih-policies-procedures-promoting-scientific-integrity-2012.pdf), which outlines NIH's role in fostering scientific integrity as a funder of research, a research institution, and a policy development agency. In 2021, the White House released its Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking (www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/). The Memorandum tasks NIH and other agencies to update their scientific integrity policies as appropriate to ensure agency alignment with the principles set forth therein and in Protecting the Integrity of Government Science (www.whitehouse.gov/wp-content/uploads/2022/01/01-22-Protecting_the_Integrity_of_Government_Science.pdf), a report of the Scientific Integrity Fast-Track Action Committee of the National Science and Technology Council (NSTC), and A Framework for Federal Scientific Integrity Policy and Practice (https://www.whitehouse.gov/wp-content/uploads/2023/01/01-2023-Framework-for-Federal-Scientific-Integrity-Policy-and-Practice.pdf), a guidance document released by the Scientific Integrity Framework Interagency Working Group of the NSTC. In response to the Memorandum, and in accordance with its continued commitment to promoting scientific integrity, NIH has developed the DRAFT Scientific Integrity Policy, which is in alignment with the guidance set forth in the Presidential Memorandum and the draft Scientific Integrity Policy of the U.S. Department of Health and Human

Services (www.hhs.gov/sites/default/files/draft-hhs-scientific-integrity-policy.pdf). The DRAFT NIH Scientific Integrity Policy articulates the procedures and processes in place at NIH that help maintain rigorous scientific integrity practices and proposes several new functions to further enhance scientific integrity at NIH and throughout the NIH biomedical research enterprise.

NIH accomplishes its mission by funding extramural researchers throughout the country, conducting research within its intramural research program, and developing policies and programs to responsibly advance biomedical research. In 2022, NIH updated its NIH Policies and Procedures for Promoting Scientific Integrity (2022) report at https://osp.od.nih.gov/wp-content/uploads/2023/09/SI_Compendium-2022Update.pdf, which describes the robust processes in place to support scientific integrity for NIH-supported extramural research, intramural research, and policies and programs. Building upon this existing infrastructure for scientific integrity, the DRAFT NIH Scientific Integrity Policy proposes several new functions to further enhance existing practices and processes. For example, the DRAFT NIH Scientific Integrity Policy includes a Federal definition of scientific integrity that is shared across the U.S. Government. This alignment across the U.S. Government will ensure consistency in guidance and language, lending clarity and uniformity to interagency efforts concerning scientific integrity. The DRAFT NIH Scientific Integrity Policy also establishes the appointments of, and roles and responsibilities for, the positions of NIH Chief Scientist (CS) and Scientific Integrity Official (SIO). The CS and SIO will have prominent and critical responsibilities in steering NIH's scientific integrity efforts, advising NIH leadership on scientific issues, and playing key roles in NIH's adjudication efforts related to scientific integrity. The DRAFT NIH Scientific Integrity policy also includes NIH practices that will address important emerging topics in biomedical research, such as protecting against political interference.

NIH looks forward to working across the U.S. Government to support our shared commitment to responsible stewardship of the Nation's investment in biomedical research by maintaining and bolstering rigorous scientific integrity practices in taxpayer-funded biomedical research.

Request for Information

NIH seeks information regarding the DRAFT NIH Scientific Integrity Policy from all interested individuals and communities, including, but not limited to, investigators, research institutions, libraries, scientific societies, healthcare providers, patients, students, educators, research participants, and other members of the public. While comments are welcome on all elements of the DRAFT NIH Scientific Integrity Policy, input would be most welcome on the specific items identified below, as they represent additions to existing NIH scientific integrity practices:

1. Role and Responsibilities of the NIH SIO

[[Page 65698]]

2. Role and Responsibilities of the NIH CS
3. Responsibilities of the NIH Scientific Integrity Council
4. Prohibitions against Political Interference

Draft Scientific Integrity Policy of the National Institutes of Health

Purpose

The purpose of this policy is to promote a continuing culture of scientific integrity at the National Institutes of Health (NIH). This policy aims to ensure the integrity of all aspects of NIH scientific activities, including proposing, conducting, reviewing, managing, and communicating about science and scientific activities, and using the results of science to inform policy and program decision-making.

Scientific Integrity at NIH

The mission of NIH is to seek fundamental knowledge about the nature and behavior of living systems and apply that knowledge to enhance health, lengthen life, and reduce illness and disability. NIH accomplishes this mission by funding extramural researchers throughout the country, conducting research within its intramural research program, and developing policies and programs to responsibly advance biomedical research. Embedding principles of scientific integrity throughout the NIH enterprise relies on two key elements. The first element is an all-hands-on-deck approach in which scientific rigor and research quality are prioritized. The second element is having inclusive, robust processes that safeguard scientific integrity.

In fostering scientific integrity, NIH aims to ensure that (1) scientific findings are objective, credible, and readily available to the public, and (2) the development and implementation of policies and programs is transparent, accountable, and evidence-based. NIH has numerous policies and procedures to ensure the Nation's investment in biomedical research is scientifically robust and rigorous and that our workforce maintains the highest standards of integrity.

Public input and accountability are woven throughout NIH processes to assure the public of the credibility of our science and our scientific findings. These activities range from presenting potential scientific solicitations at public meetings (e.g., concept clearance) to soliciting community feedback during policymaking activities. In supporting the NIH mission, all NIH researchers and staff are expected to:

- Foster an organizational culture of scientific integrity,
- Protect the integrity of the research process,
- Communicate science with integrity, and
- Safeguard scientific integrity.

NIH's long-standing commitment to fostering scientific integrity was summarized in its 2012 report NIH Policies and Procedures for Promoting Scientific Integrity at https://www.nih.gov/sites/default/files/about-nih/nih-director/testimonies/nih-policies-procedures-promoting-scientific-integrity-2012.pdf. This document was updated in 2022 at https://osp.od.nih.gov/wp-content/uploads/2023/09/SI Compendium-2022Update.pdf, partly in response to the 2021 Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/ to reflect more than a decade of updates to agency policies and procedures that support scientific integrity. The NIH Scientific Integrity Policy articulates

expectations to preserve scientific integrity throughout all NIH activities, establishes key roles and responsibilities for those who will lead the agency's scientific integrity program, and, as appropriate, establishes relevant reporting and evaluation mechanisms with a goal of ensuring scientific integrity is foundational to all NIH activities. The NIH Scientific Integrity Policy is consistent with the U.S. Department of Health and Human Services (HHS) Scientific Integrity Policy. The majority of procedures regarding scientific integrity described herein are longstanding and foundational to NIH-supported research. This Scientific Integrity Policy integrates existing and new practices under a single harmonized framework.

Effective Date and Policy Amendments

This policy goes into effect 12 months after publication of the final policy in the Federal Register. This policy will be evaluated by NIH one year after its effective date and regularly thereafter. Proposals to amend this policy will be overseen by the NIH Scientific Integrity Officer (SIO), in collaboration with the NIH Scientific Integrity Council (Council) described below, and any such amendments will be communicated to HHS and the Director of the White House Office of Science and Technology Policy (OSTP) no later than 30 days after adoption.

Applicability and Scope

All NIH employees; Public Health Service Commissioned Corps members; political appointees; clinical, research, and postdoctoral fellows; doctoral trainees; interns; and advisory committee members in their capacity as special Government employees, and those managing scientific activities and using scientific information in policymaking, are expected to adhere to NIH's policies when in the course of their official duties they propose, conduct, review, or communicate about science and scientific activities on behalf of NIH. When relevant, NIH has also implemented separate policies for contractors, collaborators, awardees, and volunteers to uphold the principles of scientific integrity established by this policy.

Exceptions

This policy will be implemented consistent with applicable Federal law.

Definitions

Allegation refers to a disclosure of a suspected loss of scientific integrity.

Chief Scientist (CS) provides oversight of all NIH scientific integrity policies and procedures. NIH recognizes organizational culture starts with leadership at the highest levels. It has designated the NIH Principal Deputy Director as the NIH CS.

Corrective scientific action refers to actions taken to restore the accuracy of the scientific record after a loss of scientific integrity has been determined, consistent with this policy, such as correction or retraction of published materials. In addition to scientific actions, administrative actions may also be taken in response to substantiated violations of this policy.

Covered individuals include all NIH employees; Public Health Service Commissioned Corps members; political appointees; clinical, research, and postdoctoral fellows; doctoral trainees; interns; and advisory committee members in their capacity as special Government employees, when in the course of their official duties they propose, conduct, review, or communicate about science and scientific activities; and all levels of employees who manage or supervise scientific activities and use scientific information in policymaking. NIH contractors, partners, permittees, lessees, grantees, and volunteers who engage or assist in NIH scientific activities are not considered covered individuals but are expected to uphold

the principles of scientific integrity described in this policy, as incorporated into the terms of their engagement with NIH.

Ethical behavior refers to activities that reflect norms for conduct that distinguish between acceptable and unacceptable behavior, such as honesty, lawfulness, equity, and professionalism, and to adherence to statutes, regulations, policies, and guidelines governing employee conduct.

Federal agency refers to an Executive department, a U.S. Government corporation, and an independent establishment.

Inclusivity refers to the practice of providing equal access to opportunities for full participation of all people and all groups, including marginalized, underserved, and underrepresented contributors, without bias or prejudice. Full participation is enabled through implementation of strategies that promote equitable access and fair treatment in the organization.

Inappropriate influence refers to the attempt to shape or interfere in scientific activities or the communication about or use of scientific activities, against well-accepted scientific methods and theories and without scientific, legal, programmatic management, or security justification.[1] [2]

\1\ Examples may include (1) suppressing a decisionmaker's ability to offer the best judgment based on scientific information; (2) suppressing, altering or delaying the release of a scientific product for any reason other than technical merit or providing advance notification; (3) removing or reassigning scientific personnel for any reason other than performance, conduct or budgetary constraints; (4) using scientific products that are not representative of the current state of scientific knowledge and research (for example because of a lack of appropriate peer review, poor methodology, or flawed analyses) to inform decision making and policy formulation; or (5) misrepresenting the underlying assumptions, uncertainties, or probabilities of scientific products. This is not intended to be an exhaustive list.

\2\ Differences of scientific opinion are not necessarily inappropriate influence. Additionally, NIH officials are regularly expected to provide agency perspectives when acting in their official capacity.

Interference refers to inappropriate, scientifically unjustified intervention in the conduct, management, communication, or use of

science. It includes censorship, suppression, or distortion of scientific or technological findings, data, information, or conclusions; inhibiting scientific independence during clearance and review; scientifically unjustified intervention in research and data collection; and inappropriate engagement or participation in peer review processes or on Federal advisory committees (FACs).

Loss of scientific integrity refers to the failure to comply with this Scientific Integrity Policy or to adhere to objectivity, transparency, and ethical behavior when conducting, managing, using the results of, and communicating about science and scientific activities. This loss may include research misconduct or inappropriate influence in the conduct, communication, management, and use of science.\3\

\3\ A report by the Scientific Integrity Fast-Track Action Committee of the National Science and Technology Council. ``Protecting the Integrity of Government Science.'' January 11, 2022. Available at: https://www.whitehouse.gov/wp-content/uploads/2022/01/01-22-Protecting the Integrity of Government Science.pdf.

Policy refers to laws, regulations, procedures, administrative actions, incentives, or voluntary practices of Governments and other institutions.

Policymaking refers to the (1) development of policies or making determinations about policy or management; (2) making determinations about expenditures of Federal agency funds; (3) implementing or managing activities that involve, or rely on, scientific activities.

Political interference is inappropriately shaping or interfering in the conduct, management, communication, or use of science for inappropriate partisan advantage or such that it undermines impartiality, nonpartisanship, or professional judgement.

Research integrity refers to the use of honest and verifiable methods in proposing, performing, and evaluating research; reporting research results with particular attention to adherence to rules, regulations, and guidelines; and following commonly accepted professional codes or norms.

Research misconduct refers to fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.\4\

\4\ Federal Research Misconduct Policy, 65 FR 76260, 76262 (Dec. 6, 2000) and https://www.ecfr.gov/current/title-42/chapter-I/subchapter-H/part-93/subpart-A/section-93.103.

Research security refers to safeguarding the research enterprise against the misappropriation of research and development to the detriment of national or economic security, related violations of research integrity, and foreign Government interference.

Science refers to the full spectrum of scientific endeavors, including basic science, applied science, evaluation, engineering, technology, economics, social sciences, and statistics, as well as the scientific and technical information derived from these endeavors.

Scientific activities refer to activities that involve the application of well-accepted scientific methods and theories in a

systematic manner, and includes, but is not limited to, data collection, inventorying, monitoring, evaluation, statistical analysis, surveying, observations, experimentation, study, research, integration, economic analysis, forecasting, predictive analytics, modeling, technology development, and scientific assessment, as well as any findings derived from these activities.

Scientific data refers to recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data does not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens.\5\

\5\ NIH Data Management and Sharing Policy at: https://sharing.nih.gov/data-management-and-sharing-policy.

Scientific integrity is the adherence to professional practices, ethical behavior, and the principles of honesty and objectivity when conducting, managing, using the results of, and communicating about science and scientific activities. Inclusivity, transparency, and protection from inappropriate influence are hallmarks of scientific integrity. (Note: this is the Official Federal Definition of Scientific Integrity, consistent with OSTP and HHS definitions.\6\)

\6\ A Framework for Federal Scientific Integrity Policy and Practice. Available at: https://www.whitehouse.gov/wp-content/uploads/2023/01/01-2023-Framework-for-Federal-Scientific-Integrity-Policy-and-Practice.pdf.

Scientific Integrity Council will assist the NIH SIO in iterative review, policy development, and priority setting to ensure that the existing policies and procedures are responsive to issues that arise in the scientific integrity space.

Scientific Integrity Official (SIO) is the primary official for responsibilities over scientific integrity matters and reports to the NIH CS. This policy empowers the NIH SIO with the independence necessary to gather and protect information to support the review and assessment of scientific integrity concerns. The NIH SIO will also advocate for appropriate engagement of scientific leadership in policymaking. NIH recognizes organizational culture starts with leadership at the highest levels. NIH has designated the Associate

Director of Science Policy as the NIH SIO.

Scientific record refers to published information resulting from scientific activities. NIH is responsible for ensuring the accuracy of elements of the scientific record that are published by NIH.

Scientist refers to an individual whose responsibilities include collection, generation, use, or evaluation of scientific and technical data, analyses, or products. NIH scientists are NIH employees and other

covered individuals who conduct these activities. It does not refer to individuals with scientific and technical training whose primary job functions are in non-scientific roles (e.g., policymakers, communicators).

Roles and Responsibilities

Chief Scientist and Scientific Integrity Official

The CS shall:

1. Provide oversight of all NIH scientific integrity policies and procedures, including the periodic updates of those policies and procedures;
2. Engage agency efforts regarding diversity, equity, inclusion, and accessibility;
3. Provide for the resourcing and staffing needs of the NIH scientific integrity program;
4. Promote scientific integrity across the agency; and
5. Serve as an alternate in scientific integrity adjudication processes if the NIH SIO is alleged to have violated NIH or HHS Scientific Integrity Policies.

The SIO shall:

1. Report to the CS on all matters related to scientific integrity;
2. Periodically update the NIH Scientific Integrity Policy;
3. Provide regular reporting on NIH scientific integrity allegations and outcomes to OSTP and the public;
4. Determine the resourcing and staffing needs of the NIH scientific integrity program;
5. Promote scientific integrity across the agency;
6. Lead the NIH Scientific Integrity Council, participate on the HHS Council, and other interagency efforts regarding scientific integrity;
7. Serve as a focal point for the receipt of agency scientific integrity allegations (particularly related to political interference) that fall outside of existing processes managed by the Office of Extramural Research (OER), the Office of Intramural Research (OIR), the Office of Management Analysis (OMA), and the HHS Office of the Inspector General (OIG);
8. Lead the review and adjudication of allegations of loss of NIH scientific integrity (particularly related to political interference) in cases where such allegations fall outside of existing processes managed by OER, OIR, OMA, and OIG; and
9. Promote agency efforts regarding diversity, equity, inclusion, and accessibility.

NIH Scientific Integrity Council

The NIH SIO shall establish an NIH Council comprising career employees from across the NIH and from relevant NIH offices. This committee will assist the SIO in iterative review, policy development, and priority setting to ensure that the existing policies and procedures are responsive to issues that arise in the scientific integrity space.

The primary responsibilities of the Council are to:

1. Ensure that a well-informed and high-level group of experts supports scientific integrity at NIH;
2. Ensure that the NIH Scientific Integrity Policy is implemented

consistently across NIH;

3. Review, assess, and revise the NIH Scientific Integrity Policy as needed;

4. Engage NIH leadership in upholding the principles of scientific integrity, and maintaining leadership awareness of scientific integrity issues as necessary and appropriate;

5. As requested, assist the SIO in adjudicating allegations of losses of NIH scientific integrity (particularly related to political interference) in cases where such allegations fall outside of existing processes managed by OER, OIR, OMA, and OIG; and

6. Determine handling of investigation and adjudication proceedings from which the HHS SIO is recused.

Background on NIH Functions

Intramural Research

The Intramural Research Program (IRP) is the internal research program of NIH, known for its synergistic approach to biomedical science. The IRP is the largest biomedical research program on earth, and its unique environment means the IRP can facilitate opportunities to conduct both long-term and high-impact science that would otherwise be difficult to undertake. The NIH IRP conducts research and training within its laboratories and clinics, and when appropriate, collaborates with the private sector to develop technologies of importance to public health. To help ensure the high quality and integrity of its intramural programs, NIH has developed and implemented NIH-wide policies and review standards for research, training, and technology transfer. The NIH Policy Manual at https://policymanual.nih.gov/is an official mechanism of issuing NIH-wide policy and all Manual Chapter issuances. More information about the NIH IRP can be found on the NIH OIR website at https://oir.nih.gov/.

Extramural Research

Approximately 80 percent of NIH's investment in biomedical and behavioral research supports extramural researchers at institutions in every state in the country. Given the size and breadth of this investment, NIH has a robust infrastructure to ensure scientific integrity is embedded throughout the extramural research continuum and its workforce. While the covered individuals for this policy consist primarily of NIH employees, the principles of scientific integrity are foundational to NIH's role in funding extramural biomedical research, and the importance of scientific integrity is integrated throughout all NIH does as a funder of biomedical research. As such, existing policies to maintain scientific integrity of extramural research will continue. More information about the NIH extramural research program can be found on the NIH OER website at https://grants.nih.gov/aboutoer/intro2oer.htm.

NIH as a Policy Development Agency

NIH promotes progress in the biomedical research enterprise through the development of sound and comprehensive policies. To achieve this, NIH engages partners within and outside of NIH to develop policies on a wide range of issues including biosafety, biosecurity, genetic testing, genomic data sharing, human subjects protections, the organization and management of the NIH, and the outputs and value of NIH-funded

research. This is accomplished through a wide range of analyses and reports, commentary on emerging policy proposals, and the development of policy proposals for consideration by NIH, the Federal Government, and the public. More information about NIH policy development can be found on the NIH Office of Science Policy (OSP) website at https://osp.od.nih.gov/.

Policy Requirements

Promoting a Culture of Scientific Integrity

NIH leadership at all levels recognizes, supports, and promotes this policy and its underlying principles, and models behavior consistent with a strong culture of scientific integrity.

[[Page 65701]]

NIH works to promote a culture of scientific integrity by creating an empowering environment for innovation and protecting scientists and the process of science from inappropriate interference. Scientific findings and products must not be suppressed, delayed, or altered for political purposes and must not be subjected to political interference or inappropriate influence.

A strong culture of scientific integrity begins with ensuring a professional environment that is safe, equitable, fair, just, impartial, honest, and inclusive. Diversity, equity, inclusion, and accessibility (DEIA) are integral components of the entire scientific process. Attention to DEIA can improve the success of the scientific workforce, foster innovation in the conduct and use of science, and provide for more equitable participation in science by diverse communities. The responsible and ethical conduct of research and other scientific activities requires an environment that is equitable, inclusive, safe, and free from harassment, discrimination, and exploitation.

NIH also works to apply scientific integrity practices in ways that are inclusive of non-traditional modes of science, such as citizen science, community-engaged research, participatory science, and crowdsourcing. This may include expanded scientific integrity practices and expectations, such as seeking greater input from communities and participants into the research questions and design, recognition of data and knowledge sovereignty, and inclusion of multiple forms of evidence, such as Indigenous Knowledge.

NIH has posted the NIH Scientific Integrity Policy prominently on its website and ensures education is available for all covered individuals, as well as contractors who perform scientific activities for the agency, on their rights and responsibilities related to scientific integrity. All NIH employees will receive scientific integrity information or training as new employees and NIH, in concert with HHS, will make available training for covered individuals and others, as applicable.

To promote a culture of scientific integrity at NIH, this policy outlines seven specific areas:

I. Protecting Scientific Processes
II. Ensuring the Free Flow of Scientific Information
III. Supporting Policymaking Processes
IV. Ensuring Accountability

V. Protecting Scientists
VI. Professional Development for Government Scientists, and
VII. Federal Advisory Committees

I. Protecting Scientific Processes

NIH has implemented a suite of efforts to protect the integrity of research processes from bias and interference, which is essential to upholding public trust and confidence. These efforts rely on transparent processes, diverse community engagement, management of real or apparent conflicts of interest, and robust and open dialogue. NIH utilizes a variety of mechanisms to achieve these aims, such as holding policy discussions in open settings, soliciting public input on future research directions, and the use of Federal advisory committees (FACs) to advise the agency. In addition, for covered individuals, NIH explicitly prohibits political interference or inappropriately shaping or interfering in the conduct, management, communication, or use of science for inappropriate partisan advantage or such that it undermines impartiality, nonpartisanship, or professional judgement. Further processes will be developed and documented to support this policy in an NIH manual chapter.

It is the policy of NIH to:

1. Prohibit political interference or other inappropriate influence in the design, proposal, conduct, management, evaluation, communication of, and use of scientific activities conducted by covered individuals.

2. Prohibit inappropriate restrictions on resources and capacity that limit and reduce the availability of science and scientific products outside of normal budgetary or priority-setting processes or without scientific, legal, or security justification.\7\

\7\ This provision is further outlined in the NIH Policy Manual Chapter 3005 on Review and Evaluation of Intramural Programs. Available at: https://policymanual.nih.gov/3005.

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3. Require that leadership and management ensure that covered individuals engaged in scientific activities can conduct their work objectively and free from political interference or other inappropriate influence.

4. Require reasonable efforts by covered individuals to ensure the fidelity of the scientific record and to correct identified inaccuracies that pertain to their contribution to any scientific records.

5. Require that covered individuals represent their contributions to scientific work fairly and accurately and neither accept nor assume unauthorized and/or unwarranted credit for another's accomplishments. To be named as an author, contributors should have made a substantial contribution or provided editorial revisions that include critical intellectual content, approved the final version, and agreed to be accountable for all aspects of the work to which they contributed. Prior consent should be obtained from each author to be represented on a particular work. Obtaining prior consent for acknowledgements is also a good practice.\8\

\8\ This provision is further outlined in the 2023 8th Edition of Guidelines and Policies for the Conduct of Research in the

Intramural Research Program at NIH. Available at: https://oir.nih.gov/system/files/media/file/2023-08/guidelines-conduct_research.pdf.

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6. Ensure independent review of scientific activities conducted by covered individuals as appropriate to ensure scientific integrity.\9\

\9\ This provision is further outlined in the NIH Policy Manual Chapter 3005 on Review and Evaluation of Intramural Programs. Available at: https://policymanual.nih.gov/3005.

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7. Require that covered individuals comply with NIH policies and procedures for planning and conducting scientific activities and show appropriate diligence toward protecting and conserving Federal research resources, such as equipment and other property, and records of data and results that are entrusted to them.

8. Prohibit research misconduct, the deliberate or reckless use of improper or inappropriate research methods or processes, and noncompliance with practices that safeguard the quality of research and other scientific activities or enhance research security for covered individuals.\10\

\10\ This provision is further outlined in the NIH Policy Manual Chapter 3006 on NIH Intramural Research Program (IRP) Research Misconduct Proceedings. Available at: https://policymanual.nih.gov/3006.

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9. Require that covered individuals design, conduct, manage, evaluate, and communicate about scientific research and other scientific activities honestly and thoroughly, and disclose any conflicts of interest to their supervisor or other appropriate NIH official(s) for their determination as to whether a recusal, disclaimer, or other action is appropriate, consistent with NIH ethics policies and procedures.\11\

\11\ This provision is further outlined in the NIH Conflict of Interest and Confidentiality Certification for Individuals Evaluating all NIH Intramural Programs. Available at: https://oir.nih.gov/system/files/media/file/2021-08/conflict_of_interest-bsc_reviews.pdf.

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10. Require that research conducted by covered individuals involving the participation of human subjects and the use of non-human animals is conducted in accordance with applicable,

[[Page 65702]]

established laws, regulations, policies, and ethical considerations.\12\

\12\ This provision is further outlined in the NIH Policy Manual Chapter 3014 on NIH Intramural Human Research Protection Program and the NIH Policy Manual Chapter 3040-2 on Animal Care and Use in the Intramural Research Program. Available at: https://policymanual.nih.gov/3014 and https://policymanual.nih.gov/3040-2 respectively.

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11. Support and enhance scientific integrity with the understanding that violations of scientific integrity can have a disproportional impact on underrepresented groups or weaken the equitable delivery of Federal Government programs.

12. Consistent with OSTP guidance and relevant HHS and NIH policy, prohibit personnel of NIH engaged in intramural research from participation in foreign talent recruitment programs, unless the participation is in an international conference or other international exchange, partnership, or program for which such participation has been approved by the appropriate authority in NIH.\13\

\13\ Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, Public Law 117-328, Division FF, title II, section 2321 (Jan 3, 2023) and Chips and Science Act, Public Law 117-167, title VI, subtitle D, section 10631 (Aug 9, 2022). OSTP guidance and relevant HHS and NIH policies to implement this legislation are forthcoming at the time of publication of this policy.

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13. Consistent with OSTP guidance and relevant HHS and NIH policy, require disclosure of participation in foreign talent recruitment programs, including the provision of copies of all grants, contracts, or other agreements related to such programs, and other supporting documentation related to such programs, as a condition of receipt of Federal extramural research funding awarded through NIH.\14\

\14\ Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, Public Law 117-328, Division FF, title II, section 2321 (Jan 3, 2023) and Chips and Science Act, Public Law 117-167, title VI, subtitle D, section 10631 (Aug 9, 2022). OSTP guidance and relevant HHS policies to implement this legislation are forthcoming at the time of publication of this policy.

II. Ensuring the Free Flow of Scientific Information

NIH is committed to the broad and equitable dissemination and promotion of rigorous and objective scientific information. The NIH Office of Communications and Public Liaison (OCPL) and communication offices within the NIH Institutes, Centers, and Offices (NIH ICOs) disseminate objective and evidence-based research findings to the public through websites, listservs, brochures, videos, social media, and other modes of communication as appropriate. NIH OCPL and the ICO communication offices also respond to public inquiries and engage with technical and non-technical audiences through media and online forums to ensure responsible communication regarding the research it funds.

At the foundation of the NIH mission is the generation of reliable, rigorous, research results, and their publication in reputable, peer-reviewed scientific journals. NIH's IRP researchers adhere to a NIH-wide Policy for Manuscript and Abstract Clearance Procedures at https://oir.nih.gov/sourcebook/submitting-research-publications/publication-abstract-clearance and follow established guidance to ensure transparency in research findings through Processes for Authorship Dispute Resolution at https://oir.nih.gov/sourcebook/ethical-conduct/authorship-guidelines-resources/nih-irp-authorship-conflict-resolution-process if the situation arises.

It is the policy of NIH to:

1. Facilitate the free flow of scientific and technological information, to the extent permissible by Federal laws and regulations. Consistent with open science expectations, NIH shall expand and promote access to scientific and technological information by making it available freely and without embargo to the public in an online digital format.[15] [16] [17] [18]

\15\ White House Office of Science and Technology Policy Memorandum for the Heads of Executive Departments and Agencies on Increasing Access to the Results of Federally Funded Scientific Research. February 22, 2013. Available at: https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf.

\16\ White House Office of Science and Technology Policy Memorandum for the Heads of Executive Departments and Agencies on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research. August 25, 2022. Available at: https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf.

\17\ This provision is further outlined in the NIH Policy Manual Chapter 1184 on Preparation and Clearance of Scientific, Technical, and Public Information Presented by NIH Employees or Produced for Distribution by NIH. Available at: https://policymanual.nih.gov/1184.

\18\ This provision is further outlined in the NIH Data Management and Sharing Policy. Available at: https://sharing.nih.gov/data-management-and-sharing-policy.

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2. Ensure that scientific findings and products created by NIH scientists are not unduly suppressed, delayed, or altered for political purposes and are not subjected to inappropriate influence.

3. Encourage, but not require, NIH scientists to participate in their official capacities in communications with the media regarding their scientific activities and areas of expertise, subject to limitations of Government ethics rules. In communicating with the media, NIH scientists are encouraged to seek advice from career NIH communications experts.

4. Allow, subject to limitations of Government ethics rules, NIH scientists to express their personal views and opinions with appropriate written or oral disclaimers, including on social media.\19\ NIH scientists may name NIH as their employer in the context of biographical information but shall refrain from making or publishing statements that could be construed as being judgments of, or recommendations on, NIH or any other Federal Government policy, including the use of NIH or other U.S. Government seals or logos, unless they have secured appropriate prior approval to do so.

\19\ This provision is further outlined in the United States Office of Government Ethics Standards of Conduct and 18 U.S.C. 208 as Applied to Official Social Media Use. Available at: https://oge.gov/web/oge.nsf/News+Releases/EAE37A7DA3C38BF38525894700775339/$FILE/LA-23-03%20The%20Standards%20of%20Conduct%20and%2018%20U.S.C.%20%C2%A7%2020 8%20as%20Applied%20to%20Official%20Social%20Media%20Use.pdf.

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5. Ensure that the work and conclusions of NIH scientists and the work and conclusions of scientists funded or supported by the Federal Government are accurately represented in NIH communications. If communication documents significantly rely on a scientist's research, identify them as an author, or represent their scientific opinion, the scientist shall be given the option to review the scientific content of proposed communication documents.

6. Ensure that NIH scientists may communicate their scientific activities objectively without political interference or other inappropriate influence. Scientific products (e.g., manuscripts for scientific journals, presentations for workshops, conferences, and symposia) shall adhere to relevant NIH technical review procedures.

7. Require that NIH officials, including communications officers, shall not alter, nor direct NIH scientists and technology experts to alter, scientific and technological research findings or presentation of research findings in a manner that may compromise the objectivity or accurate representation of those findings.

8. Require that technical review and clearance processes include provisions for timely clearance and expressly forbid censorship, unreasonable delay, and suppression of objective communication of data and results

[[Page 65703]]

without scientific, legal, or security justification.

9. Ensure that scientific information is accurately represented in responses provided by NIH to Congressional inquiries, testimony, and other requests.

10. Accurately represent the work and conclusions of NIH scientists in NIH social media communications and provide appropriate guidance to NIH scientists on the use of NIH social media.

11. Violations of clearance policies that result in suppression, delay, or alteration of scientific and technological information produced by NIH scientists without scientific, legal, or security justification constitute violations of the NIH Scientific Integrity Policy and may be reported under the procedures for Addressing Scientific Integrity Concerns.

III. Supporting Policymaking Processes

NIH utilizes multiple mechanisms for ensuring transparency and accountability in developing policy. The development of science policy at NIH generally follows procedures set forth under the Administrative Procedure Act (5 U.S.C. Subchapter II) at https://www.archives.gov/federal-register/laws/administrative-procedure, where applicable, and draft policy proposals are routinely issued through the NIH Guide and the Federal Register, as appropriate, to obtain early feedback into policy proposals. Once a proposal has been issued for public comment,

it is often supplemented with informational webinars, interactive discussion sessions, and a robust public engagement plan to promote broad dissemination and engagement in the policymaking process. NIH considers all comments submitted on draft polices and policy proposals to ensure final policy proposals are informed by the community and capable of responding to emerging opportunities and challenges. Final policies are also issued through the NIH Guide and the Federal Register, as appropriate, and incorporated into the NIH Grants Policy Statement and NIH Policy Manual, as appropriate. Policies are also posted to NIH websites with additional resources such as Frequently Asked Questions and other supplemental resources as needed.

It is the policy of NIH to:

1. Ensure the quality, accuracy, and transparency of scientific information used to support policy and decision making, including by:

a. Using scientific information that is subject to well-established scientific processes.

b. Ensuring that scientific data and research used to support policy decisions undergo review by qualified experts, where feasible and appropriate, and consistent with law.

c. Adhering to the Office of Management and Budget Final Information Quality Bulletin for Peer Review.\20\ For example, as described in the Bulletin, when independent peer reviews of scientific information products are conducted by contractors, a conflict-of-interest review shall be conducted.

\20\ Office of Management and Budget. ``Final Information Quality Bulletin for Peer Review.'' Federal Register. Doc. 05-769. Available at: https://www.federalregister.gov/documents/2005/01/14/05-769/final-information-quality-bulletin-for-peer-review.

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d. Reflecting scientific information appropriately and accurately and making scientific findings or conclusions considered or relied on in policy decisions publicly available online and in open formats, to the extent practicable.

2. Where legally permissible and appropriate, directly consult with scientists whose work is being used in policy and management decisions to ensure that the science is accurately represented and interpreted.

3. Ensure, to the extent possible, the accuracy of NIH communication of the science upon which a policy decision is based.

4. Ensure that covered individuals are free to express differing scientific opinions free from political interference or inappropriate influence.

IV. Ensuring Accountability

NIH is firmly committed to establishing and formalizing procedures to identify and adjudicate allegations regarding compromised scientific processes or technological information. NIH has established several adjudication processes with distinct offices (i.e., OER, OIR, and OMA), to address different ways in which scientific integrity may be violated. Each office handles allegations pertaining to its respective jurisdiction, but anyone may submit an oral or written allegation via email or hotline. When an allegation or complaint is received, the appropriate office determines if it is specific, credible, and meets the definition of misconduct or an integrity violation. The procedures each office takes for investigating allegations or complaints, adjudication, and appeals are further detailed in the 2022 update to

the NIH Policies and Procedures for Promoting Scientific Integrity at https://osp.od.nih.gov/wp-content/uploads/2023/09/SI Compendium-2022Update.pdf. The designation of an NIH SIO will allow for more centralized interagency communication and coordination concerning allegations to ensure effective oversight and promote scientific integrity within the Federal Government. Additionally, the NIH SIO will provide review and adjudication of allegations (particularly related to political interference) that do not fall under the purview of these existing offices.

It is the policy of NIH to:

1. Ensure correction of the scientific record and implementation of corrective scientific actions when allegations of a loss of scientific integrity are substantiated.

2. Encourage and facilitate early informal or formal consultation between NIH employees and scientific integrity officials to advise on preventing loss of scientific integrity, to determine whether a loss of scientific integrity has potentially occurred, and to ascertain whether an allegation should be referred elsewhere for resolution.

3. Provide clear guidance on how to formally and confidentially report concerns and allegations of loss of scientific integrity. Those who report concerns and allegations need not be directly involved or witness a violation.

4. Ensure that the NIH SIO or other NIH entities draft procedures, as needed, to respond to allegations of loss of scientific integrity in a timely, objective, and thorough manner. These procedures shall include an initial assessment and review, a fact-finding process, an adjudication or determination including description of remedies and preventative measures to safeguard the science, and reporting.

5. These procedures shall document the necessary aspects for each step of the process as well as the roles of NIH SIO and other agency staff in the process.

V. Protections

NIH prioritizes safe and respectful work environments that are free from harassment, including sexual harassment, discrimination, or other forms of inappropriate conduct that can result in a hostile work environment. Additionally, it is unlawful for NIH to take or threaten to take a personnel action against an employee because he or she made a protected disclosure of wrongdoing. A protected disclosure is defined as a disclosure of information that the individual reasonably believes is evidence of a violation of law, rule, or regulation; gross mismanagement; gross waste of funds; and abuse of authority; or a substantial and specific

[[Page 65704]]

danger to public health or safety. Personnel actions that are covered by this can include poor performance review, demotion, suspension, termination, or revocation or downgrade of a security clearance. If staff members believe that whistleblower retaliation has occurred, they may get more information from the HHS OIG at https://oig.hhs.gov/about-oig/.

It is the policy of NIH to:

1. Select and retain candidates for NIH scientific and technical positions based on the candidate's scientific and technical knowledge, credentials, experience, and integrity, and hold them and their supervisors to the highest standards of professional and scientific ethics.\21\

\21\ This provision is further outlined in the NIH Sourcebook on Personnel. Available at: https://oir.nih.gov/sourcebook/personnel.

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2. Promote diversity, equity, inclusion, and accessibility in the scientific workforce and to create and support the creation of safe workspaces that are free from harassment, discrimination, and exploitation.\22\

\22\ This provision is further outlined in the NIH Sourcebook Addendum to BSC Policies and Procedures. Available at: https://oir.nih.gov/sourcebook/processes-reviewing-nih-intramural-science/boards-scientific-counselors/addendum-policies-procedures.

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3. Protect from reprisal those individuals who report allegations of loss of scientific integrity in good faith. Efforts will also be made to protect from inappropriate actions those covered individuals alleged to have compromised scientific integrity.

4. Prevent NIH employees from intimidating or coercing NIH scientists to alter scientific data, findings, or professional opinions or from inappropriately influencing scientific advisory boards.

5. Comply with whistleblower protections, specifically:

a. The requirements of the Whistleblower Protection Act of 1989, and its expanded protections enacted by Public Law 103-424 and the Whistleblower Protection Enhancement Act of 2012, 5 U.S.C. part 2302(b)(8)-(9).

b. The National Defense Authorization Act's expansion of certain whistleblower protections to employees of Federal Government contractors, subcontractors, and grant recipients in 41 U.S.C. 4712.

c. Presidential Policy Directive 19, which prohibits supervisors from taking, failing to take, or threatening to take or fail to take any action affecting an employee's eligibility for access to classified information in reprisal for making a protected disclosure.

d. The Military Whistleblower Protection Act (codified at 10 U.S.C. 1034), which is made applicable to the Public Health Service Commissioned Corps officers through section 1129 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), and implemented by Commissioned Corps Directive 121.06.

6. Scientific integrity staff at NIH are protected by all applicable employee rights as required by law. Consistent with applicable law, an SIO or other scientific integrity staff may not be terminated or reassigned without good cause or legitimate organizational reason. Possible good cause reasons include, but are not limited to, consistent poor performance, inefficiency, neglect of duty, malfeasance, conviction of a felony, conduct involving moral turpitude, knowing violation of a law, rule, or regulation, gross mismanagement, gross waste of funds, and abuse of authority.

VI. Professional Development for Government Scientists

A key aspect of the NIH effort to advance scientific integrity is encouraging NIH IRP researchers to engage with the broader research community in maintaining the highest ethical standards and scientific norms. Creating an inclusive environment for scientists from all backgrounds, including those from traditionally underrepresented groups, is essential to supporting scientific integrity. The IRP

promotes professional development of all researchers from trainees at every level, to tenure-track and tenured investigators, and all other research staff. Scholarly writing, lecturing, editing, and publishing are essential parts of research and professional development. These activities are in the public interest and bring credit and distinction to both NIH and its employees. In encouraging researchers to share information about their official and professional activities, NIH seeks to advance scientific knowledge and contribute to its employees' professional education.

It is the policy of NIH to:

1. Encourage timely publication of research conducted by covered individuals such as in peer-reviewed, professional, scholarly journals, NIH technical reports and publications, or other appropriate outlets.\23\

\23\ This provision is further outlined in the NIH Data Management and Sharing Policy. Available at: https://sharing.nih.gov/data-management-and-sharing-policy.

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2. Encourage the sharing of scientific activities, findings, and materials developed by covered individuals through appropriate avenues including digital repositories.\24\

\24\ This provision is further outlined in the NIH Data Management and Sharing Policy. Available at: https://sharing.nih.gov/data-management-and-sharing-policy.

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3. Encourage covered individuals to participate in and present research at professional meetings including workshops, conferences, and symposia.\25\

\25\ This provision is further outlined in the NIH Sourcebook on Tenure in the NIH Intramural Research Program. Available at: https://oir.nih.gov/sourcebook/tenure-nih-intramural-research-program.

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4. When appropriate, permit covered individuals to serve on editorial boards, as peer reviewers, or as editors of professional or scholarly journals.

5. When appropriate, permit covered individuals to participate in professional societies, committees, task forces, and other specialized bodies of professional societies, including removing barriers to serving as officers or on governing boards of such societies, to the extent allowed by law.\26\

\26\ This provision is further outlined in the NIH Sourcebook on Activities with Outside Organizations and the NIH Official Duty Activities Chart. Available at: https://oir.nih.gov/sourcebook/ethical-conduct/research-ethics/nih-policies/intramural-extramural-collaborations/activities-outside-organizations and https://ethics.od.nih.gov/sites/default/files/topics/ODA/2-ODA-Chart.pdf,

respectively.

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6. Permit NIH scientists to receive honors and awards for contributions to scientific activities and discoveries to the extent allowed by law, and to accrue the professional recognition of such honors or awards.

7. Permit NIH scientists to perform outreach and engagement activities, such as speaking to community and student groups, as part of their official duties as appropriate.

VII. Federal Advisory Committees

FACs, as defined by the Federal Advisory Committee Act (FACA) at https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/legislation-and-regulations/the-federal-advisory-committee-act, are an important tool within NIH for ensuring the credibility, quality, and transparency of NIH science. NIH shall adhere to FACA and develop policies in coordination with the General Services Administration and consistent with the guidance on lobbyists serving on FACs when convening FACs tasked with giving scientific advice.

Consistent with all applicable laws and guidance regarding FACs, it is the policy of NIH to:

1. Promote transparency in the recruitment of new FAC members,

including, when practical and appropriate, announcing vacancies with a notification in the Federal Register.

2. Select members to serve on a scientific or technical FACs based on expertise, knowledge, and contribution to the relevant subject area.[27] [28] Additional factors that may be considered are availability of the member to serve, alignment with the relevant Federal Advisory Committee Membership Balance Plan, and the ability to work effectively on advisory committees.\29\ Ensure committee membership is fairly balanced in terms of points of view represented with respect to the functions to be performed by the FAC.[30] [31]

\27\ This provision is further outlined in How Scientists Are Selected to Be Members of a Chartered Review Group. Available at: https://public.csr.nih.gov/ForReviewers/BecomeAReviewer/CharteredReviewers.

\28\ This provision refers to not only FACA Councils that have SGE members but also peer review FACA committees that have NIH peer review consultants as members.

\29\ This provision is further outlined in the NIH Selection Criteria for NIH Advisory Committees. Available at: https://ofacp.nih.gov/sites/default/files/SelectionCriteria.pdf.

\30\ 2010 Memorandum from the White House Office of Science and Technology Policy on Scientific Integrity. Available at: https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf.

\31\ General Services Administration 41 CFR parts 101-6 and 02-3 Federal Advisory Committee Management; Final Rule. Available at: https://www.gsa.gov/system/files/FACAFinalRule_R2E-cNZ_0Z5RDZ-i34K-pR.pdf.

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3. Comply with current standards governing conflict of interest as defined in statutes and implementing regulations.[32] [33]

\32\ This provision is further outlined in the NIH Policy Manual Chapter 1810 on Procedures for Avoiding Conflict of Interest for Special and other Federal Employees Serving as Advisory Committee Members. Available at: https://policymanual.nih.gov/1810-1.

\33\ The NIH Office of Federal Advisory Committee Policy maintains the Special Government Employee (SGE) Portal for those interested in serving on an NIH Federal advisory committee as an SGE. The Portal contains all the requirements expected of advisory committee members who serve on advisory committees as SGEs, including ethics training, Foreign Activities and Lobbyist Certification, and the Confidential Financial Disclosure Report (OGE 450) at: https://sgeportal.od.nih.gov/Pages/default.aspx.

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4. Except when prohibited by law and to the extent practical, agencies should appoint members of scientific and technical FACs as Special Government Employees.

5. Treat all reports, recommendations, and products produced by FACs solely as the reports, recommendations, and products of such committees rather than of the U.S. Government, and thus not subject to intra- or inter-agency revision. The role of the FACs is to provide advice or recommendations to the agency. The agency may then craft policy based on the FACs' advice or recommendations if it chooses to adopt those recommendations.

Addressing Scientific Integrity Concerns

The NIH SIO has primary responsibility for assessing scientific integrity concerns and will develop procedures for addressing allegations of loss of scientific integrity and concerns that span or fall outside existing NIH adjudication mechanisms under the purview of OER, OIR, OMA, or OIG.\34\ In particular, the NIH SIO will manage scientific integrity concerns related to political interference, if they do not fall within existing processes. Procedures for handling scientific integrity concerns will be made available on the NIH website. For information about rights and remedies against retaliation, employees may contact the HHS OIG Whistleblower Protection Coordinator.\35\ As noted above, existing procedures under the purview of OER, OIR, OMA, and OIG should continue to be followed. When those existing mechanisms do not cover a scientific integrity concern:

\34\ OER reviews and refers allegations of research misconduct involving extramural researchers and peer review of grant applications to the HHS Office of Research Integrity (ORI) and may take corrective action against a grantee or peer reviewer based on the conduct identified in ORI findings. OIR reviews allegations related to research integrity involving NIH IRP researchers. The NIH Division of Program Integrity within OMA manages the review of allegations involving misuse of NIH grant or contractor funds, grantee or contractor conflicts of interest, and other misconduct or misuses of NIH resources by NIH employees or others doing business

with NIH. The HHS OIG investigates allegations of criminal fraud, waste, and abuse. Further information about these processes and offices will be provided in a manual chapter.

\35\ As appropriate, employees can also contact the NIH Office of Equity, Diversity, and Inclusion for information regarding retaliation based on protected equal employment opportunity, or the Office of Special Counsel for information regarding retaliation based on whistleblowing. Further information can be found at: https://www.edi.nih.gov/resolutions/resources/faqs and https://oig.hhs.gov/fraud/whistleblower/. Additionally, although encouraged to use the process detailed herein, employees may also disclose wrongdoing to their supervisor or another individual higher up in management, the HHS OIG, the Office of Special Counsel, or to Congress.

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1. Concerns about a potential loss of scientific integrity at NIH may be reported to the NIH SIO by any individual who has knowledge of the situation.
2. NIH employees are encouraged to seek an informal consultation with the NIH SIO or other relevant agency integrity officials to discuss whether a concern constitutes a potential loss of scientific integrity before submitting a formal complaint. Employees ultimately have the discretion to submit a formal complaint as they see fit.
3. The SIO will oversee an initial assessment of each reported concern and determine whether to request additional information from the complainant or others and to determine whether a formal investigation is warranted. Additionally, if any reported concern falls within the purview of existing OER, OIR, OMA, or OIG processes, those mechanisms will instead be utilized.
4. Should an investigation be opened, an investigation committee consisting of the NIH SIO and other agency integrity officials from the NIH Scientific Integrity Council will be convened to develop a factual record by exploring the allegation(s) in detail and consulting with subject matter experts, interviewing witnesses, and reviewing documentation as needed.
5. Once the investigation is complete, the NIH SIO will determine whether scientific integrity was lost and report findings to the appropriate management entity.
6. The complainant and respondent will be given the opportunity to appeal a finding or any corrective scientific actions taken.

Handling Differing Scientific Opinions

Science and decisions based on science are strengthened by vigorous discussion and debate and by considering all available evidence. The process of challenging and improving ideas helps to guard against inadequate science and flawed analysis. NIH encourages its scientists to respectfully express and engage with differing views as an integral part of the scientific process.\36\ In some cases, such as when a scientific dispute has a significant impact on public health or policy, a formal scientific dispute resolution process may be necessary. The goal of scientific dispute resolution should be to ensure that all perspectives are heard and documented in an unbiased way. A satisfactory resolution may involve adopting one opinion over another, deciding to conduct additional studies, formulating an alternate theory reconciling the differing opinions, or documenting the disagreement for

the benefit of policymakers and fellow scientists. These steps may be completed in any order and are not necessarily an exhaustive list of dispute

[[Page 65706]]

resolution measures among NIH scientists. In general:

\36\ Further information on the NIH IRP Authorship Conflict Resolution Process can be found in the NIH Sourcebook. Available at: https://oir.nih.gov/sourcebook/ethical-conduct/authorship-guidelines-resources/nih-irp-authorship-conflict-resolution-process.

A team member or group of team members with a differing opinion may engage with their colleagues to resolve the issue as soon as the difference of opinion is known. NIH recommends this type of internal discussion as a first step in most dispute resolution proceedings.

A team may choose to consult a manager. First-level managers may defer to an appropriate higher-level manager if the first-level manager has a conflict of interest or cannot offer an impartial opinion for any reason.

If the matter cannot be satisfactorily resolved by other means, a team may request assistance from OIR. The NIH SIO may be consulted if their assistance is requested or if there is a conflict of interest or perceived conflict of interest with relevant OIR staff.

Monitoring, Evaluating, and Reporting Scientific Integrity Activities and Outcomes

NIH, working through HHS, will develop and implement an evaluation plan to regularly measure, monitor, and evaluate ongoing scientific integrity activities and outcomes. The plan will include a roadmap of activities, evaluation metrics, and methods of measurement for the purpose of ongoing improvement of scientific integrity processes, procedures, and policies. As part of the monitoring and evaluation plan, an annual report on the number and outcomes of investigations involving allegations of loss of scientific integrity will be published. To the extent possible, all descriptions of investigations will be anonymized.

Related Policies and Statutes

Violations of related and supporting policies may result in a loss of scientific integrity and it is appropriate for the SIO to coordinate across the agency in these matters. The following policies and programs intersect with the development of the culture of scientific integrity within the agency.

Research Misconduct

Federal Research Misconduct Policy: https://www.federalregister.gov/documents/2000/12/06/00-30852/executive-office-of-the-president-federal-policy-on-research-misconduct-preamble-for-research

Public Health Service Policies on Research Misconduct: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-H/part-93

NIH Policy Manual Chapter 3006--NIH Intramural Research Program (IRP) Research Misconduct Proceedings: https://policymanual.nih.gov/3006

NIH IRP Policies and Procedures for Research Misconduct Proceedings: https://oir.nih.gov/system/files/media/file/2021-08/policy-nih_irp_research_misconduct_proceedings.pdf

Diversity, Equity, Inclusion, and Accessibility in Addressing and Strengthening Scientific Integrity and the Disproportional Impact of Scientific Integrity Policy Violations on Underrepresented Groups

HHS Equal Employment Opportunity and Anti-Harassment Policy: https://www.hhs.gov/about/agencies/asa/eeo/policy/index.html

Government-Wide Strategic Plan to Advance Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce: https://www.whitehouse.gov/wp-content/uploads/2021/11/Strategic-Plan-to-Advance-Diversity-Equity-Inclusion-and-Accessibility-in-the-Federal-Workforce-11.23.21.pdf

HHS Diversity, Equity, Inclusion, and Accessibility Strategic Plan 2022: https://www.hhs.gov/sites/default/files/2022-hhs-deia-strategic-plan.pdf

NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility Fiscal Years 2023-2027: https://www.nih.gov/sites/default/files/about-nih/nih-wide-strategic-plan-deia-fy23-27.pdf

Public Access

NIH Public Access Policy: https://publicaccess.nih.gov/policy.htm

OSTP Memorandum on Increasing Access to the Results of Federally Funded Research (2013): https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf

OSTP Memorandum on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research (2022): https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf

5 U.S.C. 552--Freedom of Information Act: https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-5

Human and Animal Subject Protections

Federal Policy for Protection of Human Research Subjects (the Common Rule): https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

Animal Welfare Act and Regulations: https://www.aphis.usda.gov/animal_welfare/downloads/AC_BlueBook_AWA_508_compversion.pdf

Public Health Service Policy on Humane Care and Use of Laboratory Animals: https://olaw.nih.gov/policies-laws/phs-policy.htm

Guide for the Care and Use of Laboratory Animals: https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf

U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training: https://olaw.nih.gov/policies-laws/gov-principles.htm

NIH Policy Manual Chapter 3014--NIH Intramural Human Research Protection Program: https://policymanual.nih.gov/3014
NIH Policy Manual Chapter 3040-2--Animal Care and Use in the Intramural Research Program: https://policymanual.nih.gov/3040-2

Research Security

National Security Presidential Memorandum 33 (NSPM 33): https://trumpwhitehouse.archives.gov/presidential-actions/presidential-memorandum-united-states-government-supported-research-development-national-security-policy/
Guidance for Implementing NSPM 33: https://www.whitehouse.gov/wp-content/uploads/2022/01/010422-NSPM-33-Implementation-Guidance.pdf

Whistleblower Protections

5 U.S.C. 2302--Prohibited personnel practices: https://uscode.house.gov/view.xhtml?req=29&f=treesort&num=125
Public Law 101-12--Whistleblower Protection Act of 1989: https://www.govinfo.gov/content/pkg/STATUTE-103/pdf/STATUTE-103-Pg16.pdf
Public Law 103-424--Expansion of Whistleblower Protection Act of 1989: https://www.govinfo.gov/content/pkg/STATUTE-108/pdf/STATUTE-108-Pg4361.pdf#page=3
Public Law 112-199--Whistleblower Protection Enhancement Act of 2012: https://www.congress.gov/112/statute/STATUTE-126/STATUTE-126-Pg1465.pdf
41 U.S.C. 4712--Enhancement of contractor protection from reprisal for disclosure of certain information: https://uscode.house.gov/view.xhtml?req=(title:41%20section:4712%20edition:prelim)
Presidential Policy Directive 19--Protecting Whistleblowers with Access to Classified Information: https://www.usda.gov/sites/default/files/documents/ppd.pdf
U.S. Office of Special Counsel: https://osc.gov/

[[Page 65707]]

10 U.S.C. 1034, made applicable to the Public Health Service Commissioned Corps through section 1129 of the Food and Drug Administration Safety and Innovation Act, Public Law 112-144, and implemented by Commissioned Corps Directive (CCD) 121.06: https://dcp.psc.gov/ccmis/ccis/documents/CCD121_06.pdf

Other Related Policies

NIH Data Management and Sharing Policy: https://sharing.nih.gov/data-management-and-sharing-policy
Public Law 115-435--Foundations for Evidence-Based Policymaking Act (``Evidence Act''): https://www.congress.gov/115/plaws/publ435/PLAW-115publ435.pdf
Public Law 107-174--Notification and Federal Employee Antidiscrimination and Retaliation Act (``No FEAR Act''): https://uscode.house.gov/statutes/pl/107/174.pdf
U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern: https://www.phe.gov/s3/dualuse/documents/durc-policy.pdf
U.S. Government Policy for Oversight of Life Sciences Dual Use

Research of Concern: https://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf
Public Law 92-463--The Federal Advisory Committee Act: https://uscode.house.gov/statutes/pl/92/463.pdf
Public Law 104-13--Paperwork Reduction Act: https://www.congress.gov/104/plaws/publ13/PLAW-104publ13.pdf

Authorities

Pursuant to the 2021 Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/, and consistent with the 2009 Presidential Memorandum on Scientific Integrity at https://obamawhitehouse.archives.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09 and the 2010 Memorandum from the White House Office of Science and Technology Policy on Scientific Integrity at https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf, all Federal agencies must establish a scientific integrity policy. The requirements of this policy are derived from the 2022 National Science and Technology Council (NSTC) Report of the Scientific Integrity Fast Track Action Committee, Protecting the Integrity of Government Science at https://www.whitehouse.gov/wp-content/uploads/2022/01/01-22-Protecting the Integrity of Government Science.pdf, and align with the principles set forth in the NSTC guidance document A Framework for Federal Scientific Integrity Policy and Practice at https://www.whitehouse.gov/wp-content/uploads/2023/01/01-2023-Framework-for-Federal-Scientific-Integrity-Policy-and-Practice.pdf.

This policy is established in accordance with:

1. Public Law 111-358--The America COMPETES Reauthorization Act of 2010, section 103, as amended
2. Public Law 115-435--The Foundations for Evidence-based Policymaking Act of 2018
3. Public Law 106-554--The Information Quality Act of 2000
4. 67 FR 8451--OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies
5. 70 FR 2664--OMB Final Information Quality Bulletin for Peer Review
6. 65 FR 76260-76264--Federal Policy on Research Misconduct
7. Public Law 101-12--The Whistleblower Protection Act (WPA) of 1989, as amended
8. 41 U.S.C. 4712--The National Defense Authorization Act, Enhancement of contractor protection from reprisal for disclosure of certain information
9. 5 U.S.C. 13103 et seq.--The Ethics in Government Act of 1978, as amended, and 5 CFR parts 2634 and 2635, Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture and Standards of Ethical Conduct for Employees of the Executive Branch.
10. 18 U.S.C. 201-209--Statutes regarding Bribery, Graft and Conflicts of Interest
11. 5 CFR parts 5501 and 5502--Supplemental Standards of Ethical

Conduct for Employees of the Department of Health and Human Services
12. 5 U.S.C. Ch. 10--The Federal Advisory Committee Act of 1972
13. 45 CFR part 73, Standards of Conduct
14. 5 CFR part 735, Employee Responsibilities and Conduct
15. HHS Protection of Human Subjects Regulation (45 CFR part 46).
16. PPD 19--Protecting Whistleblowers with Access to Classified Information, 2012
17. M-20-12--OMB Phase 4 Implementation of the Foundations for Evidence-Based Policymaking Act of 2018: Program Evaluation Standards and Practices
18. 42 CFR part 93--Public Health Service Policies on Research Misconduct
19. 10 U.S.C. 1034, made applicable to the Public Health Service Commissioned Corps through section 1129 of the Food and Drug Administration Safety and Innovation Act, Public Law 112-144, and implemented by Commissioned Corps Directive (CCD) 121.06
20. Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, Public Law 117-328, Division FF, title II, section 2321 (Jan 3, 2023)
21. Chips and Science Act, Public Law 117-167, title VI, subtitle D, section 10631 (Aug 9, 2022)

Dated: September 19, 2023.

Tara A. Schwetz,

Acting Principal Deputy Director, National Institutes of Health.

[FR Doc. 2023-20733 Filed 9-22-23; 8:45 am]
BILLING CODE 4140-01-P

Submit date: 10/17/2023

I am responding to this RFI: On behalf of myself

Name: Robert Charrow

Name of Organization: Self

Type of Organization: Other

Role: Member of the public

Comment:

See Attached. Comment relates to all of the above 1-5.

Uploaded File:

10-17-23-Comment-to-NIH-Policy-on-Scientific-Integrity.docx

Description: Comment

Email: rcharrow@gmail.com

October 17, 2023

Via Electronic Mail Only
https://osp.od.nih.gov/comment-form-draft-scientific-integrity-policy-for-the-national-institutes-of-health/

Tara A. Schwetz, Ph.D.
Acting Principal Deputy Director
National Institutes of Health
James Shannon Building
9000 Rockville Pike
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Subject: Request for Information on the DRAFT Scientific Integrity Policy of the National Institutes of Health

Dear Dr. Schwetz:

I am responding to your solicitation of comments to the proposed "Scientific Integrity Policy of the National Institutes of Health." *See* 88 Fed. Reg. 65,696 (Sept. 25, 2023) (referred to either as "Proposal" or "Policy"). As former General Counsel of the United States Department of Health and Human Services, I will attempt to limit my observations to those that are purely legal with an occasional detour when it comes to the philosophy of science and best practices for issuing non-legislative rules.

The integrity of science (*i.e.*, research integrity as traditionally defined and not as defined in this Policy) is critical, and any attempt by federal agencies to stifle divergent scientific views—especially of non-government actors--is abhorrent. However, I doubt that this Policy will deter those in government bent on muzzling those voicing unpopular positions and may have precisely the opposite effect. Bureaucracies, including the one to be created by this Proposal, rarely protect the dissemination of unorthodox views and instead, tend to promote conformity. *See* Robert K. Merton, SOCIAL THEORY AND SOCIAL STRUCTURE, 195-206 (Glencoe, IL: Free Press 1957). Much like the modern fable of the scorpion and the frog, that is just the nature of a bureaucracy. Hence, "be careful what you wish for."

Background**:**

The Proposal creates various new bureaucracies: (i) a Chief Scientist whose job really isn't science but rather to "provide[] oversight of all NIH scientific integrity policies and procedures[;]" (ii) a Scientific Integrity Council; and (iii) a Scientific Integrity Official who is the primary official over scientific integrity matters and reports to the Chief Scientist. However, the Policy goes on to note that cases involving real breaches of scientific integrity, *i.e.*, research misconduct, are

GOOD SCIENCE PROJECT

Introduction. We are pleased to submit these comments on the Draft Scientific Integrity Policy of the National Institutes of Health (NIH), particularly with regards to topics 1 and 3 (role and responsibilities for the NIH Scientific Integrity Officer and the Scientific Integrity Council).

NIH is to be applauded for its commitment to scientific integrity and reliability, and the Draft Scientific Integrity Policy takes an important step forward in establishing a new Scientific Integrity Official to have primary responsibility across NIH, along with the advice of a Scientific Integrity Council. These new offices will hopefully create more of a mechanism to ensure that scientific integrity is given its proper due.

Ensuring Accountability. The Draft Policy notes that there are already several NIH offices that adjudicate integrity issues "when an allegation or complaint is received," and that the new Scientific Integrity Official will help coordinate how NIH responds to "allegations to ensure effective oversight."

We believe that NIH should take one further step as to ensuring accountability: *Give the Scientific Integrity Official enough of a budget and staff to proactively look for research integrity issues, rather than merely reacting to allegations and complaints.*

The reason for this recommendation is straightforward: Problems with research integrity are *much more* prevalent than the rate of official allegations and complaints would suggest. In many cases, we will not find research integrity problems unless we look for them more proactively.

Think of the stakes for a trainee who suspects potential data fraud in a published article by a leading scholar in their field. All the incentives weigh strongly against making any such allegation. After all, making an allegation of fraud:

- Takes time away from your own research agenda and publications;
- Could create damaging controversy for your mentor(s), lab head, etc.;
- Could cause the leaders in your field to view you as a potential troublemaker rather than a scientist worth hiring; and,
- Could even lead to an expensive lawsuit for defamation.

By contrast, there are enormous incentives for academics to cheat:

- NIH hands out some $39 billion in external research funding a year

- Academics have jobs, tenure, and up to 100% salary support on the line
- Faking data is relatively easy, especially if no one is looking

Just by the balance of incentives here, there are definitely more research integrity issues than will be discovered by waiting for someone to put their own career on the line by filing an official complaint.

It should therefore be no surprise that some of the most dramatic instances of fraud have been found by anonymous Internet commenters, and often by people (such as Elizabeth Bik) who are unemployable in academia.

Consider the recent case of apparently fraudulent research in the Alzheimer's field.[1] The original 2006 article that has come into question[2] was supported by grants from the NIH to three of the authors, and has been cited more than "all but four other Alzheimer's basic research reports published since 2006." Independent investigators who reviewed the lead author's work (Sylvain Lesné) found reason to "cast doubt on hundreds of images, including more than 70 in Lesné's papers."

Notice that these potential integrity issues only came to light more than 15 years after the fact when PubPeer commenters noticed many cases of apparent image duplication. NIH program officers apparently never uncovered any problems via progress reports or any other mechanism for monitoring research output.

Nonetheless, Lesné has apparently received at least $8,762,207 in NIH support since 2008.[3] Even worse, as *Science* revealed, the very NIH program officer (Austin Yang) for Lesné's most recent R01 (which was awarded four months *after* NIH had been notified of research integrity issues) had literally been a co-author with Lesné on the apparently fraudulent 2006 article!

As this incident shows, substantial cases of fraud can contaminate an entire field of research for 15+ years, not only without anyone at NIH noticing, but with NIH continuing to send millions of dollars to the problematic researcher, even with one of his co-authors as the program officer for a major grant.

The NIH should look to the Center for Medicare and Medicaid Services, which devotes substantial resources to a Center for Program Integrity that *proactively* looks for signs of fraud, improper payments, etc. That is, the NIH Scientific Integrity Official should be given a staff and budget to proactively audit NIH-funded studies for signs of fraud, data manipulation, and other violations of research integrity. One-twentieth of one percent of NIH's overall budget would be a good starting point.

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[1] Charles Piller, "Blots on a Field?," *Science* (July 21, 2022), available at https://www.science.org/content/article/potential-fabrication-research-images-threatens-key-theory-alzheimers-disease.

[2] See Sylvain Lesné et al., "A specific amyloid-β protein assembly in the brain impairs memory," *Nature* 440 (2006): 352-357.

[3] See https://reporter.nih.gov/search/W9KkSxMJBU2WJkvp7N8SaA/projects.

already handled by the Office of Research Integrity, an office within the Public Health Service, not NIH. The Policy acknowledges that the Science Integrity Official's actual role "will [be to] manage scientific integrity concerns related to political interference, if they do not fall within existing processes." *Id*. at 65,705.

The Policy supposedly "empowers the NIH [Scientific Integrity Official] with . . . independence."[1] As such, it effectively authorizes career employees to veto or ignore the actions and orders of political appointees, such as the Secretary or Director of NIH. It also attempts to define various terms, such as "scientific integrity," "loss of scientific integrity," "interference," "inappropriate influence" (*e.g*., suppressing a decision-maker's ability to offer the best judgment based on scientific information), "science," and the like. The proposed bureaucratic labyrinth will supposedly attempt to address hypothetical issues raised in a White House Report entitled *Protecting the Integrity of Government Science* (Jan. 11, 2022) ("Report," "Administration Report," or "White House Report"), cited at 88 Fed. Reg. at 65,699 n.3. Ironically, the Report suggests that none of these concerns likely apply to NIH: "Agencies that focus mostly on funding extramural research, such as the National Science Foundation (NSF) and National Institutes of Health (NIH), are less likely to experience interference in decision-making and policymaking than science agencies with a strong regulatory role." *Id*. at 7 - 8. Therefore, it is not surprising that no examples of untoward conduct at NIH were presented in the Proposal nor were there any cost estimates for the proposed new bureaucracy.

Summary of Concerns & Observations**:**

I was somewhat surprised that the Proposal did not delineate the factual reasons underlying the sudden need for a new and massive bureaucratic structure to deal with "political interference" and other non-scientific concerns. This is especially so given that the White House Report concluded that non-regulatory agencies, such as NIH, are less likely to experience "interference" than regulatory agencies such as EPA. *See* Report at 7-8. What is it about the current structure at NIH that has proven to be inadequate and how will this proposed new structure address those inadequacies? The Proposal lacked this critical information. Actual examples would certainly help. For instance, has there been a sudden surge in problematic conduct by those supervising NIH employees which has overwhelmed or compromised the current system? Has any political appointee blocked the publication of any real scientific study by any NIH employee? If so, when and what was the nature of the study or studies and was the employee acting in his official capacity? Does NIH anticipate an upsurge in problematic behavior because it is proposing to broaden "scientific integrity" and "scientific process" to include

[1] The full sentence, written in bureaucratese, is as follows: "This policy empowers the NIH SIO with the independence necessary to gather and protect information to support the review and assessment of scientific integrity concerns." 88 Fed. Reg. at 65,699.

politically charged concepts such as "diversity, equity, inclusion, and accessibility." Indeed, the record suggests otherwise. Requests, under the Information Quality Act ("IQA"), [2] seeking to correct scientific information released by NIH have been few and far between; there have been only two such requests in the past decade.

The absence of any demonstrated need for the Proposal is compounded by the absence of any legal bases for many of its elements. There is, for instance, no statutory basis for including within the definition of "scientific integrity," the concept of "diversity, equity, inclusion, and accessibility." DEIA, or its predecessor, DEI, is not mentioned in any of the statutes cited in the Authorities section of the Proposal. *See* 88 Fed. Reg. at 65,707. This perhaps is because DEIA has nothing to do with science or the integrity of research and everything to do with one's political agenda. In that regard, a bit of intellectual honesty would have helped.

The Proposal—by authorizing career employees to ride roughshod over political appointees--raises significant legal issues under the Administrative Procedure Act, the Public Health Service Act, the Appointments Clause (*see* U.S. Const. art. II, § 2, cl. 2), and the Executive Power and Take Care Clauses of the Constitution (*see* U.S. Const. art. II, § 1, cl. 1; § 3, respectively). As the Court recently re-affirmed, "[u]nder our Constitution, the 'executive Power'—all of it—is 'vested in a President,' who must 'take Care that the Laws be faithfully executed.'" *Seila Law LLC v. Consumer Financial Protection Bureau*, 140 S. Ct. 2183, 2191 (2020). The courts have consistently held that the President acts, if not directly, then through his or her Department heads. *See Snyder v. Sickles*, 98 U.S. 203, 211 (1878) (referencing 3 Op. Att'y Gen. 137). The Proposal appears to have ignored these limitations.

One has to wonder how much the Proposal will cost the taxpayers and how many biomedical research grants (*e.g*., R01 grants) will be sacrificed to cover the Proposal's cost. Given the lack of demonstrated need, its likely cost, and doubtful legality, this Proposal is certainly worthy of congressional oversight.

Concerns & Observations:

I. There Is No Demonstrated Need for a New and Costly Bureaucratic Structure at NIH

The linchpin of any Legislative or Executive Branch action is some articulated and fact-based problem that the action is aimed at addressing. This applies even to non-legislative regulations, such as this one, which seek to spend taxpayer dollars. If there is no articulated problem to be addressed by a costly guideline or policy,

[2] Consolidated Appropriations Act, 2000, Pub. L. No. 106–554 App'x C, § 515, 114 Stat. 2763, 2763A–153 (Dec. 21, 2000).

then the agency is squandering taxpayer dollars. Here, the Federal Register notice did not articulate a demonstrable problem at NIH. If the action is prophylactic, then the agency is obligated to set out the reasons why it believes that the problem, although not present, will arise in the near future and the action contemplated is the best way of preventing the problem from emerging. No such evidence was set out in the Federal Register notice.

Second, the IQA, referenced in the Policy, requires agencies to present information objectively and to correct errors. Two decades ago, HHS implemented that Act through the Assistant Secretary for Planning and Evaluation by requiring among other things that ASPE publish requests from the public for corrections to agency information that is allegedly incorrect scientifically and the agency's responses to those requests. It is noteworthy that NIH has received only 17 requests for corrections over the past two decades and only two in the last ten years.[3] *See* https://aspe.hhs.gov/information-requests-corrections-hhs-responses. In short, the IQA has already been implemented and NIH has rarely been the subject to any request to correct, leaving us with a remedy in search of an injury and a massive bureaucracy in search of a mission.

Third, there is the pink elephant in the room that was conveniently ignored in the Proposal. The Proposal was signed on September 19, 2023. Eleven days earlier, the Fifth Circuit issued its decision in *State of Missouri v. Biden*, No. 23-30445 (5th Cir. Sept. 8, 2023), affirming an injunction against the White House, CDC, and other actors for stifling the dissemination of divergent scientific views. This is relevant given that this Proposal is based on a government-wide policy developed by various agencies and White House officials. *See* OSTP *et al*., *A Framework for Federal Scientific Integrity Policy and Practice* (Jan. 2023) ("Framework"). *See* 88 Fed. Reg. at 65,697. One of the many goals of the Framework is to promote the "free flow of scientific information." *Id*. at 10. But the White House and one of the HHS agencies involved in preparing the Framework (*i.e*., CDC) were enjoined by a federal court from doing precisely what they claim is evil—impeding the free flow of scientific information by silencing unpopular scientific views. *See State of Missouri v. Biden*, No. 23-30445, slip op. at *60-61 ("the district court did not err in determining that several officials—namely the White House, the Surgeon General, the CDC, and the FBI—likely coerced or significantly encouraged social-media platforms to moderate content, rendering those decisions state actions. In doing so, the officials likely violated the First Amendment."). The defendants were a mix of career employees and political appointees.

No one at NIH was subject to the injunction, as modified by the Fifth Circuit. This absence of untoward behavior at NIH, coupled both with the rarity of "requests to correct" NIH statements under the IQA, and the finding in the White House Report

[3] The last two requests for correction occurred in 2015 and 2019 and involved NIH statements about antimony trioxide and the ethical treatment of monkeys, respectively.

that NIH is less likely to experience interference than other agencies bring us back to the fundamental question underlying any rulemaking[4] of this type—factually, what is the demonstrated need for a new and costly bureaucracy at NIH? This question was never answered in the Federal Register document and for a good reason: All of the facts suggest that there is no need, at least at NIH, for this sort of bureaucracy designed to instill and maintain purity.

II. Attempts by an Agency of HHS to Limit the Secretary's Authority Are Unconstitutional and Inconsistent with the Organic Legislation

While this Proposal, at first glance, appears to be narrow in one sense—ostensibly limited, in certain but not all respects, to those working at NIH—it is broad in another sense—it regulates scientific management and seeks to limit the authority of political appointees, wherever employed. Specifically, the Proposal creates the concept of "scientific integrity," which is significantly broader than "research misconduct," the accepted regulatory term, and includes "equity," "inclusivity," and "protection from inappropriate influence." *See* 88 Fed. Reg. at 65,699. Equity and inclusivity have nothing to do with the integrity of research results and more to do with one's political views. "Protection from inappropriate influence" appears to be anti-science to the extent that it insulates the scientific theory du jour from criticism.

Further, the Proposal vests authority in career employees and seeks to insulate their decision-making from political appointees. Under the Proposal, a career employee is authorized to investigate the Secretary's decisions concerning management and funding. As such, the Proposal appears to be more of a manifesto by career employees directed against political appointees than a meaningful statement of federal policy and appears to inappropriately interfere with the statutory responsibilities of the Secretary and other political appointees.

The Proposal extends beyond NIH. It states that "the covered individuals for this policy consist primarily of NIH employees[.]" 88 Fed. Reg. at 65,700 (emphasis supplied). The use of the word "primarily" strongly suggests that the Policy reaches beyond NIH employees to those in other agencies within HHS and in fact, that is precisely how the term "covered individuals" is defined, as follows:

> Covered individuals include all NIH employees; Public Health Service Commissioned Corps members; political appointees; clinical, research, and postdoctoral fellows; doctoral trainees; interns; and advisory committee members in their capacity as special Government employees, when in the course of their official duties they propose, conduct, review, or communicate about science and scientific

[4] The Policy if applied to HHS employees only is a non-legislative rule under Administrative Procedure Act ("APA") §§ 1 & 4.

> activities; and all levels of employees who manage or supervise scientific activities and use scientific information in policymaking.

88 Fed. Reg. at 65,698 (emphasis supplied).

Public Health Service Commissioned Corp members are assigned to various agencies within HHS (*e.g.*, CDC, FDA, ASPR) and not just to NIH. Of greater concern is that the term includes "political appointees" in addition to "NIH employees." This can only mean "political appointees" anywhere in the Department, including the two primary political appointees at NIH (*i.e.*, the Director of NIH and the Director of NCI), as well as the Secretary, Deputy Secretary, Assistant Secretary for Health, Assistant Secretary for Public Affairs, *et cetera*.

A. Career "Employees" Cannot Check or Otherwise Impede the Actions of the President, Secretary, or Other Political Appointees Wielding Executive Authority

The Policy seeks to limit the authority of political appointees by making the Secretary and Director and those in other HHS agencies subservient to career employees at NIH. The document bars "political interference" which it defines as "inappropriately shaping or interfering in the conduct, management, communication, or use of science for inappropriate partisan advantage or such that it undermines impartiality, nonpartisanship, or professional judgement." 88 Fed. Reg. at 65,699. In particular, the Science Integrity Officer, a position created by this Policy, is supposed to "[s]erve as a focal point for the receipt of agency scientific integrity allegations (particularly related to political interference)[,]" and "[l]ead the review and adjudication of allegations of loss of NIH scientific integrity (particularly related to political interference)." 88 Fed. Reg. at 65,700. Moreover, the Policy states that "[s]cientific findings and products must not be suppressed, delayed, or altered for political purposes and must not be subjected to political interference or inappropriate influence[.]" In addition, the document proposes to adopt as NIH policy, the following:

> Prohibit political interference or other inappropriate influence in the design, proposal, conduct, management, evaluation, communication of, and use of scientific activities conducted by covered individuals.
>
> Require that leadership and management ensure that covered individuals engaged in scientific activities can conduct their work objectively and free from political interference or other inappropriate influence.

88 Fed. Reg. at 65,701.

In addition, according to the Proposal, it is the Policy of NIH to "[e]nsure that covered individuals are free to express differing scientific opinions free from political interference or inappropriate influence." *Id*. at 65,703.

These limitations on political appointees, *e.g*., Director of NIH, Secretary of HHS, run afoul of federal law. Only Congress can limit the authority of Officers and even then congressional authority is cabined by the Appointments, Executive Power, and Take Care Clauses of the Constitution. *See* OLC Op., 1988 WL 390999 (March 11, 1988) (Congress cannot delegate authority within HHS to the exclusion of the Secretary). Career employees at NIH have no such authority. Indeed, absent functioning Officers, agency actions are voidable. *See United States v. Arthrex, Inc*., ___U.S.___, No. 19-1434 (U.S. June 21, 2021) (invalidating adjudication by a panel of Inferior Officers that was not effectively reviewable by an Officer). At this time, NIH has no Officer, *i.e*., an individual appointed by the President following confirmation by the Senate. *See* U.S. Const. art. II, § 2, cl. 2.

In addition, under the Public Health Service Act and the Department's organic legislation, all decisions on funding, managing, and even communicating are those of the Secretary and Director. *See* Reorganization Act No. 1, 1953, § 1, as incorporated into 42 U.S.C. § 3501. Thus, under the PHS Act, "[i]n carrying out the purposes of section 301, the Secretary, acting through the Director of NIH" shall be responsible for "all activities for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health[.]" PHS Act § 402(b)(1). Both the Secretary and NIH director are political appointees, making NIH management, by law, inherently political. Indeed, as everyone with any understanding of our constitutional system recognizes, political appointees are supposed to implement the political views of the President and the Secretary; the Appointments Clause is designed to ensure that that occurs. This structure is designed to reflect the democratic concept that our national elections have consequences. The proposed Policy, by seeking to dictate how political appointees view and use science, is inconsistent with our Constitution.

The proposed Policy turns the Constitution on its head. Operative terms, such as "inappropriate," are vague, but that is only a minor problem in comparison to the structural constitutional problems which are fatal. For example, under the Proposal, career employees would be the ones authorized by this Policy to decide whether the Secretary's or other political appointees' behavior is appropriate. In short, under this Policy, a GS-15 gets to decide what the Secretary can and cannot do, notwithstanding Article II of the Constitution, the PHS Act, the Reorganization Act, and 5 U.S.C. § 301.[5] The Proposal failed to discuss any of these issues

[5] Section 301 provides, in pertinent part, as follows:

> The head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its

demonstrating either a lack of appreciation or understanding of the fundamentals of our Constitution.

As the Court has consistently held, those who wield executive authority serve at the pleasure of the President or Secretary and may be terminated without cause at any time by either, depending on who appointed the official.[6] *See Seila Law LLC v. Consumer Financial Protection Bureau*, 140 S. Ct. at 2191-92 ("The President's power to remove—and thus supervise—those who wield executive power on his behalf follows from the text of Article II, was settled by the First Congress"). Indeed, the ability to wield executive authority depends on whether the individual can be removed at will by the appointing authority. Only those who can be so removed can wield such authority. Career employees, who are neither Officers nor Inferior Officers, and who cannot be summarily removed by the President or the Secretary, cannot wield executive authority and thus, cannot check or impede the actions of someone who is wielding such authority. *United States v. Arthrex, Inc*., *supra*, requires that all executive actions must be subject to review and reversal by a political appointee--an individual appointed by the President with the advice and consent of the Senate.

B. The Proposed Policy Conflicts with Existing Law by Injecting a Specific Political Agenda into the Concept of Scientific Integrity

The Proposal is internally inconsistent. On the one hand, it touts the pollyannaish virtue of a scientific enterprise funded with taxpayer dollars that is free of political oversight. On the other hand, though, it overtly injects into the scientific enterprise, under the guise of "scientific integrity," inherently political concepts, such as "Diversity, Equity, Inclusion, and Accessibility" and purity. It appears that the Proposal's aim is to stuff as many "politically charged" concepts into the orbit of scientific integrity as permitted by the English language, whether it has anything to do with integrity or science. Three of these are worth noting.

> employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.

It should be noted that of the three categories of government agents—Officers, Inferior Officers, and employees--the only one not authorized by the Constitution is the employee category. *See* Pendleton Act, 22 Stat. 403 (Jan. 16, 1883) (requiring employees to be selected based on merit rather than through patronage).

[6] In *Morrison v. Olson* , 487 U.S. 654 (1988), the Court held that Congress could provide tenure protections to certain Inferior Officers, such as an Independent Counsel, with narrowly defined duties. I am not aware of any such Inferior Officer within the Department of Health and Human Services.

1. Proposal Conflicts with Existing Law that Precludes Career Employees, Acting in their Official Capacities, from Expressing their Views Without Prior Approval

Under current law, employees of NIH, in their official capacities, are not permitted to express views publicly that have not been cleared by the appropriate official. This is a longstanding legislative rule across the federal bureaucracy. *See, e.g.,* 45 C.F.R. § 73.735-103; *Garcetti v. Ceballos*, 547 U.S. 410, 421 (2006) ("We hold that when public employees make statements pursuant to their official duties, the employees are not speaking as citizens for First Amendment purposes, and the Constitution does not insulate their communications from employer discipline."); *cf. Lane v. Franks*, 573 U.S. 228, 239 (2014) (speech fell outside normal duties and was therefore entitled to First Amendment protection). The proposed Policy (*i.e.,* "[e]nsure that covered individuals are free to express differing scientific opinions free from political interference or inappropriate influence") appears to be at odds with this legislative rule at § 73.735-103 and is therefore void *ab initio*. *See F.C.C. v. Fox Television Stations, Inc*., 556 U.S. 502, 515 (2009); *Berkovitz v. United States*, 486 U.S. 531 (1988) (HHS' agency is not free to ignore the Department's legislative rules); *Motor Vehicle Manufs. Ass'n v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29 (1983).

2. DEIA Has Nothing to Do With Either Science or Integrity and Is of Doubtful Constitutionality

The Policy states as follows:

> Diversity, equity, inclusion, and accessibility (DEIA) are integral components of the entire scientific process. Attention to DEIA can improve the success of the scientific workforce, foster innovation in the conduct and use of science, and provide for more equitable participation in science by diverse communities. The responsible and ethical conduct of research and other scientific activities requires an environment that is equitable, inclusive, safe, and free from harassment[.]

88 Fed. Reg. at 65,701 (col. a).

There is nothing to demonstrate that the first two sentences quoted above are true or in any way related to reality. The absence of a single study is telling. Indeed, the absence of any sound empirical linkage between "scientific integrity," as understood by those actually toiling in laboratories, and DEIA, suggests that including DEIA in the definition of "scientific integrity" represents a loss of scientific integrity and is inconsistent with the IQA, which among other things requires that policies and procedures "ensur[e] and maximize[e] the quality, objectivity, utility, and integrity of information[.]" § 515(a), 114 Stat. at 2763A–154. Here, the quality

and objectivity are at a nadir since nothing supports the proposed definition of "scientific integrity," other than pure ideology.

Moreover, DEIA is not mentioned in the IQA or The America COMPETES Reauthorization Act of 2010, § 103, as amended, Pub. L. No. 111–358, which is the primary statute authorizing the Director of OSTP and the various agencies to develop policies for the dissemination of scientific information. Those policies gave rise to the NIH Proposal, which is the subject of this Comment.

One cannot help but notice that the concept of DEIA as part of the "scientific process" and "scientific integrity" is itself an inappropriate effort to infuse a political agenda that is of questionable constitutionality into the "scientific process." The legal propriety of DEIA, as part of a government program, is in doubt in light of the Court's recent decisions involving affirmative action admissions policies. *See Students for Fair Admissions, Inc. v. President and Fellows of Harvard College*, ___U.S.___, No. 20-1199 (U.S. June 29, 2023). The scientific process is normally within the ambit of such thinkers as Francis Bacon and Karl Popper, neither of whom mentioned DEIA or even DEI in their writings and neither of whom received any mention in this Proposal.

3. Definition of "Science" Makes No Sense and Conflicts with the Department's Structure and Organization

The Proposal defines "science" as "the full spectrum of scientific endeavors, including basic science, applied science, evaluation, engineering, technology, economics, social sciences, and statistics, as well as the scientific and technical information derived from these endeavors." 88 Fed. Reg. at 65,699. Forget, for a moment, that this definition would cause Bacon, Popper, Hume, and Kuhn to roll over in their graves, and consider the practical ramifications. Under this definition, the Department's chief economist, namely the Assistant Secretary for Planning and Evaluation, would have to take a back seat to everyone at NIH when it comes to matters of economics.[7] This does not make a whit of sense.

This, of course, assumes that economics and the other social sciences are "sciences." Along those lines and under this Policy, a political scientist's views could not be affected by partisan politics, when in fact that is an aspect of political science. Indeed, the social sciences are so mushy and have such low replication rates, that crafting federal policy based solely on social science studies is a perilous

[7] "The Assistant Secretary for Planning and Evaluation (ASPE) is the principal advisor to the Secretary of the U.S. Department of Health and Human Services on policy development, and is responsible for major activities in policy coordination, legislation development, strategic planning, policy research, evaluation, and economic analysis." ASPE.HHS.GOV

undertaking. It is the job of the Secretary to synthesize a national policy based on all sources he or she deems relevant and to ignore or give significantly less weight to those viewed as problematic. This Policy seeks to improperly hobble the Secretary and other policymakers.

As an aside, many argue that theoretical statistics, in most respects, is not a science since, like mathematics, its propositions and theorems can be proved, *i.e.*, it is a "closed axiom-based system;" scientific theories, on the other hand, cannot be proved, only disproved, *i.e.*, science is an "open system." *See* Karl Popper, CONJECTURES AND REFUTATIONS: THE GROWTH OF SCIENTIFIC KNOWLEDGE 37 (5th ed. 1989) ("[T]he criterion of the scientific status of a theory is its falsifiability, or refutability, or testability"), as quoted by the Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593 (1993). And finally, engineering and science differ, at least according to the National Academy of Engineering which noted that a "scientist seeks to understand nature while the engineer seeks nature's modification." *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 148 (1999) (quoting from brief of the National Academy of Engineering).

Attempts to define "science" is a fool's errand. Great minds have for more than four centuries labored to articulate the concept with differing outcomes—most though are remarkably sophisticated. In contrast, the definition posited in the Federal Register notice would likely get a failing grade in a philosophy of science course—it is over-inclusive, never really defines "science," and instead is circular, *i.e.*, "the full spectrum of scientific endeavors."

III. Application of this Policy to the Extramural Program Would Run Afoul of the Administrative Procedure Act and Public Health Service Act

The Policy states that

> [w]hile the covered individuals for this policy consist primarily of NIH employees, the principles of scientific integrity are foundational to NIH's role in funding extramural biomedical research, and the importance of scientific integrity is integrated throughout all NIH does as a funder of biomedical research. As such, existing policies to maintain scientific integrity of extramural research will continue. More information about the NIH extramural research program can be found on the NIH OER website at https://grants.nih.gov/aboutoer/ intro2oer.htm.

88 Fed. Reg. at 65,700.

Any attempt to apply this HHS-internal Policy to the extramural community, as implied above, would run into two brick walls. First, an "extramural policy" made obligatory on grantees constitutes a legislative rule. A legislative rule is one that affects the rights or obligations of those outside government or limits the discretion

of those inside government. *See Am. Bus. Ass'n v. United States*, 627 F.2d 525, 529 (D.C. Cir. 1980). Legislative rules "are those that have the 'force and effect of law[.]'" *Perez v. Mortgage Bankers Assn*., 575 U. S. 92, ___ (2015) (slip op., at 2–3); *see* Robert Charrow, *This Word Salad Needs a Dressing*, YALE J. REG. (June 1, 2023).

Merely because an issuance is labeled as policy statement and not as legislative rule is not binding. *See Barrick Goldstrike Mines Inc. v. Browner*, 215 F.3d 45, 48 (D.C. Cir. 2000) (holding that an agency rule does not escape review under the APA merely because it is labeled an "informal" guideline); *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 384–85 (D.C. Cir. 2002) (holding that a purported Guidance Document was a legislative rule, not a policy statement, and thus reviewable); *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1322 (D.C. Cir. 1988) (holding that a purported interpretive rule was in fact a legislative rule and thus subject to review); *Novartis Pharm. Corp. v. Espinosa*, No. 21-cv-1479 (DLF), at *18 (D.D.C. Nov. 5, 2021) (holding that change in guidance document dictating terms of a standard contract is a substantive rule and that the agency lacked legislative rulemaking authority under the PHS Act).

Legislative rules can only issue through notice-and-comment rulemaking, formal rulemaking, or negotiated rulemaking. *See* 5 U.S.C. § 553(b) & (c) and § 561 et seq.*; see also e.g., Kisor v. Wilkie ,* 588 U.S. ____, ____, 139 S.Ct. 2400, 2420 (2019) ("[A] legislative rule, ... to be valid[,] must go through notice and comment"); *id. ,* at ____, 139 S.Ct., at 2434 (Gorsuch, J., concurring in judgment) (same); *Perez v. Mortgage Bankers Assn. ,* 575 U.S. 92, 96 (2015)*; cf. Azar v. Allina Health Services ,* 587 U.S. ____, ____, 139 S.Ct. 1804, 1808 (2019) (same with respect to similar procedures under the Medicare Act); *E.B. v. U.S. Dep't of State*, 583 F. Supp. 3d 58, 62 (D.D.C. 2022) ("The APA generally requires substantive rules to be promulgated through notice-and-comment rulemaking."). In short, legislative rules cannot be issued unilaterally, as here, through a set of guidelines or as policy statements.

Second, under Public Health Service Act § 202, the Secretary is expressly precluded from delegating "the making of regulations," and even if such delegation were permitted, it is unlikely that a non-PAS, such as the addressee of this Comment, could be the recipient of delegated legislative rulemaking authority.

Conclusion:

More than 30 years ago, a federal court in reviewing NIH's then-Office of Scientific Integrity, commented from the bench that its operations and procedures were "amateurish" and "embarrassing." *See* Robert Charrow, LAW IN THE LABORATORY 49 (U. Chicago Press, Chicago, Ill. 2010). NIH and OSTP should carefully assess whether those judicial comments apply to the current Proposal.

Sincerely,

Robert P. Charrow
Rcharrow@gmail.com
301-908-0424

Submit date: 10/17/2023

I am responding to this RFI: On behalf of myself

Name: Payson Sheets

Name of Organization: University of Colorado

Type of Organization: University

Role: Scientific researcher

Comment:

#4.I strongly support this section. We really need it. The future integrity of research requires it.

Submit date: 10/19/2023

I am responding to this RFI: On behalf of myself

Name: Ruqaiijah Yearby

Name of Organization: The Ohio State University

Type of Organization: University

Role: Scientific researcher

Comment:

I am writing about the prohibitions against political interference. Particularly, I suggest adding the word objectivity to the definition of political interference as a way to show how it connects to the problem of scientific integrity.

Below is my revised definition for political interference:

¡ Political interference is inappropriately shaping or interfering in the conduct, management, communication, or use of science for inappropriate partisan advantage or such that it undermines objectivity, impartiality, nonpartisanship, or professional judgement.

Email: yearby.1@osu.edu

Submit date: 10/23/2023

I am responding to this RFI: On behalf of myself

Name: William Bauza

Type of Organization: Professional org association

Role: Member of the public

Comment:

I'm a retired NY State retired 7th grade Middle Level Life Science teacher with both BS and MS in Sec Ed Bio from Buffalo State University. Raised, educated and

retired from NY State Public schools I'm grateful for the well-rounded, professional teachings I received. In today's world Science is less revered, respected or chosen as

a reference, a career, or positive influence. I was very disappointed when so many people avoided and belittled the COVID-19 pandemic: I spoke to clear misconceptions and

outright lies that continue today. I blame the prevalence and lack of policing by the social media, and the blind neglect of the undereducated. Therefore I am speaking positively for a leadership committee which reflects on recognized professional development and proven leadership in conversation and publication as you consider persons for the positions within and representing the NIH.

Scientific integrity is earned via rigorous education resulting in advanced degrees and evidence of continued study and involvement. The average layperson has no clue as to the challenging courses, lab experiences and self-control Science demands. There are great television programs available on PBS and cloud media, but those are selected by individual choice. To reach the masses we need more general exposure to combat ignorance/intolerance, to present and certify newly appointed leaders, to instill trust and the need for compliance. To protect the masses we need to monitor and eliminate the doomsday negativity of anti-establishment provocateurs, be it a president or the kid down the block on his tablet! I am an active member of the AAAS and the Union of Concerned Scientists, and retired member of the National Science Teachers' Association, the National Middle Level Science Teacher's Association, the NEA, AFT and New York State Teacher's Association.

Email: bauza2014@comcast.net

Submit date: 10/30/2023

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

Name: Stuart Buck

Name of Organization: Good Science Project

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Institutional official

Comment:

See attachment.

Uploaded File:

Comments-on-NIH-Integrity-Policy.docx

GOOD SCIENCE PROJECT

Introduction. We are pleased to submit these comments on the Draft Scientific Integrity Policy of the National Institutes of Health (NIH), particularly with regards to topics 1 and 3 (role and responsibilities for the NIH Scientific Integrity Officer and the Scientific Integrity Council).

NIH is to be applauded for its commitment to scientific integrity and reliability, and the Draft Scientific Integrity Policy takes an important step forward in establishing a new Scientific Integrity Official to have primary responsibility across NIH, along with the advice of a Scientific Integrity Council. These new offices will hopefully create more of a mechanism to ensure that scientific integrity is given its proper due.

Ensuring Accountability. The Draft Policy notes that there are already several NIH offices that adjudicate integrity issues "when an allegation or complaint is received," and that the new Scientific Integrity Official will help coordinate how NIH responds to "allegations to ensure effective oversight."

We believe that NIH should take one further step as to ensuring accountability: *Give the Scientific Integrity Official enough of a budget and staff to proactively look for research integrity issues, rather than merely reacting to allegations and complaints.*

The reason for this recommendation is straightforward: Problems with research integrity are *much more* prevalent than the rate of official allegations and complaints would suggest. In many cases, we will not find research integrity problems unless we look for them more proactively.

Think of the stakes for a trainee who suspects potential data fraud in a published article by a leading scholar in their field. All the incentives weigh strongly against making any such allegation. After all, making an allegation of fraud:

- Takes time away from your own research agenda and publications;
- Could create damaging controversy for your mentor(s), lab head, etc.;
- Could cause the leaders in your field to view you as a potential troublemaker rather than a scientist worth hiring; and,
- Could even lead to an expensive lawsuit for defamation.

By contrast, there are enormous incentives for academics to cheat:

- NIH hands out some $39 billion in external research funding a year

- Academics have jobs, tenure, and up to 100% salary support on the line
- Faking data is relatively easy, especially if no one is looking

Just by the balance of incentives here, there are definitely more research integrity issues than will be discovered by waiting for someone to put their own career on the line by filing an official complaint.

It should therefore be no surprise that some of the most dramatic instances of fraud have been found by anonymous Internet commenters, and often by people (such as Elizabeth Bik) who are unemployable in academia.

Consider the recent case of apparently fraudulent research in the Alzheimer's field.[1] The original 2006 article that has come into question[2] was supported by grants from the NIH to three of the authors, and has been cited more than "all but four other Alzheimer's basic research reports published since 2006." Independent investigators who reviewed the lead author's work (Sylvain Lesné) found reason to "cast doubt on hundreds of images, including more than 70 in Lesné's papers."

Notice that these potential integrity issues only came to light more than 15 years after the fact when PubPeer commenters noticed many cases of apparent image duplication. NIH program officers apparently never uncovered any problems via progress reports or any other mechanism for monitoring research output.

Nonetheless, Lesné has apparently received at least $8,762,207 in NIH support since 2008.[3] Even worse, as *Science* revealed, the very NIH program officer (Austin Yang) for Lesné's most recent R01 (which was awarded four months *after* NIH had been notified of research integrity issues) had literally been a co-author with Lesné on the apparently fraudulent 2006 article!

As this incident shows, substantial cases of fraud can contaminate an entire field of research for 15+ years, not only without anyone at NIH noticing, but with NIH continuing to send millions of dollars to the problematic researcher, even with one of his co-authors as the program officer for a major grant.

The NIH should look to the Center for Medicare and Medicaid Services, which devotes substantial resources to a Center for Program Integrity that *proactively* looks for signs of fraud, improper payments, etc. That is, the NIH Scientific Integrity Official should be given a staff and budget to proactively audit NIH-funded studies for signs of fraud, data manipulation, and other violations of research integrity. One-twentieth of one percent of NIH's overall budget would be a good starting point.

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[1] Charles Piller, "Blots on a Field?," *Science* (July 21, 2022), available at https://www.science.org/content/article/potential-fabrication-research-images-threatens-key-theory-alzheimers-disease.

[2] See Sylvain Lesné et al., "A specific amyloid-β protein assembly in the brain impairs memory," *Nature* 440 (2006): 352-357.

[3] See https://reporter.nih.gov/search/W9KkSxMJBU2WJkvp7N8SaA/projects.

Submit date: 11/1/2023

I am responding to this RFI: On behalf of myself

Name: jean publie

Name of Organization: american citizen

Type of Organization: Other

Type of Organization-Other: american citizen

Role: Member of the public

Comment:

rereach papers that have no scientifi.c integrity. we have a real problem here. american taxpayers already pay for several agenciesin the nih/cdc niahd to check on the work of researchers and see that it is accurate but apparntly they arent catching anything at all .we have a private org called retraction watch that needs to catch these cheats. why are taxpayers paying for non effective work. at the federal level

it appear to me that every single alleged research accomplishment needs to have an agency that is mandatorily required to check it out and verify that it has merit.

oviiously the taxpayers are gettign rotten work from the nih, cdc for the huge massive amounts of tax dollars we pay these cheats who put out rotten research.

it evidently takes 7years sometimes to catch these cheats and meanwhile ther is alot of bad rotten medicine that is going on based on not ctching research cheaters.

and we shoudl not re emplt=oy them when they are caught doing substandard work. they should be fired. go somewhere else than the federal govt to doyour work.taxpayes do not want to pay salaries to research cheats.the entire operation at the cdc nih is rotten tot he core and needs a criminal invstigqtion. criminal investition. none of them should get further grants when they have been caught cheating on research. research wacth cites several examples what are disgusting.

Email: jeanpublic1@gmail.com

Submit date: 11/2/2023

I am responding to this RFI: On behalf of myself

Name: Guido Frosina

Type of Organization: Nonprofit research organization

Role: Scientific researcher

Comment:

As for any human activity, behaviours deviating from the usual rules of ethics have always been present in Scientific Research. The current economic crisis with dropped resources for Science has led to an increase in these phenomena, periodically reported by the most important scientific journals. Why this happens is largely a matter of culture and education and once again school, university and family may exert a major role in educating young researchers to refrain from looking for shortcuts. However, many research institutions face this problem fearfully, in the concern that openly addressing cases of scientific malpractice may demotivate the public from donations. But in Scientific Research, the lack of transparency often creates more problems than it solves and hiding, or downsizing altered scientific practices may facilitate their spreading. An open discussion may witness the ability of Research institutions to honestly deal with these problems and warrant donors more transparent, fair and reliable Scientific Research. Eventually, the scientific community may only take advantage of openly opposing altered practices, without waiting for someone else to do it. It's excellence, not flaw.

This field is completely devoid of legislative instruments. There are no shared rules about what can or cannot be done from an ethical point of view in Scientific Research and this certainly fosters confusion.

This bill (which is in English because the problem is not limited to Italy) is based on a few simple principles aimed at increasing the transparency, fairness and reliability of Scientific Research:

Prevention of conflict of interest: those sitting on the evaluation board cannot participate in the competition [neither in person nor through their collaborators (who can be precisely defined)]. Peer evaluating is a mandatory task of any Research job and is subject to rotation.

Transparency and freedom of information: any administrative act of the Research institution (subject to the exceptions of the Law: e.g. sensitive data) must be readily and easily accessible to anyone.

Quality control: quality control of data, especially concerning ethical aspects, is to be performed by the affiliated Research institution besides Journal Editorial Boards. It might be wise for everybody to take care of a bit more of quality and a bit less of quantity.

Uploaded File:

021123-Proposed-law_Rules-on-the-integrity-of-Scientific-Research.pdf

Email: guidofrosina7@gmail.com

Proposed law – Sept 22, 2018 draft

RULES ON THE INTEGRITY OF SCIENTIFIC RESEARCH

Art. 1.

General principles and considerations

1. Reputation is of fundamental importance to any research institution from a legal, economic and social point of view. It translates into the consideration, trust and credibility that the institution emanates towards its employees, the scientific community of reference, and the public.

2. Conflict of interest is defined as the involvement and / or participation in the adoption of decisions in the field of scientific research that may involve one's own interests or interests of those with whom one has or has had a relationship of collaboration and / or habitual attendance. Interest may be of financial nature or not.

3. Freedom of information must be intended as total accessibility to any administrative act except those protected by EU and national regulations on sensitive data and ensured through the publication of all information relating to administrative procedures. Transparency has the aim of creating an open administration at the service of the citizen. It must guarantee the integrity and legality of the administrative action, making sure that the documents are correct and effective and that they can be widely used.

4. Scientific integrity is the pursuit of scientific knowledge in active adherence to the ethical principles, norms, and professional standards essential for the responsible practice of research. Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

5. The terms of this decree statute apply to all investigators of research institutions that receive any type of research support from the government.

Art 2.

Prevention of conflict of interest

1. Following the issuing of calls for research project grants or for research positions with tenure, boards of experts in the field of application of the call are established by the issuing research institution, independently of its legal status.
2. The boards referred to under paragraph 1 shall be made up of fifty percent members of domestic nationality and fifty percent members of foreign nationality.
3. The identity of board members referred to under paragraph 2 is disclosed in the call text.
4. The serving of board members referred to under paragraph 2 is remunerated.
5. Those who assume the functions of board member, at any level and for any type of call, must respect the principles of integrity and transparency, act in good faith, and refuse to serve or resign in the event of a conflict of interest.
6. The members of the selection board of experts or those who have been associated with them during the last five years cannot apply to the call (whether for research projects or for research positions). Recusing himself or herself from specific cases in which there is a conflict of interest (so-called "exit from the room") is not permitted.
7. The association of a proposing researcher / candidate with a board member is determined by the presence of the proponent / candidate and of the board member as co-authors in one or more scientific publications or by any other working relationship during the five years preceding the date of publication of the call. The following situations include examples of conflict of interest:

- The board member is named in the proposal in a major professional role.
- The board member has a direct financial interest: he/she or a close family member would receive a direct financial benefit if the proposal is approved.
- The board member is from an institution that is included as a subcomponent of the proposal.
- Within the past five years, the board member has been a collaborator (e.g. coauthor in scientific publications) or has had any other professional relationship (e.g., served as a mentor) with any person who has a major role in the proposal.
- The proposal includes a letter of support or recommendation letter from the board member.

- The board member has indirect financial interests: he/she has received more than € 2000 (in the form of honoraria, stocks or fees) from the Principal Investigator or any applying Institution in the previous 24 months

8. To ensure an adequate rotation, the board members referred to under paragraph 2 may exercise their function for a single selecting procedure (whether for research projects or for research positions) during a solar two years period.

9. Serving as a board member referred to under paragraph 2 is mandatory as it falls within the duties of the office. Its declining must be adequately justified. Impossibility to participate to the call on its own or through a collaborator is not a valid justification.

10. The rules of this article apply to every order and degree of scientific responsibility at the issuing research institution, except for the mere organizational functions.

Art. 3.

Obligations of the administrative director of the research institution and of the director of the research unit on transparency

1. The administrative director of the research institution is responsible for the completeness, clarity and updating of all published information.

2. The administrative director shall systematically monitor the fulfillment of the publication obligations.

3. To this end, the administrative director is obliged to collect observations from any interested person ["stakeholder" (call applicant or simple citizen)], on the usefulness and completeness of the published data. The administrative director checks the reliability and responds in writing to any comments and / or complaints within fifteen working days from receipt.

4. Each selecting procedure, both for the allocation of funding and for job positions must call for applications with the widest diffusion through IT (publication on the institutional website) and conventional (media) procedures.

5. Each selecting procedure, both for the allocation of funding and for job positions, must be eventually accompanied by the publication on the institutional website of detailed and exhaustive minutes of the adopted procedure and the criteria, parameters used, and

scores assigned to all applicants. To the results of those minutes' report, observations and / or appeals are allowed within the term of fifteen working days from the publication.

6. The administration of the research institution must respond to the submitted observations within fifteen working days from receipt. Until the publication of this reply, the results of the selecting procedure are suspended.

7. If the response is deemed insufficient, the observer may appeal second instance to the competent National Administrative Law Organs.

8. The non-publication or incomplete publication of the prescribed information causes the whole selecting procedure to be null and void, constitutes a violation of the research institute's quality standards and must be assessed as management responsibility.

9. If the administrative director ascertains facts that may present disciplinary relevance in terms of lack of transparency, he/she must promptly inform his hierarchical superior as well as the institutional disciplinary proceedings office.

10. The directors of the research units are responsible for fulfilling the transparency obligations for the administrative acts relating to their units.

11. The director of each research unit has full and exclusive responsibility for the accuracy, completeness and timeliness of the transmission of administrative data relating to his / her unit to the institutional administrative direction for the purpose of publication.

12. The lack of collaboration of the individual directors of research with the administrative management to the aim of administrative transparency, represents element of managerial responsibility according to the following art. 6.

Art 4.

Freedom of information

1. Anyone can submit a request to access information. The right to access information is unconditional and can be exercised without the need for motivation. Applicants should be able to access information free of charge.

2. The right to information applies to all documents, information or data that the public administrations are required to publish pursuant to EU and national regulations (e.g. the Italian Legislative Decree 14 March 2013, n. 33 and subsequent amendments), should they have failed to make them available on the institutional website.

3. The right to information applies to all documents relating to the administration of public funds at research institutions that receive such funds, including those involving investigations and data processing. In general, access to the categories of documents that allow punctual and general monitoring of the work of investigators at the research institution is permitted.

4. The sensitive data that may be present in the document must be treated according to the EU and national regulations (e.g. the Italian legislative decree 30 June 2003, n. 196).

5. Institutions must identify on their websites the person to whom request for access of information must be submitted. Requests must be answered within 30 working days from receipt by publishing the requested documents, information or data on the institutional website and transmitting copy of it to the applicant.

6. The administrative director of the research institution is responsible for ensure monitoring compliance with the provision of this section. Failure to comply in this regard will represent an element of managerial responsibility according to the following art. 6.

Art. 5

“Publish or Perish” and the reproducibility crisis

Scientific advances can only be based on robust and reliable data that may serve as a solid foundation on which further advances can be built. The scientific community is increasingly concerned with the proportion of published data that cannot be partially or totally reproduced in subsequent studies [*Kaiser, J., (2015) Science 348: 6242*].

Reproducibility of results is a pillar of the Scientific Method and its crisis in basic and translational research may be the result of failure to adhere to good scientific practice and the desperation to publish or perish. The issue is prevalent and of concern and must be monitored and addressed at the policy level [*Baker M. (2016) Nature, 533: 452*].

Researchers, in carrying out their activity, shall conform their conduct to the observance of the ethical regulations and to the international principles of scientific integrity, ensuring the reproducibility of the published data [*Munafò MR, Davey Smith G (2018) Nature. 553(7689):399-401*].

Misconducts related to principles referred to under paragraph 3 are regulated by the institutional Committee for the quality control of scientific research referred to in Article 6 [*Begley et al (2015) Nature 525, 23-27*].

Art. 6

Committee for the quality control of scientific research.

1. Each research institution must establish a Committee for the quality control of scientific research.
2. This Committee shall be comprised of three members, all of which must hold permanent research positions.
3. Member of the Committee are appointed by the Administrative Director in consultation with the heads of the departments. Members shall serve for a term of two calendar years. Their appointment can be renewed one time.
4. The main task of the committee is to verify the quality intended as compliance with ethical standards as well as reliability and reproducibility of scientific results published by investigators working at the research institution.
5. To this aim, the committee shall draw each calendar semester one sample article whose corresponding author is a scientist working at the research institution, published online or in print during the preceding 36 months.
6. The committee requests the corresponding author of the article the documentation concerning the raw experimental data from which the published scientific results were generated.
7. The quality control committee verifies the correctness of the elaboration of the published experimental data. In discharging this duty, the Committee may seek the assistance of external experts in the field of published research.
8. In case of suspicions of scientific misconduct, the Committee shall hold a hearing at which the corresponding author and / or one or more non-corresponding authors are offered an opportunity to address the Committee's concerns.
9. In the event the Committee concludes that scientific misconduct occurred, the Chair of the Committee must inform the journal where the data were published of its findings and must begin disciplinary proceedings against the corresponding author as well as other authors that, in the judgment of the Committee, engaged in scientific misconduct.

10. The disciplinary sanctions are graduated according to the entity and / or possible reiteration of non-compliance according to the following art. 7.

Art. 7.

Protection of whistleblowers and sanctions

1. Each employee, in relation to his / her duties, shall promptly report to his / her superior with respect to possible violations of this law and, in the event of supervisor's inaction protracted for a reasonable amount of time, shall inform to the senior managers in the hierarchical ladder. Whistleblowers shall be protected according to EU and national regulations (e.g. the Italian ANAC determination n. 6 of 28 April 2015).

2. Failure to comply with the terms of this law may result in invalidating previous appointments and the obligation to return research funds of the research institution as well legal responsibility under current to criminal, civil, or administrative laws. Sanctions shall be gradual and proportionate to the severity the violation.

Submit date: 11/3/2023

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

Name: Jeff Ruch

Name of Organization: Public Employees for Environmental Responsibility (PEER)

Type of Organization: Other

Type of Organization-Other: Public interest advocacy organization assisting government scientists

Role: Member of the public

Comment:

November 6, 2023

Tara A. Schwetz,

Acting Principal Deputy Director

National Institutes of Health

Attn: Scientific Integrity Comments

9000 Rockville Pike

Bethesda, Maryland 20892

Submitted electronically at https://osp.od.nih.gov/comment-form-draft-scientific-integrity-policy-for-the-national-institutes-of-health/.

RE: PEER Comments on draft Scientific Integrity Policy of the National Institutes of Health

Public Employees for Environmental Responsibility (PEER) wishes to express its profound disappointment with the provisions of the draft Scientific Integrity Policy of the National Institutes of Health (NIH) now available for public comment.

PEER has provided legal representation to federal scientist struggling with scientific integrity issues for more than 30 years. Our work help lay the foundation for the 2009 Obama Directive on Scientific Integrity. During the Obama presidency, PEER filed more complaints on behalf of scientists for violations of agency scientific integrity policies than any other organization.

Based upon this experience, PEER has provided the White House Office of Science &Technology Policy (OSTP) extensive feedback in its development of its Model Policy Framework. However, both the OSTP Model Policy and NIH draft policy continue exhibit the same fundamental weaknesses that led President Biden to issue his January 2021 Memorandum on Restoring Trust in Government through Scientific Integrity and Evidence Based Policymaking in the first place.

as President Biden pledged in his government-wide memorandum to public trust in the integrity of federal science. Unfortunately, based upon our analysis as detailed below, the proposed NIH policy will do almost nothing to accomplish this. Notably, the policy lacks fundamental safeguards against the suppression or political manipulation of science. It leaves key functions blank, such as how investigations of alleged scientific misconduct will be conducted, to be filled in later. Further, it lacks any protections for scientists who express dissenting scientific opinions or face reprisal due to the controversial implications of their research.

Significantly, the NIH draft policy uses the word "integrity" 152 times in its 33 pages of text but contains scant concrete provisions that would work to secure or promote scientific integrity.

PEER's comments address five gaps in NIH's draft policy:

I. Inappropriate, Inconsistent and Illegal Restrictions on Scientist Communications

II. No Process for Independent Investigation of Misconduct Allegations

III. Opaque Transparency Provisions Allow Suppression of Research

IV. No Meaningful Protections for Scientists Against Retaliation

V. Complete Lack of Accountability for Violators

Turning to each of these concerns in order:

I. Inappropriate, Inconsistent and Illegal Restrictions on Scientist Communications

A. Contradictory Language

The NIH draft declares that scientists may "express their personal views and opinions with appropriate written or oral disclaimers, including on social media" but then states that scientists "shall refrain from making or publishing statements that could be construed as being judgments of, or recommendations on, NIH or any other Federal Government policy…" (Emphasis added)

The draft policy makes no attempt to reconcile these two seemingly conflicting statements. Nor does, NIH identify what public policy is served by this poorly written sweeping restriction on scientist speech.

The fundamental sentiment behind this restriction seems to be that federal scientific research is fine if it does not ruffle any political feathers. NIH apparently fails to recognize that scientific research that carries policy implications is at the greatest risk of suppression or political manipulation – for precisely that reason – and, therefore, is in greater need for protection.

NIH should resolve this apparent contradiction. Optimally, NIH should completely discard this misguided prohibition against statements that "could be construed' as comments or recommendations on federal policies. In PEER's view, this language (underlined above) has no place in any agency scientific policy.

B. Conflicted Role

The NIH draft describes itself as a "Policy Development Agency" using the following language:

"NIH promotes progress in the biomedical research enterprise through the development of sound and comprehensive policies. To achieve this, NIH engages partners within and outside of NIH to develop policies on a wide range of issues including biosafety, biosecurity, genetic testing, genomic data sharing, human subjects protections, the organization and management of the NIH, and the outputs and value of NIH-funded research. This is accomplished through a wide range of analyses and reports, commentary on emerging policy proposals, and the development of policy proposals for consideration by NIH, the Federal Government, and the public."

It is unclear how NIH scientists can play a role in policy development across this broad range of topics without being able to make statements that "could be construed" as judgments on or recommendations about how policies should evolve.

C. Similar Provision Abused by U.S. Department of Agriculture

This provision is apparently based upon a similar provision in the U.S. Department of Agriculture's scientific integrity policy. On July 14, 2021, PEER wrote to OSTP specifically warning about this provision in the USDA policy. Unfortunately, our warning to OSTP was not heeded as it included this language in its "Model Scientific Integrity Policy" released this past January. Further, OSTP did not respond to a letter sent in April 2023 by PEER and more than a dozen public interest groups urging the removal of this language from the OSTP Model.

Among the reasons for these warnings was that USDA had used this provision as the basis for ordering a staff entomologist represented by PEER to remove his name from a peer-reviewed journal article on how monoculture farming reduces diversity in insect populations, limiting beneficial pollinators. This same provision of the USDA policy was also cited as the basis for barring this scientist from speaking at a conference about effects on pollinators from genetically modified crops and the insecticides used to treat them. He later resigned in frustration, convinced that he could no longer conduct meaningful research while employed at USDA.

In addition tp our entomologist client, PEER received reports from other USDA scientists that managers had initiated –

- Directives not to publish data on certain topics of particular sensitivity to industrial agricultural interests, such as pesticide manufacturers;

- Orders to rewrite scientific articles already accepted for publication in a peer-reviewed journal to remove sections which could provoke industry objections; and

- Inordinate, sometimes indefinite, delays in approving submission for publication of scientific papers that may be controversial with agricultural interests.

In short, this provision that NIH proposes to adopt was used, and is still being used, to pressure USDA scientists working on topics with direct relevance to industry interests not to do anything to upset important "stakeholders."

NIH should be aware that its adoption of such a far-reaching restriction is bound to create a chilling effect among scientists, just as it did at USDA. Rather than encouraging sharing of information by federal scientists it has – and continues to have – the opposite effect of constraining it.

D. Broad Chilling Effect – Dickey Amendment Amplified

In the 1997 federal omnibus spending bill, Congress inserted a rider, called The Dickey Amendment (named after its author Rep. Jay Dickey [R-AR] that provided "none of the funds made available for injury prevention and control at the Centers for Disease Control and Prevention & Prevention (CDC) may be used to advocate or promote gun control."

Although the Dickey Amendment did not explicitly prohibit research on gun violence, for nearly two decades the CDC avoided all research on gun violence for fear it would be financially penalized. Such research finally resumed after Congress narrowed the language and earmarked funding for gun violence research in the federal omnibus spending bill for FY2020.

The Dickey Amendment language was not nearly as broad as the language NIH proposes to insert in its Scientific Integrity Policy. The former language banned activity "to advocate or promote…" By contrast, the NIH draft language outlaws any statement "that may be construed as a judgment of, or recommendation on" any policy by any federal agency (not just NIH agencies) – a far more nebulous and potentially wide-ranging prohibition.

If the Dickey bar against blatant advocacy and promotion worked to effectively stifle research, our concern is that this more far-reaching NIH language could have a far more extensive chilling effect on research across an array of controversial subjects studied by NIH scientists. Under the broad draft language, it is not difficult to imagine many scenarios in which this provision could be used to threaten public scientists or stifle controversial research across a wide range of topics. For example, publicizing medical breakthroughs achieved in National Institutes of Health funded research using fetal tissues could be construed as a recommendation for HHS Secretary Becerra's recent actions to resume federal funding for research using fetal tissues.

Further, it is also quite possible the NIH language could spur self-imposed restrictions on gun violence research to avoid statements that could be construed as judgments on weak federal gun control policies.

E. Restriction Subject to Abuse – Especially with Change of Administration

While current NIH leadership may have no intention of applying this language in ways suggested above, it has no control over how a succeeding administration may use this prohibition. In other words, NIH should have had second thoughts about adopting language that a differently constituted administration could use to stifle research – all while claiming with a straight face that they are simply enforcing a Biden scientific integrity protection.

Consider the case of Dr. George Luber, an epidemiologist, who served as Chief of the Climate and Health Program at CDC. He had been the very public face of climate science at CDC, frequently appearing on TV news and speaking at professional conferences. He is the lead author of the Fourth National Climate Assessment's Chapter on Human Health, released in 2018 and was the lead author for a report the U.S. Supreme Court cited in its seminal 2007 ruling that greenhouse gases should be regulated under the Clean Air Act.

In February 2017, shortly after the Trump inauguration, CDC cancelled, over his objections, a symposium Dr. Luber was slated to host featuring Al Gore. He was then directed to stop using the phrase "climate change" and forbidden from responding to any further media or congressional inquiries.

In March 2018, CDC revoked his badge, phone, and credentials, placing him on a BOLO (be on the lookout) list as a security risk, barring him from entering the facility except under armed guard and with prior approval, and then only to retrieve materials. Every time he went to his office, Dr. Luber and his car were thoroughly searched in front of his colleagues.

In a letter dated October 22, 2018, CDC Environmental Health Center Director Patrick Breysse (the same official who ordered Dr. Luber to stop using the term "climate change") proposed his removal based upon an alleged failure to obtain permission to author a 2015 book, give lectures at Emory University, and more than 30 other charges. Had the NIH policy been in place at CDC, Dr. Luber could also have been charged with lectures and writing that could easily be construed as judgments on the effects of several federal policies, including those related to the release of greenhouse gases.

This proposed action was withdrawn after a reporter for the New York Times called to inquire about it. PEER later successfully negotiated an outplacement for Dr. Luber so that he is able to continue his research free from the constraints CDC wished to impose. The point of this episode is to underline how quickly political strictures can be placed upon scientists, even those within agencies such as CDC.

The many other attempts to stifle science during the Trump tenure need not be recounted here , except to note that they were the basis for President Biden declaring that the Obama-era scientific integrity policies obviously did not work to prevent these abuses and must be strengthened. Above all, NIH must act to strengthen its Scientific Integrity Policy, not weaken it.

F. Unconstitutional As Applied to Scientists' Personal Statements

This provision could be used to violate a government scientist's First Amendment right to speak freely in their capacity as citizens on matters of public concern. In addition, this provision can be used to prevent agency scientists, as well as private scientists collaborating with or contracting with a federal agency, from even discussing the policy implications of vital research.

The First Amendment is not absolute, however, and courts apply a balancing test that weighs the public importance of the speech versus any potential disruption of efficient government operations. Such a calculus should weigh heavily in favor of the public interest value of research conducted by a federal government scientist against potential embarrassment to a government agency.

Significantly, one of the stated aims of the NIH draft policy is to promote a free and open exchange of scientific information. Yet, this poorly worded, overly broad provision clearly does the opposite.

II. No Process for Independent Investigation of Misconduct Allegations

Under the NIH draft policy, the key official reviewing allegations of scientific misconduct or lack of integrity will be an official known as the Scientific Integrity Officer or SIO. Among the key responsibilities of this position are to "Lead the review and adjudication of allegations of loss of NIH scientific integrity (particularly related to political interference) in cases where such allegations fall outside of existing processes…"

A. No Independence

The draft policy designates the Associate Director of Science Policy to serve as the NIH SIO. The draft policy further declares:

"This policy empowers the NIH SIO with the independence necessary to gather and protect information to support the review and assessment of scientific integrity concerns."

The NIH SIO reports directly to the NIH Chief Scientist. The only provision in the draft policy addressing SIO independence reads –

"Consistent with applicable law, an SIO or other scientific integrity staff may not be terminated or reassigned without good cause or legitimate organizational reason. Possible good cause reasons include, but are not limited to, consistent poor performance, inefficiency, neglect of duty, malfeasance, conviction of a felony, conduct involving moral turpitude, knowing violation of a law, rule, or regulation, gross mismanagement, gross waste of funds, and abuse of authority…"

While it is of scant comfort that NIH will accord its designated SIOs "all applicable employee rights as required by law," that is hardly an assurance that they are independent or will exercise judgment independent of their superiors, particularly on matters of political sensitivity. Further, the notion that an SIO may be removed for an unspecified "legitimate organizational reason" apart from good cause underlines the political vulnerability of the occupants of this pivotal post.

More importantly, this supposed safeguard overlooks the greater likelihood that SIOs will act to do anything possible to avoid situations that could trigger official reprisal. In PEER's experience, we have seen several examples of SIOs dismissing valid complaints, declining to investigate complaints restricting the scope of investigations when they occur, or shielding political appointees.

In PEER's experience, senior civil servants occupying positions such as Associate Director are often unwilling to take actions that will hinder their later career ascension or success. Acting to confirm a scandal within agency ranks or leadership, especially by political appointees, is usually not a path for career advancement.

An example of the type of political interference that can hinder an SIO's work can be found in PEER's representation of an SIO who was removed after pursuing a complaint against the staff of the Secretary of Interior.

In short, it is simply not credible for a system designed to ensure integrity to depend almost entirely on an official designated by the top officials he is supposed to investigate. It is certainly not an arrangement that would restore public trust in the credibility of NIH science. Rather than relying solely on one senior official to make all of these decisions, NIH should consider using panels of outside experts to make or confirm sensitive judgments about the loss of scientific integrity.

B. No Procedures for Investigation and Adjudication

It is somewhat surprising that neither current NIH policies or this draft policy specify how allegations of misconduct in its intramural program are to be investigated and adjudicated. Instead, the NIH policy declares an intention to develop such policies:

"NIH is firmly committed to establishing and formalizing procedures to identify and adjudicate allegations regarding compromised scientific processes or technological information."

Further, NIH is proposing no process for how these policies will be developed but instead the policy provides it will "Ensure that the NIH SIO or other NIH entities draft procedures, as needed, to respond to allegations of loss of scientific integrity in a timely, objective, and thorough manner." This language suggests that the SIO is free to make up rules in an ad hoc fashion "as needed."

The complete absence of these procedures is particularly surprising for an intramural program that the draft describes as "the largest biomedical research program on earth."

Further, the SIO is confined to matters that fall outside the "existing processes managed by the Office 11 of Extramural Research (OER), the Office of Intramural Research (OIR), the Office of Management

Analysis (OMA), and the HHS Office of the Inspector General (OIG)." By law, the OIG jurisdiction is not limited, thus it is unclear what matters the SIO can address that are outside the purview of the OIG.

C. Murky Path to Appeal

The NIH policy states "The complainant and respondent will be given the opportunity to appeal a finding or any corrective scientific actions taken."

The draft does not specify to whom an aggrieved party may appeal or what procedures govern this appeal. Nor is there a firm timetable for the promulgation of these procedures. Further, it appears that these procedures will be developed without any further input or review from the public, employee unions, or anyone else.

Under current scientific integrity policies, when an SIO arbitrarily dismisses or derails a complaint, there is little recourse provided. Similarly, it is not clear whether NIH SIO findings that no investigation is warranted will be appealable.

Despite claiming that these eventual procedures to ensure the redress of deviations from scientific integrity will occur "in a timely, objective, and thorough manner" the genesis of this draft policy does not bode well for the timeliness or thoroughness of the promised final rule. Since the final NIH rules are a largely unfinished work in progress, their own ultimate objectivity and integrity remain to be seen.

D. No Transparency

The closest the NIH policy comes to specificity about investigations is the following passage:

"Should an investigation be opened, an investigation committee consisting of the NIH SIO and other agency integrity officials from the NIH Scientific Integrity Council will be convened to develop a factual record by exploring the allegation(s) in detail and consulting with subject matter experts, interviewing witnesses, and reviewing documentation as needed. Once the investigation is complete, the NIH SIO will determine whether scientific integrity was lost and report findings to the appropriate management entity."

The draft policy charges the Council with overseeing investigations, while providing little detail on how these investigations will function. The pertinent provision of the draft policy reads –

"Should an investigation be opened, an investigation committee consisting of the HHS SIO and at least two other Scientific Integrity Council members, or their delegates, will be convened. The committee will develop a factual record by exploring the allegation(s) in detail and consulting with subject matter experts, interviewing witnesses, and reviewing documentation as needed. This record will be documented in a report from the committee to the SIO."

There is no provision that this report of investigation be made publicly available. To the contrary, the draft policy suggests that NIH will take steps to cloak the specifics of cases from public view:

"As part of the monitoring and evaluation plan, an annual report on the number and outcomes of investigations involving allegations of loss of scientific integrity will be published. To the extent possible, all descriptions of investigations will be anonymized." (Emphasis added)

It is not clear on what basis such a report could be withheld from release under the Freedom of Information Act. In the past, PEER has successfully used to FOIA to force release of such reports over agency objections.

More significantly, President Biden's directive that started this process had the words "Restoring Trust in Government Through Scientific Integrity" in its title. It is hard to argue that releasing only after-the-fact summaries that have been "anonymized" to be devoid of any detail will restore public trust in the integrity of federal science. Public credibility in the integrity of federal science requires a degree of transparency that this draft policy sorely lacks.

III. Opaque Transparency Provisions Allow Suppression of Research

The NIH draft defines "Interference" to include "suppression" of "scientific or technological findings, data, information, or conclusions." Yet the draft policy does not specify how it will prevent such suppression.

The draft makes reference to the "NIH-wide Policy for Manuscript and Abstract Clearance Procedures" but these procedures contain no timeline for clearance, not criteria for denying clearance, and no appeal where clearance is denied. Rather it merely specifies the form to use when applying for publication clearance.

Instead, as with investigations of alleged misconduct, NIH's draft only pledges to develop "technical review and clearance processes include provisions for timely clearance and expressly forbid censorship, unreasonable delay, and suppression of objective communication of data and results without scientific, legal, or security justification."

Again, there is no timeline for the promulgation of these processes or any indication as to who develops these clearance provisions. Nor does the draft policy –

- Define what is meant by “timely clearance” or what constitutes impermissible delay:

- Specify what is a legitimate basis for “technical review”; or

- Indicate if there is any avenue of appeal to speed up an untimely clearance process.

As outlined above, the NIH draft policy appears to invite managers to screen potential publications to ensure that they contain no statements that can be construed as judgements on or recommendations about any federal policy. Depending on the topic, such a review may take weeks and involve considerable internal debate.

The draft policy further indicates that “Violations of clearance policies that result in suppression, delay, or alteration of scientific and technological information produced by NIH scientists without scientific, legal, or security justification constitute violations of the NIH Scientific Integrity Policy and may be reported under the procedures for Addressing Scientific Integrity Concerns.”

However, since clearance policies are not specified, it is unclear what constitutes a “Violation of clearance policies.” Moreover, this remedy requires a formal complaint that may ultimately be referred for resolution back to the very officials who are obstructing its clearance for publication in the first place.

Thus, despite all the rhetoric in the NIH draft about promoting “timely publication” and “sharing” of scientific data, there is nothing the policy that ensures those goals are met or that victimized scientists have any realistic recourse.

IV. No Meaningful Protections for Scientists Against Retaliation

The NIH draft contains some language suggesting that scientists should not be subject to retaliation, but the language merely restates current law. For example, the draft states:

“[I]t is unlawful for NIH to take or threaten to take a personnel action against an employee because he or she made a protected disclosure of wrongdoing. A protected disclosure is defined as a disclosure of information that the individual reasonably believes is evidence of a violation of law, rule, or regulation; gross mismanagement; gross waste of funds; and abuse of authority; or a substantial and specific danger to public health or safety.”

That is merely a restatement of the Whistleblower Protection Act (WPA) – a statute that NIH has no power to modify. As such, the draft offers no additional safeguards beyond what NIH is statutorily required to do anyway.

Similarly, the draft declares a policy of protecting those who are involved with scientific integrity allegations, with this language –

"Protect from reprisal those individuals who report allegations of loss of scientific integrity in good faith. Efforts will also be made to protect from inappropriate actions those covered individuals alleged to have compromised scientific integrity."

First, it is curious that the NIH drafters are express equal concern about protecting those accused of scientific misconduct as about protecting those who disclose the misconduct. Nor are the promised protections for the accused delineated.

Second, the purported protection from reprisal is limited to those "who report allegations of loss of scientific integrity in good faith." However, those who file these reports already have legal protection through the WPA which already covers employee disclosures of any violation of agency rules, and a scientific integrity policy would be such a rule. Thus, scientists who file scientific misconduct/integrity complaints are disclosing an alleged violation of a rule and, for that reason, already have whistleblower status. In this regard, PEER has successfully represented scientists who suffered reprisal after filing these complaints before the Office of Special Counsel (OSC) on the basis that filing that complaint entitled that person whistleblower protection.

However, the 2009 Obama Scientific Integrity Directive called for "additional" expanded whistleblower protections or procedures to prevent retaliation against or suppression of scientific work due to its policy, economic, or political implications. This part of Obama's directive was largely ignored or given lip service by both the OSTP and federal agencies during the intervening years -- and is not addressed at all in the NIH draft.

The WPA does not protect scientists who are not whistleblowers yet who are suffering retaliation or obstruction for pursuing research on controversial matters or publishing research that does not support an agency position.

Nor does the WPA shield scientists who face blowback after expressing a differing professional opinion – an option explicitly endorsed by the NIH draft policy. Notably the NIH draft posits a goal to "Ensure that covered individuals are free to express differing scientific opinions free from political interference or inappropriate influence." It further declares a policy to "Prevent NIH employees from intimidating or coercing NIH scientists to alter scientific data, findings, or professional opinions."

However, the draft does not specify through what mechanism those goals will be achieved. In discussing differing scientific opinions, the draft states –

"In some cases, such as when a scientific dispute has a significant impact on public health or policy, a formal scientific dispute resolution process may be necessary."

Yet, it does not indicate what that formal dispute resolution process is or who administers it other than noting that the "NIH SIO may be consulted if their assistance is requested…"

In short, President Obama's promise of "additional" protections for scientists who face reprisals due to the substance or content of their research findings will remain unfulfilled by the proposed NIH policy.

Protection of whistleblowers required the enactment of a law. The ideal solution would be for Congress to enact a Scientist Protection Act which would provide protections that are enforceable against the Executive Branch in court, in the same manner that, for example, the WPA is enforced.

In the absence of a new statute, there is an administrative path to address enforcement of scientific integrity policies. Apart from protecting whistleblowers, OSC has very broad but little used jurisdiction under 5 USC § 1216:

"(a) In addition to the authority otherwise provided in this chapter, the Special Counsel shall, except as provided in subsection (b), conduct an investigation of any allegation concerning . . . (4) activities prohibited by any civil service law, rule, or regulation, including any activity relating to political intrusion in personnel decision making." (Emphasis added.)

For example, OSC uses this authority to take action to remedy and prevent discrimination on the basis of sexual orientation in the federal workplace by enforcing an executive order to that effect. Similarly, OSC could extend protection to scientists if they were covered by an executive directive to that effect, or a directive from a Cabinet Secretary, such as the HHS Secretary.

PEER urges that NIH policy be amended to fill this scientist protection vacuum so that its scientists have some legal protection from official reprisal due to the content of their research or the unwelcome implications flowing from it. Safeguarding these emerging inconvenient truths should be central to any scientific integrity policy.

V. Complete Lack of Accountability for Violators

The NIH draft provides that the cure to the loss of scientific integrity would be a "corrective action" which it defines as follows:

"Corrective scientific action refers to actions taken to restore the accuracy of the scientific record after a loss of scientific integrity has been determined, consistent with this policy, such as correction or retraction of published materials. In addition to scientific actions, administrative actions may also be taken in response to substantiated violations of this policy."

Administrative action appears to be synonymous with disciplinary action, such as demotion, suspension, involuntary transfer, up to termination.

In a significant gap, the draft does not specify whose role it is to ensure that appropriate corrective scientific and/or administrative actions are taken as a result of investigative findings. PEER has seen cases where a presidential appointee has failed to take any action despite review panels who have found a favored manager guilty of serious and deliberate misconduct.

A. No Assurance of Consistency in Penalties

Nor does the draft specify what penalty applies to what type of violation or a repeat violation. Thus, there is no guardrail to assure consistent application of sanctions.

B. No Punishment for Political Appointees

A major anomaly in these policies supposedly aimed at curbing political manipulation of government science is the lack of clear application to political appointees. It is political appointees, after all, who presumably are a major source for politically motivated misconduct.

Political appointees, however, are beyond the reach of the civil service disciplinary process. They are only answerable to the political official who appointed them. To the extent that the official is acting to further the agency's political agenda, it is unlikely that person will face any punishment and, in fact, may even be promoted.

In 2021, when a member of the White House staff was reported to have engaged in threatening behavior, President Biden immediately had that official removed. The White House also issued a statement indicating zero tolerance for acts of incivility by its staff.

The NIH draft purports to cover political appointees but lacks a similar zero tolerance policy that any political appointee found guilty of scientific misconduct (or the loss of scientific integrity) should be removed from federal service.

Further, when an SIO or review panel determines that a political appointee has engaged in scientific misconduct or caused the loss of scientific integrity, the policy should provide the identity of that official should be reported by the Secretary to the White House and that report should be publicly displayed on the agency website.

Conclusion

For the reasons articulated above, PEER believes that the draft NIH scientific integrity policy fails to meet the standards that President Biden laid out in his Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking of January 27, 2021. We urge that NIH withdraw this draft and rework it to include –

- A guarantee that scientists may freely discuss and write about the possible implications of their research;

- Transparent procedures for independent investigation of allegations, as well as public review of investigatory results and corrective action decisions;

- Clear written policies delineating any clearance procedures for scientists to publish, lecture, or communicate with the media and public about their areas of expertise, including practical and timely enforcement of those guarantees;

- Protections for scientists from retaliation for the content or implications of their research and for scientists who express scientific dissent; and

- Rule providing for consistent penalties for those who violate scientific integrity prohibitions, including provisions for holding political appointees accountable.

We believe that these elements should be the bedrock of any federal scientific integrity policy, but unfortunately, they are largely absent from this NIH draft.

Sincerely,

Jeff Ruch

Pacific Director

Public Employees for Environmental Responsibility (PEER)

Uploaded File:

PEER-comments-on-NIH-Draft-Scientific-Integrity-Policy-11-6-23.pdf

PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY
962 Wayne Ave • Suite 610 • Silver Spring, MD 20910

November 6, 2023

Tara A. Schwetz,
Acting Principal Deputy Director
National Institutes of Health
Attn: Scientific Integrity Comments
9000 Rockville Pike
Bethesda, Maryland 20892

Submitted electronically at *https://osp.od.nih.gov/comment-form-draft-scientific-integrity-policy-for-the-national-institutes-of-health/*.

RE: PEER Comments on draft Scientific Integrity Policy of the National Institutes of Health

Public Employees for Environmental Responsibility (PEER) wishes to express its profound disappointment with the provisions of the draft Scientific Integrity Policy of the National Institutes of Health (NIH) now available for public comment.

PEER has provided legal representation to federal scientist struggling with scientific integrity issues for more than 30 years. Our work help lay the foundation for the 2009 Obama Directive on Scientific Integrity.[1] During the Obama presidency, PEER filed more complaints on behalf of scientists for violations of agency scientific integrity policies than any other organization.

Based upon this experience, PEER has provided the White House Office of Science &Technology Policy (OSTP) extensive feedback in its development of its Model Policy Framework. However, both the OSTP Model Policy and NIH draft policy continue exhibit the same fundamental weaknesses that led President Biden to issue his January 2021 Memorandum on Restoring Trust in Government through Scientific Integrity and Evidence Based Policymaking[2] in the first place.

as President Biden pledged in his government-wide memorandum to public trust in the integrity of federal science. Unfortunately, based upon our analysis as detailed below, the proposed NIH policy will do almost nothing to accomplish this. Notably, the policy lacks fundamental safeguards against the suppression or political manipulation of science. It leaves key functions blank, such as how investigations of alleged scientific misconduct will be conducted, to be filled in later. Further, it lacks any protections for scientists who express dissenting scientific opinions or face reprisal due to the controversial implications of their research.

Significantly, the NIH draft policy uses the word “integrity” 152 times in its 33 pages of text but

[1] Memorandum for the Heads of Executive Departments and Agencies 3-9-09 | whitehouse.gov (archives.gov)
[2] Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking | The White House

contains scant concrete provisions that would work to secure or promote scientific integrity.

PEER's comments address five gaps in NIH's draft policy:

I. Inappropriate, Inconsistent and Illegal Restrictions on Scientist Communications
II. No Process for Independent Investigation of Misconduct Allegations
III. Opaque Transparency Provisions Allow Suppression of Research
IV. No Meaningful Protections for Scientists Against Retaliation
V. Complete Lack of Accountability for Violators

Turning to each of these concerns in order:

I. Inappropriate, Inconsistent and Illegal Restrictions on Scientist Communications

A. Contradictory Language

The NIH draft declares that scientists may "express their personal views and opinions with appropriate written or oral disclaimers, including on social media" but then states that scientists "shall refrain from making or publishing statements that could be construed as being judgments of, or recommendations on, NIH or any other Federal Government policy…" (Emphasis added)

The draft policy makes no attempt to reconcile these two seemingly conflicting statements. Nor does, NIH identify what public policy is served by this poorly written sweeping restriction on scientist speech.

The fundamental sentiment behind this restriction seems to be that federal scientific research is fine if it does not ruffle any political feathers. NIH apparently fails to recognize that scientific research that carries policy implications is at the greatest risk of suppression or political manipulation – for precisely that reason – and, therefore, is in greater need for protection.

NIH should resolve this apparent contradiction. Optimally, NIH should completely discard this misguided prohibition against statements that "could be construed' as comments or recommendations on federal policies. In PEER's view, this language (underlined above) has no place in any agency scientific policy**.**

B. Conflicted Role

The NIH draft describes itself as a "Policy Development Agency" using the following language:

> "NIH promotes progress in the biomedical research enterprise through the development of sound and comprehensive policies. To achieve this, NIH engages partners within and outside of NIH to develop policies on a wide range of issues including biosafety, biosecurity, genetic testing, genomic data sharing, human subjects protections, the organization and management of the NIH, and the outputs and value of NIH-funded research. This is accomplished through a wide range of analyses and reports, commentary on emerging policy proposals, and the development of policy proposals for consideration by NIH, the Federal Government, and the public."

It is unclear how NIH scientists can play a role in policy development across this broad range of topics without being able to make statements that "could be construed" as judgments on or recommendations about how policies should evolve.

C. Similar Provision Abused by U.S. Department of Agriculture

This provision is apparently based upon a similar provision in the U.S. Department of Agriculture's scientific integrity policy.[3] On July 14, 2021, PEER wrote to OSTP specifically warning about this provision in the USDA policy.[4] Unfortunately, our warning to OSTP was not heeded as it included this language in its "Model Scientific Integrity Policy" released this past January.[5] Further, OSTP did not respond to a letter sent in April 2023 by PEER and more than a dozen public interest groups urging the removal of this language from the OSTP Model.[6]

Among the reasons for these warnings was that USDA had used this provision as the basis for ordering a staff entomologist represented by PEER to remove his name from a peer-reviewed journal article on how monoculture farming reduces diversity in insect populations, limiting beneficial pollinators. This same provision of the USDA policy was also cited as the basis for barring this scientist from speaking at a conference about effects on pollinators from genetically modified crops and the insecticides used to treat them. He later resigned in frustration, convinced that he could no longer conduct meaningful research while employed at USDA.

In addition tp our entomologist client, PEER received reports from other USDA scientists that managers had initiated –

- Directives not to publish data on certain topics of particular sensitivity to industrial agricultural interests, such as pesticide manufacturers;

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In short, this provision that NIH proposes to adopt was used, and is still being used, to pressure USDA scientists working on topics with direct relevance to industry interests not to do anything to upset important "stakeholders."

NIH should be aware that its adoption of such a far-reaching restriction is bound to create a chilling effect among scientists, just as it did at USDA. Rather than encouraging sharing of information by federal scientists it has – and continues to have – the opposite effect of constraining it.

D. Broad Chilling Effect – Dickey Amendment Amplified

[3] See USDA DR/1074-001, Sec.6(e)1)c1
[4] https://peer.org/wp-content/uploads/2021/07/7_14_21-SI-Should-Not-Vary-from-Agency-to-Agency.pdf
[5] https://peer.org/ostp-slips-gag-rule-into-model-scientific-integrity-policy/
[6] https://peer.org/wp-content/uploads/2023/04/Organization_Letter_Scientific_Integrity_Framework.pdf

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If the Dickey bar against blatant advocacy and promotion worked to effectively stifle research, our concern is that this more far-reaching NIH language could have a far more extensive chilling effect on research across an array of controversial subjects studied by NIH scientists. Under the broad draft language, it is not difficult to imagine many scenarios in which this provision could be used to threaten public scientists or stifle controversial research across a wide range of topics. For example, publicizing medical breakthroughs achieved in National Institutes of Health funded research using fetal tissues *could be construed as* a recommendation for HHS Secretary Becerra's recent actions to resume federal funding for research using fetal tissues.[9]

Further, it is also quite possible the NIH language could spur self-imposed restrictions on gun violence research to avoid statements that *could be construed* as judgments on weak federal gun control policies.

E. Restriction Subject to Abuse – Especially with Change of Administration

While current NIH leadership may have no intention of applying this language in ways suggested above, it has no control over how a succeeding administration may use this prohibition. In other words, NIH should have had second thoughts about adopting language that a differently constituted administration could use to stifle research – all while claiming with a straight face that they are simply enforcing a Biden scientific integrity protection.

Consider the case of Dr. George Luber, an epidemiologist, who served as Chief of the Climate and Health Program at CDC. He had been the very public face of climate science at CDC, frequently appearing on TV news and speaking at professional conferences. He is the lead author of the Fourth National Climate Assessment's Chapter on Human Health, released in 2018 and was the lead author for a report the U.S. Supreme Court cited in its seminal 2007 ruling that greenhouse gases should be regulated under the Clean Air Act.

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[7] https://www.govinfo.gov/content/pkg/PLAW-104publ208/pdf/PLAW-104publ208.pdf
[8] https://www.nature.com/articles/d41586-019-03882-w
[9] https://www.npr.org/2021/04/16/988221424/heres-what-you-should-know-about-bidens-new-rules-for-fetal-tissue-research

In February 2017, shortly after the Trump inauguration, CDC cancelled, over his objections, a symposium Dr. Luber was slated to host featuring Al Gore. He was then directed to stop using the phrase "climate change" and forbidden from responding to any further media or congressional inquiries.

In March 2018, CDC revoked his badge, phone, and credentials, placing him on a BOLO (be on the lookout) list as a security risk, barring him from entering the facility except under armed guard and with prior approval, and then only to retrieve materials. Every time he went to his office, Dr. Luber and his car were thoroughly searched in front of his colleagues.[10]

In a letter dated October 22, 2018, CDC Environmental Health Center Director Patrick Breysse (the same official who ordered Dr. Luber to stop using the term "climate change") proposed his removal based upon an alleged failure to obtain permission to author a 2015 book, give lectures at Emory University, and more than 30 other charges. Had the NIH policy been in place at CDC, Dr. Luber could also have been charged with lectures and writing that could easily be construed as judgments on the effects of several federal policies, including those related to the release of greenhouse gases.

This proposed action was withdrawn after a reporter for the *New York Times* called to inquire about it. PEER later successfully negotiated an outplacement for Dr. Luber so that he is able to continue his research free from the constraints CDC wished to impose. The point of this episode is to underline how quickly political strictures can be placed upon scientists, even those within agencies such as CDC.

The many other attempts to stifle science during the Trump tenure need not be recounted here[11], except to note that they were the basis for President Biden declaring that the Obama-era scientific integrity policies obviously did not work to prevent these abuses and must be strengthened. Above all, NIH must act to strengthen its Scientific Integrity Policy, not weaken it.

F. Unconstitutional As Applied to Scientists' Personal Statements

This provision could be used to violate a government scientist's First Amendment right to speak freely in their capacity as citizens on matters of public concern.[12] In addition, this provision can be used to prevent agency scientists, as well as private scientists collaborating with or contracting with a federal agency, from even discussing the policy implications of vital research.

The First Amendment is not absolute, however, and courts apply a balancing test that weighs the public importance of the speech versus any potential disruption of efficient government operations.[13] Such a calculus should weigh heavily in favor of the public interest value of research conducted by a federal government scientist against potential embarrassment to a government agency.

[10] https://peer.org/persecution-of-top-federal-climate-scientist/
[11] https://www.scientificamerican.com/article/what-you-know-about-trumps-assault-on-science-was-just-the-tip-of-the-iceberg/
[12] See https://peer.org/usda-sued-to-end-scientific-censorship/
[13] See Pickering v. Board of Education, 391 U.S. 563 (1968)

Significantly, one of the stated aims of the NIH draft policy is to promote a free and open exchange of scientific information. Yet, this poorly worded, overly broad provision clearly does the opposite.

II. No Process for Independent Investigation of Misconduct Allegations

Under the NIH draft policy, the key official reviewing allegations of scientific misconduct or lack of integrity will be an official known as the Scientific Integrity Officer or SIO. Among the key responsibilities of this position are to "Lead the review and adjudication of allegations of loss of NIH scientific integrity (particularly related to political interference) in cases where such allegations fall outside of existing processes…"

A. No Independence

The draft policy designates the Associate Director of Science Policy to serve as the NIH SIO. The draft policy further declares:

> "This policy empowers the NIH SIO with the independence necessary to gather and protect information to support the review and assessment of scientific integrity concerns."

The NIH SIO reports directly to the NIH Chief Scientist. The only provision in the draft policy addressing SIO independence reads –

> "Consistent with applicable law, an SIO or other scientific integrity staff may not be terminated or reassigned without good cause or legitimate organizational reason. Possible good cause reasons include, but are not limited to, consistent poor performance, inefficiency, neglect of duty, malfeasance, conviction of a felony, conduct involving moral turpitude, knowing violation of a law, rule, or regulation, gross mismanagement, gross waste of funds, and abuse of authority…"

While it is of scant comfort that NIH will accord its designated SIOs "all applicable employee rights as required by law," that is hardly an assurance that they are independent or will exercise judgment independent of their superiors, particularly on matters of political sensitivity. Further, the notion that an SIO may be removed for an unspecified "legitimate organizational reason" apart from good cause underlines the political vulnerability of the occupants of this pivotal post.

More importantly, this supposed safeguard overlooks the greater likelihood that SIOs will act to do anything possible to avoid situations that could trigger official reprisal. In PEER's experience, we have seen several examples of SIOs dismissing valid complaints, declining to investigate complaints restricting the scope of investigations when they occur, or shielding political appointees.[14]

In PEER's experience, senior civil servants occupying positions such as Associate Director are often unwilling to take actions that will hinder their later career ascension or success. Acting to confirm a scandal within agency ranks or leadership, especially by political appointees, is usually not a path for career advancement.

[14] https://peer.org/can-biden-science-task-force-break-old-bad-habits/

An example of the type of political interference that can hinder an SIO's work can be found in PEER's representation of an SIO who was removed after pursuing a complaint against the staff of the Secretary of Interior.[15]

In short, it is simply not credible for a system designed to ensure integrity to depend almost entirely on an official designated by the top officials he is supposed to investigate. It is certainly not an arrangement that would restore public trust in the credibility of NIH science. Rather than relying solely on one senior official to make all of these decisions, NIH should consider using panels of outside experts to make or confirm sensitive judgments about the loss of scientific integrity.

B. No Procedures for Investigation and Adjudication

It is somewhat surprising that neither current NIH policies[16] or this draft policy specify how allegations of misconduct in its intramural program are to be investigated and adjudicated. Instead, the NIH policy declares an intention to develop such policies:

> "NIH is firmly committed to establishing and formalizing procedures to identify and adjudicate allegations regarding compromised scientific processes or technological information."

Further, NIH is proposing no process for how these policies will be developed but instead the policy provides it will "Ensure that the NIH SIO or other NIH entities draft procedures, as needed, to respond to allegations of loss of scientific integrity in a timely, objective, and thorough manner." This language suggests that the SIO is free to make up rules in an *ad hoc* fashion "as needed."

The complete absence of these procedures is particularly surprising for an intramural program that the draft describes as "the largest biomedical research program on earth."

Further, the SIO is confined to matters that fall outside the "existing processes managed by the Office 11 of Extramural Research (OER), the Office of Intramural Research (OIR), the Office of Management Analysis (OMA), and the HHS Office of the Inspector General (OIG)." By law, the OIG jurisdiction is not limited, thus it is unclear what matters the SIO can address that are outside the purview of the OIG.

C. Murky Path to Appeal

The NIH policy states "The complainant and respondent will be given the opportunity to appeal a finding or any corrective scientific actions taken."

The draft does not specify to whom an aggrieved party may appeal or what procedures govern this appeal. Nor is there a firm timetable for the promulgation of these procedures. Further, it appears that these procedures will be developed without any further input or review from the public, employee unions, or anyone else.

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[15] https://peer.org/scientific-whistleblower-complaint-resolved/

[16] The NIH draft policy references the 2022 update to the NIH Policies and Procedures for Promoting Scientific Integrity. This update, however, does not contain any investigatory or adjudication procedures.

Under current scientific integrity policies, when an SIO arbitrarily dismisses or derails a complaint, there is little recourse provided. Similarly, it is not clear whether NIH SIO findings that no investigation is warranted will be appealable.

Despite claiming that these eventual procedures to ensure the redress of deviations from scientific integrity will occur "in a timely, objective, and thorough manner" the genesis of this draft policy does not bode well for the timeliness or thoroughness of the promised final rule. Since the final NIH rules are a largely unfinished work in progress, their own ultimate objectivity and integrity remain to be seen.

D. ***No Transparency***

The closest the NIH policy comes to specificity about investigations is the following passage:

> "Should an investigation be opened, an investigation committee consisting of the NIH SIO and other agency integrity officials from the NIH Scientific Integrity Council will be convened to develop a factual record by exploring the allegation(s) in detail and consulting with subject matter experts, interviewing witnesses, and reviewing documentation as needed. Once the investigation is complete, the NIH SIO will determine whether scientific integrity was lost and report findings to the appropriate management entity."

The draft policy charges the Council with overseeing investigations, while providing little detail on how these investigations will function. The pertinent provision of the draft policy reads –

> "Should an investigation be opened, an investigation committee consisting of the HHS SIO and at least two other Scientific Integrity Council members, or their delegates, will be convened. The committee will develop a factual record by exploring the allegation(s) in detail and consulting with subject matter experts, interviewing witnesses, and reviewing documentation as needed. This record will be documented in a report from the committee to the SIO."

There is no provision that this report of investigation be made publicly available. To the contrary, the draft policy suggests that NIH will take steps to cloak the specifics of cases from public view:

> "As part of the monitoring and evaluation plan, an annual report on the number and outcomes of investigations involving allegations of loss of scientific integrity will be published. To the extent possible, all descriptions of investigations will be anonymized." (Emphasis added)

It is not clear on what basis such a report could be withheld from release under the Freedom of Information Act. In the past, PEER has successfully used to FOIA to force release of such reports over agency objections.[17]

[17] See https://peer.org/senior-officials-skewed-science-to-benefit-xl-pipeline/

More significantly, President Biden's directive that started this process had the words "Restoring Trust in Government Through Scientific Integrity" in its title. It is hard to argue that releasing only after-the-fact summaries that have been "anonymized" to be devoid of any detail will restore public trust in the integrity of federal science. Public credibility in the integrity of federal science requires a degree of transparency that this draft policy sorely lacks.

III. Opaque Transparency Provisions Allow Suppression of Research

The NIH draft defines "Interference" to include "suppression" of "scientific or technological findings, data, information, or conclusions." Yet the draft policy does not specify how it will prevent such suppression.

The draft makes reference to the "NIH-wide Policy for Manuscript and Abstract Clearance Procedures" but these procedures contain no timeline for clearance, not criteria for denying clearance, and no appeal where clearance is denied. Rather it merely specifies the form to use when applying for publication clearance.

Instead, as with investigations of alleged misconduct, NIH's draft only pledges to develop "technical review and clearance processes include provisions for timely clearance and expressly forbid censorship, unreasonable delay, and suppression of objective communication of data and results without scientific, legal, or security justification."

Again, there is no timeline for the promulgation of these processes or any indication as to who develops these clearance provisions. Nor does the draft policy –

- Define what is meant by "timely clearance" or what constitutes impermissible delay:
- Specify what is a legitimate basis for "technical review"; or
- Indicate if there is any avenue of appeal to speed up an untimely clearance process.

As outlined above, the NIH draft policy appears to invite managers to screen potential publications to ensure that they contain no statements that can be construed as judgements on or recommendations about any federal policy. Depending on the topic, such a review may take weeks and involve considerable internal debate.

The draft policy further indicates that "Violations of clearance policies that result in suppression, delay, or alteration of scientific and technological information produced by NIH scientists without scientific, legal, or security justification constitute violations of the NIH Scientific Integrity Policy and may be reported under the procedures for Addressing Scientific Integrity Concerns."

However, since clearance policies are not specified, it is unclear what constitutes a "Violation of clearance policies." Moreover, this remedy requires a formal complaint that may ultimately be referred for resolution back to the very officials who are obstructing its clearance for publication in the first place.

Thus, despite all the rhetoric in the NIH draft about promoting "timely publication" and "sharing" of scientific data, there is nothing the policy that ensures those goals are met or that victimized scientists have any realistic recourse.

IV. No Meaningful Protections for Scientists Against Retaliation

The NIH draft contains some language suggesting that scientists should not be subject to retaliation, but the language merely restates current law. For example, the draft states:

> "[I]t is unlawful for NIH to take or threaten to take a personnel action against an employee because he or she made a protected disclosure of wrongdoing. A protected disclosure is defined as a disclosure of information that the individual reasonably believes is evidence of a violation of law, rule, or regulation; gross mismanagement; gross waste of funds; and abuse of authority; or a substantial and specific danger to public health or safety."

That is merely a restatement of the Whistleblower Protection Act (WPA) – a statute that NIH has no power to modify. As such, the draft offers no additional safeguards beyond what NIH is statutorily required to do anyway.

Similarly, the draft declares a policy of protecting those who are involved with scientific integrity allegations, with this language –

> "Protect from reprisal those individuals who report allegations of loss of scientific integrity in good faith. Efforts will also be made to protect from inappropriate actions those covered individuals alleged to have compromised scientific integrity."

First, it is curious that the NIH drafters are express equal concern about protecting those accused of scientific misconduct as about protecting those who disclose the misconduct. Nor are the promised protections for the accused delineated.

Second, the purported protection from reprisal is limited to those "who report allegations of loss of scientific integrity in good faith." However, those who file these reports already have legal protection through the WPA which already covers employee disclosures of any violation of agency rules, and a scientific integrity policy would be such a rule. Thus, scientists who file scientific misconduct/integrity complaints are disclosing an alleged violation of a rule and, for that reason, already have whistleblower status. In this regard, PEER has successfully represented scientists who suffered reprisal after filing these complaints before the Office of Special Counsel (OSC) on the basis that filing that complaint entitled that person whistleblower protection.[18]

However, the 2009 Obama Scientific Integrity Directive called for "additional" expanded whistleblower protections or procedures to prevent retaliation against or suppression of scientific work due to its policy, economic, or political implications. This part of Obama's directive was largely ignored or given lip service by both the OSTP and federal agencies during the intervening years[19] -- and is not addressed at all in the NIH draft.

[18] See https://www.peer.org/scientific-whistleblower-complaint-resolved/
[19] See https://www.peer.org/whistleblower-protections-for-scientists-sidelined/

The WPA does not protect scientists who are not whistleblowers yet who are suffering retaliation or obstruction for pursuing research on controversial matters or publishing research that does not support an agency position.

Nor does the WPA shield scientists who face blowback after expressing a differing professional opinion – an option explicitly endorsed by the NIH draft policy.[20] Notably the NIH draft posits a goal to "Ensure that covered individuals are free to express differing scientific opinions free from political interference or inappropriate influence." It further declares a policy to "Prevent NIH employees from intimidating or coercing NIH scientists to alter scientific data, findings, or professional opinions."

However, the draft does not specify through what mechanism those goals will be achieved. In discussing differing scientific opinions, the draft states –

> "In some cases, such as when a scientific dispute has a significant impact on public health or policy, a formal scientific dispute resolution process may be necessary."

Yet, it does not indicate what that formal dispute resolution process is or who administers it other than noting that the "NIH SIO may be consulted if their assistance is requested…"

In short, President Obama's promise of "additional" protections for scientists who face reprisals due to the substance or content of their research findings will remain unfulfilled by the proposed NIH policy.

Protection of whistleblowers required the enactment of a law. The ideal solution would be for Congress to enact a Scientist Protection Act which would provide protections that are enforceable against the Executive Branch in court, in the same manner that, for example, the WPA is enforced.[21]

In the absence of a new statute, there is an administrative path to address enforcement of scientific integrity policies. Apart from protecting whistleblowers, OSC has very broad but little used jurisdiction under 5 USC § 1216:

> "(a) In addition to the authority otherwise provided in this chapter, the Special Counsel shall, except as provided in subsection (b), conduct an investigation of any allegation concerning . . . (4) activities prohibited by any civil service law, rule, or regulation, including any activity relating to political intrusion in personnel decision making." (Emphasis added.)

For example, OSC uses this authority to take action to remedy and prevent discrimination on the basis of sexual orientation in the federal workplace by enforcing an executive order to that effect.[22] Similarly, OSC could extend protection to scientists if they were covered by an

[20] For example, EPA's SIP Sec. IV declares that the agency "welcomes differing views and opinions on scientific and technical matters…"

[21] PEER has proposed such a statute that would protect those who participate in the peer review process either as authors or reviewers. See https://www.peer.org/federal-scientists-face-official-barriers-in-publishing/

[22] https://www.eeoc.gov/mou/memorandum-understanding-between-us-office-special-counsel-and-equal-employment-opportunity

executive directive to that effect, or a directive from a Cabinet Secretary, such as the HHS Secretary.

PEER urges that NIH policy be amended to fill this scientist protection vacuum so that its scientists have some legal protection from official reprisal due to the content of their research or the unwelcome implications flowing from it. Safeguarding these emerging inconvenient truths should be central to any scientific integrity policy.

V. Complete Lack of Accountability for Violators

The NIH draft provides that the cure to the loss of scientific integrity would be a "corrective action" which it defines as follows:

> "Corrective scientific action refers to actions taken to restore the accuracy of the scientific record after a loss of scientific integrity has been determined, consistent with this policy, such as correction or retraction of published materials. In addition to scientific actions, administrative actions may also be taken in response to substantiated violations of this policy."

Administrative action appears to be synonymous with disciplinary action, such as demotion, suspension, involuntary transfer, up to termination.

In a significant gap, the draft does not specify whose role it is to ensure that appropriate corrective scientific and/or administrative actions are taken as a result of investigative findings. PEER has seen cases where a presidential appointee has failed to take any action despite review panels who have found a favored manager guilty of serious and deliberate misconduct.[23]

A. No Assurance of Consistency in Penalties

Nor does the draft specify what penalty applies to what type of violation or a repeat violation. Thus, there is no guardrail to assure consistent application of sanctions.

B. No Punishment for Political Appointees

A major anomaly in these policies supposedly aimed at curbing political manipulation of government science is the lack of clear application to political appointees. It is political appointees, after all, who presumably are a major source for politically motivated misconduct.[24]

Political appointees, however, are beyond the reach of the civil service disciplinary process. They are only answerable to the political official who appointed them. To the extent that the official is acting to further the agency's political agenda, it is unlikely that person will face any punishment and, in fact, may even be promoted.

[23] See https://peer.org/fish-and-wildlife-service-sued-over-scientific-fraud-documents/
[24] See, *e.g.*, https://www.peer.org/scientific-fraud-infests-fish-and-wildlife-service-top-ranks/

In 2021, when a member of the White House staff was reported to have engaged in threatening behavior, President Biden immediately had that official removed.[25] The White House also issued a statement indicating zero tolerance for acts of incivility by its staff.

The NIH draft purports to cover political appointees but lacks a similar zero tolerance policy that any political appointee found guilty of scientific misconduct (or the loss of scientific integrity) should be removed from federal service.

Further, when an SIO or review panel determines that a political appointee has engaged in scientific misconduct or caused the loss of scientific integrity, the policy should provide the identity of that official should be reported by the Secretary to the White House and that report should be publicly displayed on the agency website.

Conclusion

For the reasons articulated above, PEER believes that the draft NIH scientific integrity policy fails to meet the standards that President Biden laid out in his Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking of January 27, 2021. We urge that NIH withdraw this draft and rework it to include --

- A guarantee that scientists may freely discuss and write about the possible implications of their research;

- Transparent procedures for independent investigation of allegations, as well as public review of investigatory results and corrective action decisions;

- Clear written policies delineating any clearance procedures for scientists to publish, lecture, or communicate with the media and public about their areas of expertise, including practical and timely enforcement of those guarantees;

- Protections for scientists from retaliation for the content or implications of their research and for scientists who express scientific dissent; and

- Rule providing for consistent penalties for those who violate scientific integrity prohibitions, including provisions for holding political appointees accountable.

We believe that these elements should be the bedrock of any federal scientific integrity policy, but unfortunately, they are largely absent from this NIH draft.

Sincerely,

Jeff Ruch

[25] https://thehill.com/homenews/administration/538788-white-house-press-aide-resigns-after-threatening-politico-reporter

Pacific Director
Public Employees for Environmental Responsibility (PEER)

Submit date: 11/5/2023

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

Name: AAMC

Name of Organization: Association of American Medical Colleges

Type of Organization: Professional org association

Role: Institutional official

Comment:

Uploaded File:

AAMC-Comments-on-NIH-draft-scientific-integrity-policy.pdf

Description: AAMC Comments on NIH Draft Scientific Integrity Policy

AAMC

Association of
American Medical Colleges
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400 F 202 828 1125
www.aamc.org

November 3, 2023

NIH Office of Science Policy
9000 Rockville Pike
Bethesda, Maryland 20892

Re: Request for Information on the DRAFT Scientific Integrity Policy of the National Institutes of Health (88 FR 65696)

Submitted electronically at https://osp.od.nih.gov/comment-form-draft-scientific-integrity-policy-for-the-national-institutes-of-health/.

The Association of American Medical Colleges (AAMC) appreciates the opportunity to provide feedback to the National Institutes of Health (NIH) on the agency's draft scientific integrity policy.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers.

The AAMC strongly supports the effort led by the White House Office of Science and Technology Policy (OSTP) to strengthen, institutionalize, and implement scientific integrity policies across the federal government and the release of a framework[1] to inform the development of these policies and

[1] A Framework for Federal Scientific Integrity Policy and Practice. Guidance by the Scientific Integrity Framework Interagency Working Group of the National Science and Technology Council. January 2023. https://www.whitehouse.gov/wp-content/uploads/2023/01/01-2023-Framework-for-Federal-Scientific-Integrity-Policy-and-Practice.pdf

practices at the agency level. As AAMC previously noted in joint comments[2] to inform OSTP's work, "Protecting the integrity of science and ensuring the use of evidence in policymaking should be a national priority across administrations."

AAMC recently commented on the HHS draft scientific policy[3] and appreciates NIH's engagement of the scientific community as it also develops a scientific integrity policy based on the OSTP framework. The importance of having formalized scientific integrity policies across the federal government, and particularly for NIH, comes at a critical juncture. Public trust in science, and relatedly, the use of scientific evidence to inform public health recommendations, has been shaken by anti-science rhetoric, a lack of transparency, and questions about the validity of science conducted and supported by the federal government. Nowhere was this more evident than in the challenges experienced during the COVID-19 pandemic, which included vaccine hesitancy and a surge of dissemination of misinformation regarding viruses and immunity and scientific research. As we have seen, public attitudes toward science impact not only the federal government, but the whole of the scientific community and enterprise, including the nation's ability to effectively respond to ever greater health threats.

Overall, we are very encouraged by the draft policy that has been proposed by NIH and the detailed requirements that the agency has set forth. We are strongly in agreement that preserving scientific integrity across the federal government will be dependent on strong policies which are frequently reviewed, updated as needed, and closely monitored for effectiveness as well as compliance.

In particular, we appreciate that the agency has specifically designated responsibilities for a Chief Scientist (CS), Scientific Integrity Official (SIO) and Scientific Integrity Council to formalize and ensure policy adherence and implementation. We note that the CS and SIO roles have been assigned to existing leadership positions at NIH which are already responsible for extremely sizeable portfolios and recommend that NIH consider closely the resourcing and staffing needed to successfully execute the policy.

We would also like to reiterate our previous comments[2] on the importance of evaluation as NIH undertakes the policy development process: "Strengthening policies on scientific integrity is a good start, but ensuring that these policies are adhered to, and evaluating outcomes from their implementation, should be a key part of the process to improve scientific integrity."

We appreciate that NIH intends to regularly evaluate the policy and develop and implement a monitoring and evaluation plan to better understand ongoing scientific integrity activities and outcomes. We strongly encourage the agency to amend this draft so that the final policy includes

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[2] AAAS, AAMC, AAU, APLU, and COGR Letter to the White House Office of Science and Technology Policy re: Request for Information to Improve Federal Scientific Integrity Policies (86 FR 34064). July 27, 2021. https://www.aamc.org/media/55711/download?attachment.

[3] AAMC Letter to HHS re: Request for Comments on the Draft HHS Scientific Integrity Policy (88 FR 46802). Sept. 1, 2023. https://www.aamc.org/media/69396/download?attachment

additional detail on what measures will be collected and reported under this plan, to increase transparency and provide assurance that the scientific integrity policy is achieving the intended outcomes. We also recommend that any proposals to amend the policy involve an opportunity for community input, whether through town halls, webinars, or more formal requests for information. We are very appreciative of the work NIH has undertaken to formalize a scientific integrity policy. The AAMC looks forward to continued engagement with NIH as the policy is finalized and implemented. Please feel free to contact me or my colleague Anurupa Dev, PhD, Director of Science Policy and Strategy (adev@aamc.org) with any questions about these comments.

Sincerely,

Heather H. Pierce, JD, MPH
Acting Chief Scientific Officer
Senior Director for Science Policy and Regulatory Counsel

cc: David J. Skorton, MD, AAMC President and Chief Executive Officer

Submit date: 11/6/2023

I am responding to this RFI: On behalf of myself

Name: Nick Felker

Type of Organization: Other

Role: Member of the public

Comment:

Dear NIH,

I am writing to express my strong support for the draft Scientific Integrity Policy and to encourage the inclusion of specific provisions that promote the use of open-source software (OSS) in biomedical research. OSS has emerged as a powerful tool for ensuring the reproducibility and integrity of scientific research. By making research code openly accessible, OSS allows for independent scrutiny, replication, and extension of research findings. This transparency is essential for building trust in scientific results and fostering a culture of open collaboration.

In the context of biomedical research, OSS can play a critical role in addressing the growing concerns about p-hacking, a questionable research practice that involves manipulating data or statistical analyses to produce statistically significant results. OSS can help to mitigate p-hacking by making it easier for researchers to share and validate their code, allowing others to assess the robustness of their findings.

Furthermore, OSS can encourage a more exploratory and data-driven approach to research by facilitating the development and sharing of novel analytical methods and tools. By providing access to a vast repository of open-source code, researchers can easily experiment with different data analysis techniques, including randomization and simulation, to gain a deeper understanding of their data and generate more robust conclusions.

In addition to its benefits for scientific integrity, OSS also promotes efficiency and innovation in biomedical research. By eliminating the need to repeatedly reinvent the wheel, OSS allows researchers to focus on the core scientific questions rather than spending time and resources developing custom software tools. This can accelerate the pace of research and lead to new breakthroughs.

Therefore, I strongly urge the NIH to explicitly endorse the use of OSS in biomedical research and to provide incentives for researchers to adopt open-source practices. This can be achieved by requiring researchers to share their code as a condition of funding, providing training and support for OSS development, and recognizing the value of OSS contributions in promotion and tenure decisions.

By embracing OSS, the NIH can play a leading role in fostering a more transparent, reproducible, and innovative biomedical research ecosystem. This will ultimately benefit the scientific community and the public at large.

Thank you for your consideration.

Email: nickfelker@gmail.com

Submit date: 11/7/2023

I am responding to this RFI: On behalf of myself

Name: Madison Carolyn Feehan

Name of Organization: Space Copy / Moon Trades / NASA

Type of Organization: Other

Type of Organization-Other: Small Business / Private Organization

Role: Member of the public

Comment:

Good Day:

I am responding to this request for comment for the Draft NIH Scientific Integrity Policy on behalf of topic area 2: Role and Responsibilities of the NIH Chief Scientist (CS).

All comments are my own personal opinion based on the merit of the Draft Policy in which I have reviewed. Please find my attached PDF. Thank you for your time and consideration.

Sincerely,

Madison C. Feehan

madisonfeehan@shaw.ca

Uploaded File: Feedback-Comments-For-The-2023-Updated-Scientific-Integrity-Policy-of-the-National-Institutes-of-Health-NIH-Topic-Area-2_-Role-and-Responsibilities-of-the-NIH-Chief-Scientist-CS-.pdf

Description: Feedback Comments For The 2023 Updated Scientific Integrity Policy of the National Institutes of Health (NIH) - Topic Area #2 Role and Responsibilities of the NIH Chief Scientist (CS)

Email: mailto:madisonfeehan@shaw.ca

Feedback Comments For The 2023 Updated Scientific Integrity Policy of the National Institutes of Health (NIH)

Topic Area #2: Role and Responsibilities of the NIH Chief Scientist (CS)

Author Contact Information:

Ms Madison C. Feehan; B.Com; COO & Founder, Space Copy; CFO & Founder, Moon Trades; NASA NSPIRES, Executive Panelist; UN COPUOS GEGSLA, Panelist, NASA LSIC, Member; Women In Aerospace Canada, Member; ESA, Data Analyst;
+1-(780)-488-9780; madisonfeehan@shaw.ca

Foreword:

The purpose of this document is to provide constructive feedback for the *National Institute of Health (NIH)* on behalf of their open call for comments on the form: *Draft Scientific Integrity Policy*, namely, the role of: *Chief Scientist (CS)*, which is described in the following capacity:

"Provides oversight of all NIH scientific integrity policies and procedures.
NIH recognizes organizational culture starts with leadership at the highest levels. It has designated the NIH Principal Deputy Director as the NIH CS."

I am specifically soliciting these comments on behalf of myself for topic areas two: *Role and Responsibilities of the NIH Chief Scientist (CS)*. The document I am referencing can be found by visiting this page:
https://osp.od.nih.gov/wp-content/uploads/2023/09/Draft_SI_Policy.pdf

Thank you for your consideration of my input.

Comments:

The provided guidelines on page 10 of the draft document appear to clearly outline the management of scientific integrity within the National Institutes of Health (NIH) and the roles and responsibilities of the Chief Scientist (CS).

1. Oversight of Scientific Integrity Policies:

- Feedback: Providing oversight of NIH scientific integrity policies and procedures is a crucial responsibility. Periodic updates are necessary to keep policies aligned with evolving best practices and ethical standards.

- Recommendation: Ensure that the oversight process includes regular reviews by external experts or an independent committee to maintain objectivity and transparency in policy updates. Encourage stakeholder engagement and feedback when revising policies.

2. Engage in Diversity, Equity, and Inclusion (DEI), and Accessibility Efforts:

- Feedback: Addressing diversity, equity, inclusion, and accessibility is essential for ensuring the fairness and inclusivity of scientific processes within NIH.

- Recommendation: Promote specific initiatives and metrics to track progress in DEI and accessibility efforts with regularly generated reports. Foster collaboration with external organizations and encourage researchers to benefit from a broader range of perspectives and experiences by conducting outreach events. Communicating regular updates and exploring new policies through workshops, webinars and events with the greater science community to showcase NIH's efforts would also be intrinsic to maintaining a standard of high scientific integrity.

3. Resourcing and Staffing Needs:

- Feedback: Adequate resources and staffing are vital for the effective operation of the scientific integrity program.

- Recommendation: Develop a transparent budgeting and resource allocation process that ensures sufficient funds and personnel for the program. Regularly assess the workload and staffing needs to adapt to changing demands.

4. Promote Scientific Integrity:

- Feedback: Promoting scientific integrity across the agency is a commendable goal, as it helps create a culture of trust and ethical conduct.

- Recommendation: Implement a comprehensive training program to educate NIH staff about scientific integrity principles and the consequences of misconduct. Encourage leadership at all levels to lead by example in upholding these principles. The role of Chief Scientist will be geared towards upholding and maintaining these standards for the long-term, therefore it is crucial to appoint the role to an individual of both high scientific caliber and strong professional ethics.

5. Serve as an Alternate in Adjudication:

- Feedback: Having a backup option in the event of an alleged violation by the NIH SIO is a prudent measure to ensure impartiality.

- Recommendation: Clearly define the selection and roles of alternates in the adjudication process. Ensure that alternates are independent and impartial, possibly from outside the agency, to avoid conflicts of interest. Long-term appointments should be decided by a member-wide voting process.

Overall, these guidelines serve as critical performance indicators for maintaining scientific integrity within NIH. To enhance their effectiveness, it's crucial to ensure transparency, accountability, and the inclusion of diverse perspectives. Additionally, regularly evaluating and adapting these guidelines in response to changing scientific and ethical standards is essential for continued success. The draft guidelines cover these fundamental concepts, though it is critical to ensure that there is no ambiguity in the manner of which these proposed guidelines are enforced and monitored.

Submit date: 11/7/2023

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

Name: Roi Turalde

Name of Organization: American Association of Colleges of Osteopathic Medicine (AACOM)

Type of Organization: Professional org association

Role: Member of the public

Comment:

On behalf of the American Association of Colleges of Osteopathic Medicine (AACOM), please find attached our comments regarding aspect #5, specifically on Federal Advisory Committees (FACs).

Uploaded File:

AACOM-Response-to-Draft-Scientific-Integrity-Policy-of-the-NIH-RFI.pdf

Description: AACOM Response to Draft Scientific Integrity Policy of the NIH RFI

Email: rturalde@AACOM.org

AACOM
American Association of Colleges of Osteopathic Medicine

November 9, 2023

Tyrone Spady, Ph.D.,
Director of the Science Policy Coordination, Collaboration & Reporting Division
Office of Science Policy
National Institutes of Health
6705 Rockledge Drive, Suite 630
Bethesda, MD 20892

Re: Request for Information on the National Institutes of Health DRAFT Scientific Integrity Policy

Dear Dr. Spady,

On behalf of the American Association of Colleges of Osteopathic Medicine (AACOM), thank you for the opportunity to comment and provide feedback on the National Institutes of Health (NIH)'s DRAFT NIH Scientific Integrity Policy. AACOM supports the NIH's goal of promoting a culture of scientific integrity and establishing a diverse and equitable environment that fosters scientific innovation.

AACOM believes that the physicians and scientists trained at our nation's colleges of osteopathic medicine (COMs) play an important role in growing this enhanced community. We stand ready to work with you and your colleagues to explore methods that will strengthen scientific integrity and advance NIH research.

Increasing Osteopathic Representation on NIH Federal Advisory Committees

The NIH policy states that Federal Advisory Committees (FACs) are needed "for ensuring the credibility, quality, and transparency of NIH science." AACOM agrees with that position and is committed to assisting NIH in "select[ing] members to serve on scientific and technical FACs based on expertise, knowledge and contribution to the relevant subject area." **We believe that this goal can be achieved by greater representation from the osteopathic profession.**

Although COMs comprise one quarter of all medical schools, they are severely underrepresented on NIH scientific review groups, advisory councils, and Boards of Scientific Counselors compared to allopathic researchers. **There is not a single DO among the 3,233 grant reviewing study section members, compared to 493 MDs**. Similarly, **DOs hold only 2 out of the 462 positions on NIH National Advisory Councils, whereas MDs account for 213 spots**. **Only 1 DO sits on an NIH Board of Scientific Counselors**. In fact, DOs have lower than 1 percent representation in critical positions within NIH despite representing twenty-five percent of all medical students.

AACOM
American Association of Colleges of Osteopathic Medicine

Osteopathic researchers are committed to furthering clinical research that can be used to enhance life and reduce illness and disability. However, these researchers face challenges that limit their ability to fully contribute to the NIH scientific community. These barriers stifle clinical research, especially in fields such as primary care, non-prescription treatments for pain management, chronic disease and elderly care, and treatment of rural and underserved populations.

The underrepresentation results in a substantial gap in access to research funding. Currently, **COMs receive only 0.1 percent ($60.2 million) of all NIH grant funding**.[1] On the other hand, allopathic medical schools receive 42 percent ($25.11 billion) of the NIH's $59.27 billion research budget.[2] This disparity in funding for COMs frustrates osteopathic medical research and puts our medical students at a disadvantage for residency placement because they lack access to research opportunities.

While osteopathic medical schools have the expertise, infrastructure and processes in place to manage NIH funding, outdated NIH policies and procedures fail to take advantage of what the profession has to offer. These system failures and biases discourage osteopathic researchers from applying for and receiving NIH grants resulting in critical clinical areas being underexplored.

AACOM Policy Recommendations

Osteopathic medicine has a blueprint for improving patient outcomes that relies on research-backed practices for continuous improvement. The osteopathic research community is willing and able to contribute to the scientific integrity of the NIH through improved osteopathic representation. We respectfully offer the following recommendation to achieve this goal:

> **Ensure representation from the osteopathic profession on NIH Federal Advisory Committees.** Researchers at colleges of osteopathic medicine are qualified and available to serve on NIH scientific and technical FACs. The NIH Scientific Integrity Policy should ensure that researchers from osteopathic and allopathic medical schools are represented on policy committees to increase diversity and provide the greatest breadth and depth of knowledge and expertise.

On behalf of our nation's osteopathic medical schools, their medical students, and the patients they serve, thank you for your consideration of our views and recommendations. We are eager to be a resource as you develop the Scientific Integrity Policy. Please contact me at dbergman@aacom.org if AACOM can provide further clarification or information.

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[1] NIH Reporter, available at https://reporter.nih.gov/search/gVVIo6UHiEa0GkXng7-Idg/projects
[2] NIH Reporter, available at https://reporter.nih.gov/search/29_xshqmRU2RdZfREbhLnA/projects

AACOM
American Association of Colleges of Osteopathic Medicine

Sincerely,

David Bergman, JD
Senior Vice President, Government Relations and Health Affairs
AACOM

Submit date: 11/7/2023

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

Name: Mary-Ann Bjornsti, PhD

Name of Organization: Federation of American Societies for Experimental Biology

Type of Organization: Professional org association

Role: Scientific researcher

Comment:

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.

Uploaded File:

FASEB-Comments-on-Draft-NIH-Scientific-Integrity-Policy_FINAL_20231107.pdf

Description: PDF file are FASEB's comments on formal letterhead and signed.

Email: yseger@faseb.org

FASEB
Federation of American Societies for Experimental Biology

Representing Over 110,000 Researchers

6120 Executive Blvd., Suite 230, Rockville, MD 20852 | faseb.org

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,

Mary-Ann Bjornsti, PhD
FASEB President

Submit date: 11/8/2023

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

Name: Matthew Rizzo, MD

Name of Organization: American Brain Coallition

Type of Organization: Professional org association

Role: Medical provider

Comment:

Uploaded File:

NIH-Scientific-Integrity-Comments-from-ABC_final-submission.pdf

Description:

Email: pjones@dc-crd.com

November 8, 2023

Tyrone Spady, Ph.D.
Director of the Science Policy Coordination, Collaboration & Reporting Division
Office of Science Policy
6705 Rockledge Drive
#750
Bethesda, MD 20817

Dear Dr. Spady,

Thank you for allowing our American Brain Coalition (ABC) to comment on the recent draft of the National Institutes of Health (NIH) Scientific Integrity Policy. As the largest public funder of biomedical and behavioral research worldwide, the NIH is integral to the health and wellbeing of every American. We are pleased to share some thoughts on the Chief Scientist (CS) and Scientific Integrity Official (SIO), the Scientific Integrity Council (SIC) roles and responsibilities, and the impact of political interference on research and data.

ABC is a non-profit organization comprising many of the leading patient advocacy and voluntary health organizations in the US, as well as professional neurological, psychological, and psychiatric associations, and industry partners. Together, we seek to advance understanding of brain functions and reduce the burden of brain disorders through public education, engagement and advocacy with Congress, the administration, and the public.

Proposed changes in the Draft Scientific Integrity Policy will reinforce NIH's standing within the science community as a beacon of true data and research production. ABC supports the proposed role and responsibilities of the CS and the SIO. ABC recognizes that a CS is responsible for oversight of all NIH scientific integrity policies and procedures, and to efforts regarding equity, inclusion, and accessibility. The most valuable research depends on a wide range of data sources: the more diverse the data, the greater value the research findings hold for the broader public. A CS ensures that the work conducted fairly represents the diverse perspectives and experiences of our society. CS guidance and leadership will advance the frontiers of knowledge and empower individuals from all backgrounds to participate and benefit from the discoveries, advancing a more equitable future for all.

ABC also supports the proposed role and responsibility of the NIH SIO, to keep the NIH a trustworthy source of information and improve transparency of the Scientific Integrity Program. SIO participation in the HHS Data Council provides a pipeline to government collaboration and ensures that data-driven decisions are based on the highest standards of integrity and accuracy. Collaboration between the SIO and HHS Data Council strengthens the NIH's commitment to responsible and ethical scientific pursuit.

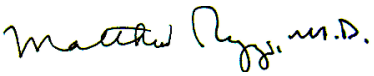
The NIH SIC framework of policies and procedures offers robust safeguards, and a culture of accountability and ethical conduct across the NIH. Through clear and consistent guidelines, the NIH

Scientific Integrity Council supports swift resolution of integrity-related concerns, rigorous standards for pursuit and discovery, and greater public trust in science.

ABC strongly supports research following established scientific protocols, including peer review when applicable, ensuring needed privacy, and free of political interference. Political bias would undermine public trust and introduce bias and injustice in research findings. Policymakers, like scientists, need unbiased data and research results to safeguard the integrity of their work.

We are grateful that the NIH has the foresight to address scientific integrity. ABC is happy to serve as a resource for you and your staff. If you have any questions or would like to discuss this issue further, please reach out to ABC's Executive Director, Katie Sale, at ksale@americanbraincoallition.org.

Sincerely,



Matthew Rizzo, MD
Chair
American Brain Coalition

Submit date: 11/8/2023

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

Name: Carter Alleman

Name of Organization: American Society for Pharmacology and Experimental Therapeutics (ASPET)

Type of Organization: Professional org association

Role: Member of the public

Comment:

The American Society for Pharmacology and Experimental Therapeutics (ASPET) appreciates the opportunity to provide comments on the Request for Information regarding the DRAFT Scientific Integrity Policy of the National Institutes of Health. ASPET is a 4,000-member scientific society whose members conduct basic and clinical pharmacological research and work in academia, government, industry, and non-profit organizations. ASPET members conduct research leading to the development of new medicines and therapeutic agents to fight existing and emerging diseases. ASPET is a global pharmacology community that advances the science of drugs and therapeutics to accelerate the discovery of cures for disease. We are in constant pursuit of our Mission through research, education, innovation, and advocacy.

ASPET appreciates the opportunity to provide comments on proposed updates to the NIH Scientific Integrity Policy. ASPET agrees that defining individuals and parties responsible for developing, evaluating, and upholding scientific integrity policies is important and believes that that the proposed roles and responsibilities of the NIH Scientific Integrity Officer and Chief Scientist as well as the proposed designated individuals to take on those roles fitting and align with existing responsibilities of the designated individuals. ASPET also agrees with the proposed roles of the NIH Scientific Integrity Council in supporting the role of the SIO.

In regard to the prohibitions Against Political Interference, ASPET appreciates the effort NIH has put in the draft to call out various ways in which it prohibits political interference and inappropriate influence. ASPET also encourages NIH to incorporate language in the draft on how the newly proposed NIH scientific integrity infrastructure will interface with the Office of Research Integrity at the Department of Health and Human Services.

Thank you for the opportunity to offer comments on the update for the Scientific Integrity Policy of the National Institutes of Health and we look forward to its implementation.

Uploaded File:

NIH-RFI-on-Scientific-Integrity-Policy-of-the-National-Institutes-of-Health-ASPET-Comment.pdf

Description: ASPET Comment Letter

Email: calleman@aspet.org

ASPET
Transforming Discoveries into Therapies

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

Submitted via online portal on November 7, 2023

The American Society for Pharmacology and Experimental Therapeutics (ASPET) appreciates the opportunity to provide comments on the Request for Information regarding the DRAFT Scientific Integrity Policy of the National Institutes of Health. ASPET is a 4,000-member scientific society whose members conduct basic and clinical pharmacological research and work in academia, government, industry, and non-profit organizations. ASPET members conduct research leading to the development of new medicines and therapeutic agents to fight existing and emerging diseases. ASPET is a global pharmacology community that advances the science of drugs and therapeutics to accelerate the discovery of cures for disease. We are in constant pursuit of our Mission through research, education, innovation, and advocacy.

ASPET appreciates the opportunity to provide comments on proposed updates to the NIH Scientific Integrity Policy. ASPET agrees that defining individuals and parties responsible for developing, evaluating, and upholding scientific integrity policies is important and believes that that the proposed roles and responsibilities of the NIH Scientific Integrity Officer and Chief Scientist as well as the proposed designated individuals to take on those roles fitting and align with existing responsibilities of the designated individuals. ASPET also agrees with the proposed roles of the NIH Scientific Integrity Council in supporting the role of the SIO.

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Thank you for the opportunity to offer comments on the update for the Scientific Integrity Policy of the National Institutes of Health and we look forward to its implementation.

Submit date: 11/8/2023

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

Name: Mary Jo Hoeksema

Name of Organization: Population Association of America/Association of Population Centers

Type of Organization: Professional org association

Role: Institutional official

Comment:

Uploaded File:

PAA-APC-comments-to-NIH-re-scientific-integrity-policy-

FINAL-11-23.docx

Email: maryjo@popassoc.org

POPULATION ASSOCIATION OF AMERICA

OFFICE OF GOVERNMENT AND PUBLIC AFFAIRS
1436 Duke Street • Alexandria, VA 22314
www.populationassociation.org • www.popcenters.org • 301-565-6710 x 1006

ASSOCIATION OF POPULATION CENTERS

November 8, 2023

Submitted electronically to: https://osp.od.nih.gov/comment-form-draft-scientific-integrity-policy-for-the-national-institutes-of-health/

To whom it may concern:

On behalf of the members of the Population Association of America (PAA) and Association of Population Centers (APC), we are pleased to respond to a request from the National Institutes of Health (NIH) for public comments on the agency's draft Scientific Integrity Policy.

As you may know, PAA and APC are two affiliated organizations that together represent over 3,000 social and behavioral scientists and the over 40 population research centers that receive federal funding and conduct research on the implications of population change. Our members, which include demographers, economists, sociologists, and epidemiologists, conduct scientific and applied research, analyze changing health, demographic, and socio-economic trends, develop policy and planning recommendations, and train undergraduate and graduate students. Their research expertise covers a wide range of issues, including adolescent health and development, aging, health disparities, immigration and migration, marriage and divorce, education, social networks, housing, retirement, and labor. NIH is the primary source of competitive, discretionary grant funding supporting the population sciences. As a result, PAA and APC monitor and often respond to proposed changes governing NIH extramural research activities.

Strengthening Federal scientific integrity policy has been a major priority for the Biden Administration. PAA and APC appreciate the White Office of Science and Technology Policy (OSTP) embracing this priority and leading efforts to: promote public trust in Federal scientific agencies; improve the communication of scientific and technological information; encourage adoption of effective scientific integrity policies and practices; and enhance support for the scientific workforce. To that end, PAA and APC submitted comments in 2021, in response to OSTP's Request for Information, "To Improve Federal Scientific Integrity Policies."

We are pleased that NIH is aligning its scientific integrity policy and practices to reflect priorities outlined by OSTP and to make the agency's policy consistent with the Department of Health and Human Services' Scientific Integrity Policy. The NIH proposal clearly details specific roles and responsibilities of its proposed Chief Scientist, Scientific Integrity Official, and NIH Scientific Integrity Council.

Given the nature of these positions, we understand why the policy does not stipulate advisory or participatory roles for outside experts. Nonetheless, we urge NIH to reassure the scientific research community that these officials and council will seek input from stakeholders when it is appropriate and communicate relevant information in a timely and clear manner.

Thank you for considering our views as you develop the agency's final scientific integrity policy.

Sincerely,

Dr. Lisa Berkman
2023 PAA President

Dr. Jennie Brand
2023-2024 APC President

Submit date: 11/8/2023

I am responding to this RFI: On behalf of myself

Name: Nanwei Cao

Name of Organization: NIAAA

Type of Organization: Government agency

Role: Government official

Comment:

The section "Roles and responsibilities" doesn’t list Role and Responsibilities of the NIH top leader, managers and supervisors, employees, and other covered entities, such as principal investigators of extramural grants, especially principal investigators of grants to foreign organizations.

Submit date: 11/8/2023

I am responding to this RFI: On behalf of myself

Name: Dr. Anon

Type of Organization: University

Role: Scientific researcher

Comment:

1) Cap the # of R01s to 2/PI. I've been in and around labs with 2, 3 and 4+ concurrent R01s and they are all fraud factories. Nothing is real out of those labs. Those PIs are experts in psychology and not areas of their "research field". They hire desparate people and manipulate them into quick and fraudulent data. The PI gets $200-800k base salary (e.g., UCSD) and fame all built on bullsh1t. In my opinion, 80% of published research is completely fraudulent (no experiments actually performed). Cap the concurrent R01s to 2. This simple act will remove these mega fraud labs from the research enterprise.

2. Unrelated, the NIH needs to train and perform oversight of their staff. Incompetence and corruption at the NIH are the most common traits that I've identified after a couple of decades of dealing with them. I've personally experienced professional threats from a CSR for adding a researcher to a request not to review my grant app. I witnessed this same CSR getting wasted at The Society for Neuroscience conference social while he was bad mouthing a couple of smaller institutions. I've also been appalled to have a grant rejected at the door of an NIH institute (not even reviewed) after discussing the grant app with a PO at that institute that said it was a "good fit". The PO didn't apologize and even recommended that I submit it as an R21 at NIGMS which doesn't even have an R21. I have dozens of these personal anecdotes. The early career reviewer program is a sham. It's a program designed to allow powerful PIs to rotate off of a study section and the CSR to appoint the PI's postdoc in their place as an "early career reviewer". This allows the powerful PI to maintain control via their NIH-sanctioned proxy. I applied for this program twice as a pre-tenure faculty member. I was never contacted during that time despite following up with emails to CSRs and POs. However, I did receive an email requesting my participation in this program AFTER I was tenured and thus no longer eligible. I'm sure that it is a just a coincidence that the program application form has the expected date of tenure.

No matter how badly broken that the NIH is, there are some great and honest researchers out there fighting for a better future. I encourage everyone to contact their Congressman/Congresswoman a and media to expedite change.

Submit date: 11/9/2023

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

Name: Liz Borkowski

Name of Organization: Eleven organizations: APA Justice Task Force, AAFEN, CRR, Equity Forward, GAP, GIW, JIWH, NCHR, POGO, PEER, UCS

Type of Organization: Other

Type of Organization-Other: Organizations whose work involves federal scientific integrity issues

Role: Member of the public

Comment:

Please see the attached comment from eleven organizations whose work involves federal scientific integrity issues.

Uploaded File

11-Organizations-Comment-to-NIH-on-Draft-Scientific-Integrity-Policy.pdf

Description: Comment from eleven organizations whose work involves federal scientific integrity issues regarding the NIH draft scientific integrity policy

Email: borkowsk@gwu.edu

November 9, 2023

Science Policy Coordination, Collaboration & Reporting Division
National Institutes of Health, U.S. Department of Health and Human Services
Submitted electronically

Re: Request for Information on the DRAFT Scientific Integrity Policy of the National Institutes of Health (88 FR 65696)

As organizations whose work involves federal scientific integrity issues, we appreciate the opportunity to comment on the draft scientific integrity policy from the National Institutes of Health (NIH). Our comment relates to the four aspects of the draft policy NIH outlined in its call for comments — Role and Responsibilities of the NIH Scientific Integrity Officer, Role and Responsibilities of the NIH Chief Scientist, Responsibilities of the NIH Scientific Integrity Council, and Prohibitions against Political Interference — as well as other aspects.

NIH's draft policy represents an important step toward ensuring that agency scientists and decisionmakers can generate and use the best available evidence to advance the agency's mission to seek and apply knowledge in order to "enhance health, lengthen life, and reduce illness and disability." We recommend several revisions to make the NIH scientific integrity policy an even stronger tool for protecting science and science-based decision-making from political interference. Specifically, we urge that that the NIH scientific integrity policy contain:

1) Protections and accountability for grantees;
2) Commitment to equity for grantees and the scientific workforce;
3) More explicit procedures for investigating allegations;
4) Specifics that delineate scientists' ability to communicate with the media and public about their areas of expertise, without leaving scientists vulnerable to bad-faith attacks;
5) Clarification of the scope and duration of scientific clearance procedures;
6) Penalties sufficient to deter wrongdoing and hold accountable all scientific integrity violators, including political appointees;
7) Specific protections from retaliation for those engaged in scientific activities that may put them at risk for reprisal;
8) Public availability of advisory committee members' conflict-of-interest waivers;
9) A mechanism for addressing allegations that involve multiple agencies and/or high-level officials; and
10) Specifics regarding issues to be addressed by the SIO as opposed to other offices.

In reviewing the draft NIH scientific integrity policy, we also examined the model policy released by the White House Office of Science and Technology Policy as part of *A Framework for Federal Scientific*

Integrity Policy and Practice[1] and the draft scientific integrity policy from the Department of Health and Human Services (HHS).[2] We note areas where the NIH draft policy improves upon the model policy as well as areas where using more of the model policy's language would enhance the NIH policy.

Scientific integrity is essential to ensure that all people have access to information and programs that can help them lead healthy lives. When individuals with political motivations meddle in research or undermine decisions that should be based on science, the health of communities across the nation, particularly BIPOC (Black, Indigenous, and people of color) communities, can suffer. NIH should design its scientific integrity policy to provide protections against politically motivated meddling and effective avenues for correction when interference occurs. NIH should also consider the possibility of individuals acting in bad faith using the policy to harass scientists who are doing their jobs, and NIH should erect barriers to such bad-faith attempts.

1. Protections and accountability for grantees

Although the problematic 2019 decisions restricting research involving human fetal tissue were made at the HHS, rather than NIH, level[3] and have been reversed to some degree, they illustrate the potential for politically motivated actions to interfere with research grants. We recommend additional protections against grant cancellations, changes to ease the remaining barriers to research involving human fetal tissue, and making grantees accountable for upholding scientific integrity:

A. **Prohibition against terminating grants early for political reasons:** We recommend that the revised policy include specific protections against early termination of research grants for political reasons. For instance, the "Protecting Scientific Processes" section could include a prohibition against terminating intramural or extramural research funding for reasons other than breach of contract, abusive behavior, or gross mismanagement.

B. **Changes to grant policies for research involving human fetal tissue:** We support the changes recommended by Katherine MacDuffie and colleagues to ease the remaining barriers to research involving human fetal tissue (HFT): 1) move the HFT justification out of the constrained research strategy section of grant applications, so researchers using HFT are not disadvantaged by having fewer words to describe their research; 2) remove restrictions on trainees' participation in HFT research; and 3) establish standard informed consent language for HFT donation to ward off

[1] Scientific Integrity Framework Interagency Working Group of the National Science and Technology Council. (2023). *A Framework for Federal Scientific Integrity Policy and Practice*. https://www.whitehouse.gov/wp-content/uploads/2023/01/01-2023-Framework-for-Federal-Scientific-Integrity-Policy-and-Practice.pdf

[2] U.S. Department of Health and Human Services. (2023). The Scientific Integrity Policy of the U.S. Department of Health and Human Services: Draft for Public Comment. https://www.hhs.gov/sites/default/files/draft-hhs-scientific-integrity-policy.pdf

[3] Wadman M. (2019). Trump administration restricts fetal tissue research. *Science*. https://www.science.org/content/article/trump-administration-restricts-fetal-tissue-research

future challenges.[4]

C. **Accountability for grantees:** We appreciate that the draft policy makes clear that extramural grantees "are expected to uphold the principles of scientific integrity described in this policy." We recommend that NIH's next version of the Grants Policy Statement, which sets out policies for extramural grantees, incorporate this requirement of adhering to the scientific integrity policy and include consequences for those found to have violated the policy, such as being barred from receiving a new NIH grant for two years following the determination of a serious violation. NIH should then take steps to ensure grantees are educated sufficiently about the policy to enable compliance.

2. Commitment to equity for grantees and the scientific workforce

We applaud NIH for a) stating that the Chief Scientist's responsibilities include "Engage agency efforts regarding diversity, equity, inclusion, and accessibility" and b) tasking the Scientific Integrity Official to "Promote agency efforts regarding diversity, equity, inclusion, and accessibility." Assigning these functions to high-level officials demonstrates an admirable recognition of the importance of diversity and inclusion in advancing scientific integrity.

However, reports indicate that NIH investigations into grantees' spending and disclosures have led to the profiling or silencing of Asian American scientists — in some cases with the result that scientists resigned their faculty positions under pressure — and chilling collaboration between scientists in the US and China.[5,6,7,8] Whether or not government overreach is behind the inequitable treatment of scientists based on their national origins or ties to certain countries, the outcomes of reduced international cooperation and more Chinese scientists foregoing future NIH grant applications hinder the scientific enterprise, which is by nature collaborative.

We recommend that the revised policy assign the Chief Scientist the responsibility of identifying and addressing policies, practices, or procedures that have the effect of disproportionately burdening or discriminating against people from a marginalized group. We also recommend that NIH take steps to prevent future changes that disproportionately harm certain groups of scientists, repair the damage that its aggressive investigation into grantees' spending and disclosures have caused to Asian American

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[4] MacDuffie KE, Hyun I, Krogen MM, Dempsey JC, Murry CE, Copp AJ, Glass IA, & Doherty D. (2021). Rescuing human fetal tissue research in the United States: A call for additional regulatory reform. *Stem Cell Report*, 16(12): 2839-2843. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8693650/

[5] Fischer K. (2023). Can U.S. Research Recover From the China Initiative? *Chronicle of Higher Education*, April 6, 2023. https://www.chronicle.com/article/can-u-s-research-recover-from-the-china-initiative

[6] Mervis J. (2023). Pall of Suspicion. *Science*, 379(6638). https://www.science.org/content/article/pall-suspicion-nihs-secretive-china-initiative-destroyed-scores-academic-careers

[7] Thorp HH. (2022). The China Initiative must end. *Science Advances*, 8(8): eabo6563. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8870733/

[8] Widener A. (2022). Scientists' work impacted by NIH probe. *Chemical & Engineering News*, 100(14). https://cen.acs.org/policy/research-funding/Scientistswork-impacted-NIH-probe/100/i14

scientists, and include in its revised model policy statements related to equity in the scientific workforce that appear in the model policy.

A. **Identifying and addressing policies, practices, or procedures that result in disproportionate harm:** We recommend that the revised policy contain an additional responsibility for the Chief Scientist: "Monitor policies, practices, and procedures to a) identify instances in which a marginalized group disproportionately experiences harmful side effects from implementation, and b) develop and implement a plan to reduce such harmful impacts on affected groups."

B. **Applying an equity lens to future policy and practice changes:** We recommend that, in addition to conducting equity training for staff at all levels — as required by Executive Order 14091[9] — NIH leadership analyze with an equity lens proposed new policies, procedures, and practices. They should identify any potential disproportionate impacts on marginalized groups and modify the policies and procedures to avoid such impacts.

C. **Rebuilding trust:** To reverse the chilling of engagement and collaboration that followed NIH's aggressive investigation of allegations against scientists with ties to China, NIH should undertake meaningful engagement with the Asian American community to rebuild trust. This could include listening sessions and formation of a community advisory board, and the Chief Scientist or another senior leader should commit to responding to suggestions NIH receives from these sources regarding changes to agency policies, procedures, and practices.

D. **Equity in the scientific workforce:** In V.2., we recommend that the sentence "Promote diversity, equity, inclusion, and accessibility in the scientific workforce and to create safe workspaces that are free from harassment and discrimination" be followed by the sentence that follows it in the model policy: "Support scientists and researchers including, but not limited to, Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQI+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality; and advance the equitable delivery of Federal programs."

3. More explicit procedures for investigating allegations

We appreciate the draft policy's inclusion of procedures for "Addressing Scientific Integrity Concerns" and the fact that the procedures include the possibility of informal consultations, formal complaints and investigations, and appeals from both complainants and respondents. We recommend that the revised policy contain the following as well, and that procedures be published in the Federal Register.

[9] Biden, JR. (2023). Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Executive Order 14091. https://www.federalregister.gov/documents/2023/02/22/2023-03779/further-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal

A. **Independent appeal mechanisms on findings and decisions:** Agency personnel will be reassured that investigations and findings are handled appropriately if an independent appeal process exists. The revised policy should give more specifics about the appeals process(es) that will be available to all affected personnel, including those found to have violated scientific integrity policies and those whose allegations were not investigated or remedied. The policy should establish an independent mechanism for appeals, such as the ability to appeal to the National Science and Technology Council (NSTC) Subcommittee on Scientific Integrity, and affirm that procedures will protect employees' due process rights.

B. **Additional mechanisms to safeguard the independence of investigators:** We appreciate that section V.6 of the draft policy specifies "Consistent with applicable law, an SIO or other scientific integrity staff may not be terminated or reassigned without good cause or legitimate organizational reason." This kind of protection is essential for allowing SIOs and Council members to avoid undue pressure from their supervisors or political appointees. To further bolster such protection, we recommend that the revised policy specify avenues for safeguarding independence when allegations involve high-level officials, such as by allowing investigators to coordinate with their inspector general's office and/or the NSTC Subcommittee on Scientific Integrity.

C. **Timeliness provisions:** Scientific integrity policies should include provisions to assure the timely resolution of an allegation of a loss of scientific integrity. For instance, a decision to investigate an allegation could be required within 10 working days and a determination within another 45 working days, and the appeal process could be limited to 30 working days. Exceptions to the timeline should be allowed at the request of employees for reasons such as needing more time to hire counsel or build their case.

4. Specifics that delineate scientists' ability to communicate with the media and public about their areas of expertise, without leaving scientists vulnerable to bad-faith attacks

Ensuring that scientists are able to communicate efficiently with members of the media and publish findings promptly can help improve public awareness of and trust in agency activities. Scientists are most likely to make use of opportunities to speak with members of the media and the public when the policies related to these activities are explicit and unambiguous. Some text in the draft policy is too ambiguous, and one provision could be weaponized by bad-faith actors who disapprove of a particular area of research, such as one related to reproductive health. We recommend the following changes:

A. **Eliminate problematic language that could be weaponized by bad-faith actors.** Section II.4 contains the extremely broad statement that NIH scientists "shall refrain from making or publishing statements that could be construed as being judgments of, or recommendations on, NIH or any other Federal Government policy." A bad-faith actor seeking to harass a scientist whose work they find distasteful could claim to have "construed" virtually any statement as a judgment of government policy. For instance, a scientist who makes a factual statement about the effect of a policy — for instance, explaining how a Trump administration directive to stop

procuring fetal tissue halted work on an HIV study — could be accused of criticizing that policy decision. We recommend that NIH remove this text from its scientific integrity policy to avoid creating a weapon for bad-faith actors and chilling scientists' communications.

B. **Specifics regarding ethics rules:** In item II.3, "Encourage, but not require, NIH scientists to participate in their official capacities in communications with the media regarding their scientific activities and areas of expertise, subject to limitations of government ethics rules," and Item II.4, "Allow, subject to limitations of government ethics rules, NIH scientists to express their personal views and opinions with appropriate written or oral disclaimers, including on social media," we recommend the revised policy specify what kinds of ethics rules apply to communications with media and the public – e.g., "the limitations of government ethics rules regarding compensation for speaking engagements."

C. **Explicit language reinforcing federal anti-gag rules:** To comply with the Whistleblower Protection Enhancement Act and guard against any potential chilling effect on employees concerned about communicating with the media or the public, NIH should ensure that any communication policy, and any directives or instructions distributed to employees explaining such policies, contains the explicit language the Whistleblower Protection Enhancement Act mandates must be included under the "anti-gag" provisions of § 115 and 5 U.S.C. § 2302(b)(13) in any nondisclosure policy, form, or agreement:

   "These provisions are consistent with and do not supersede, conflict with, or otherwise alter the employee obligations, rights, or liabilities created by existing statute or Executive order relating to (1) classified information, (2) communications to Congress, (3) the reporting to an Inspector General of a violation of any law, rule, or regulation, or mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, or (4) any other whistleblower protection. The definitions, requirements, obligations, rights, sanctions, and liabilities created by controlling Executive orders and statutory provisions are incorporated into this agreement and are controlling."

   We recommend the addition of this language at the end of Section II., Ensuring the Free Flow of Scientific Information.

5. Clarification of the scope and duration of scientific clearance procedures

We applaud the NIH draft policy for requiring that "technical review and clearance processes include provisions for timely clearance and expressly forbid censorship, unreasonable delay, and suppression of objective communication of data and results without scientific, legal, or security justification" (II.8) and specifying in II.11 that "Violations of clearance policies that result in suppression, delay, or alteration of scientific and technological information produced by NIH scientists without scientific, legal, or security justification constitute violations of the NIH Scientific Integrity Policy and may be reported under the procedures for Addressing Scientific Integrity Concerns." To augment the policy's ability to encourage timely and appropriate clearance, we recommend the following additions:

A. **Clarification of the scope of scientific clearance procedures:** Scientific clearance procedures typically relate to quality control of scientific materials intended for publication or presentation rather than to interview or public speaking requests, and we recommend making this distinction explicit. One option for doing so would be to add a sentence stating "Scientific clearance procedures are only applicable to scientific materials intended for publication or presentation and do not apply to interview and speaking requests" at the end of item II.8. Another option would be to assure that communications officers and political appointees are prohibited from conducting scientific clearance review.

B. **Specifics regarding timely clearance:** We recommend the addition of the following provision regarding clearance procedures:

   "Each Institute and Center must have a written clearance policy that specifies who must review work products and gives deadlines by which comments must be given or the product can move to the next stage (e.g., if a supervisor does not clear or provide comments on a product five days after receiving it, it moves to the next-level approver; if there is no next-level approver, the author may submit the paper to a journal, deliver the presentation, etc.). The policy must also provide an appeal mechanism for those who are denied clearance and a method for obtaining a second opinion if an author disagrees with a requested revision."

6. Penalties sufficient to deter wrongdoing and hold accountable all scientific integrity violators, including political appointees

The draft policy makes appropriate references to corrective actions to be taken after a loss of scientific integrity is determined to have occurred. In order to deter wrongdoing and promote accountability, we urge that it also specify penalties for those found to have attempted to cause a loss of scientific integrity, whether or not they were successful; these penalties, of course, should only be enforced after those found in violation of the policy have declined or exhausted appeal opportunities. We recommend:

A. **Specific penalties for violations:** Penalties for violating scientific integrity policies should appear in NIH's official table of penalties, and the scientific integrity policy should reference them and task the SIO and Secretary with ensuring they are enforced. Penalties should be sufficiently meaningful to discourage violations — e.g., warnings, suspension, demotion, or removal.

B. **Penalties should apply to attempted, as well as successful, violations:** We appreciate that the definition of "Inappropriate influence" includes "the attempt to shape or interfere in scientific activities." We recommend that the policy also explicitly state that an attempt to violate the scientific integrity policy need not result in a loss of scientific integrity in order for a finding of wrongdoing to be made and an appropriate penalty to be administered, and that attempted violations are violations in all contexts (not only in the context of "inappropriate influence").

Our justice system punishes attempted crimes, and the system to safeguard scientific integrity should do so as well.

C. **Consequences comparable to those for ethics violations.** We recommend that NIH include in its policy the following responsibility — which OSTP included in its own agency scientific integrity policy[10]— for the Chief Scientist: "Ensures that violations of scientific integrity policies be considered comparable to violations of government ethics rules, with comparable consequences. There must be appropriate consequences for scientific integrity violations."

D. **Publicly identify appointees found to have violated policies:** When an investigation determines that a political appointee has caused the loss of scientific integrity, the identity of that official should be made public and reported through their chain of command and to the NSTC Subcommittee on Scientific Integrity and the relevant Cabinet Officer.

7. Specific protections from retaliation for those engaged in scientific activities that may put them at risk for reprisal

We applaud the NIH draft policy for going beyond the model policy to protect SIOs and others involved with scientific integrity policy implementation from reprisal (in V.3 and V.6), rather than relying on existing whistleblower protections alone. Although current laws and policies to protect whistleblowers are important and beneficial, their protections are not sufficient. We recommend that NIH add to its policy additional protections for those who could face reprisal when scientific integrity is compromised or when a bad-faith actor tries to misuse the scientific integrity policy to target an individual or area of research for inappropriate reasons. We recommend the following:

A. Include the model policy's language regarding conducting work free from reprisal or concern for reprisal: It is important that NIH not only take corrective action and assess penalties when reprisal is found to have occurred; preventing retaliation and ensuring employees can work free from concern for reprisal is also essential to avoid the chilling effect that occurs when employees see a colleague face reprisal or the threat of reprisal. We appreciate the value of NIH stating that it is NIH policy for leadership and management to ensure covered individuals can conduct their work "objectively and free from political interference and other inappropriate influence" (I.3); however, we urge that the NIH policy also include the model policy's requirement that covered individuals be able to conduct their work "free from reprisal or concern for reprisal."

B. Offer additional protections against specific forms of retaliation. We urge that NIH's policy specifically provide protections against blocklisting/blacklisting and retaliatory investigations

[10] White House Office of Science and Technology Policy. (2023). White House Office of Scientific Integrity Policy (OSTP) Scientific Integrity Policy. https://www.whitehouse.gov/wp-content/uploads/2023/06/OSTP-SCIENTIFIC-INTEGRITY-POLICY.pdf

and offer an affirmative defense to whistleblowers who are subjected to civil or criminal lawsuits.

C. **Acknowledge the possibility of reprisal and retaliation for scientific activities that do not meet the definition of whistleblowing.** We recommend adding a statement that reprisal or retaliation based on the topic or implications of an area of research is considered a violation of this scientific integrity policy.

8. Public availability of advisory committee members' conflict-of-interest waivers

To improve transparency regarding federal advisory committees, we recommend that Section VII include the following item, which appears in the model policy: "Except when prohibited by law, NIH should make all COI waivers granted to committee members publicly available."

9. A mechanism for addressing allegations that involve multiple agencies and/or high-level officials

We appreciate that the draft policy gives the Chief Scientist the responsibility to "Serve as an alternate in scientific integrity adjudication processes if the NIH SIO is alleged to have violated NIH or HHS Scientific Integrity Policies" and the SI Council the responsibility to "Determine handling of investigation and adjudication proceedings from which the HHS SIO is recused." In addition, the "Addressing Scientific Integrity Concerns" procedures should establish one or more mechanisms for addressing situations when SIOs from multiple HHS OpDivs/StaffDivs or agencies are involved or when the person accused of violating the scientific integrity policy is a high-level official.

One possible mechanism is that those with concerns involving multiple agencies or a high-level official be instructed to contact the NSTC Subcommittee on Scientific Integrity. The framework explains that this Subcommittee's roles include "provid[ing] advisory responses to agency requests for another agency to review their internal scientific integrity policies and processes, such as inquiries related to senior-level officials, political appointees, or scientific integrity officials" and "sharing of analysis or commentary on public allegations of scientific integrity violations that cannot be suitably handled at an individual agency-, department-, or Executive Office of the President component-level, such as allegations involving senior-level officials, political appointees, or SIOs or allegations involving multiple agencies."

10. Specifics regarding issues to be addressed by the SIO as opposed to other offices

The SIO's responsibilities include "Serve as a focal point for the receipt of agency scientific integrity allegations (particularly related to political interference) that fall outside of existing processes managed by the Office of Extramural Research (OER), the Office of Intramural Research (OIR), the Office of Management Analysis (OMA), and the HHS Office of the Inspector General (OIG)." Given that these offices have broad authority, we recommend that the revised policy more explicitly delineate what

kinds of issues are primarily the responsibility of the SIO as opposed to these other offices. In particular, the OIG has a broad purview, so it is important that the revised policy specify the kinds of allegations for which the SIO is the first point of contact.

The changes described above will make the NIH scientific integrity policy an even stronger tool for protecting science and science-based decision-making from political interference.

Thank you for the opportunity to comment on NIH's draft scientific integrity policy. If you have any questions, please contact Liz Borkowski of the Jacobs Institute of Women's Health at borkowsk@gwu.edu.

APA Justice Task Force
Asian American Federal Employees for Nondiscrimination
Center for Reproductive Rights
Equity Forward
Government Accountability Project
Government Information Watch
Jacobs Institute of Women's Health
National Center for Health Research
Project On Government Oversight
Public Employees for Environmental Responsibility (PEER)
Union of Concerned Scientists

Submit date: 11/9/2023

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

Name: Janine McCarthy

Name of Organization: Physicians Committee for Responsible Medicine

Type of Organization: Nonprofit research organization

Role: Scientific researcher

Comment:

Uploaded File:

PCRM-Comment_NIH-draft-scientific-integrity-policy.pdf

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November 9, 2023

RE: Public Comment on Draft Scientific Integrity Policy of the National Institutes of Health

Submitted electronically via https://osp.od.nih.gov/comment-form-draft-scientific-integrity-policy-for-the-national-institutes-of-health/

Dear Dr. Tyrone Spady:

On behalf of the Physicians Committee for Responsible Medicine, a nonprofit health advocacy organization based in Washington, DC, thank you for the opportunity to provide feedback on the draft Scientific Integrity Policy (Policy) of the National Institutes of Health (NIH). We appreciate the critical role scientific integrity plays in making sure that research is conducted, managed, communicated, and used in ways that preserve its accuracy and objectivity.

Our comments address the importance of scientific integrity policies in maximizing the human relevance and scientific utility of medical research to patient populations.

We appreciate your attention to these recommendations and welcome further dialog to ensure their implementation.

Sincerely,

Janine McCarthy, MPH
Science Policy Program Manager
Physicians Committee for Responsible Medicine

1. Promoting a culture of scientific integrity at NIH

Scientific integrity is defined in the draft Policy as the adherence to professional practices, ethical behavior, and the principles of honesty and objectivity when conducting, managing, using the results of, and communicating about science and scientific activities.[1]

The draft Policy outlines seven specific areas to promote a culture of scientific integrity at the NIH. We recommend that several of these areas should be expanded to encompass a broader scope of scientific integrity.

I. Protecting Scientific Processes

This subsection acknowledges that research involving the use of non-human animals must be conducted in accordance with applicable, established laws, regulations, policies, and ethical considerations. However, to best protect and improve human health, the NIH must ensure that the research methods and models used are most relevant to patient populations and clinical outcomes. Nonanimal methods,

also called novel alternative methods, new approach methodologies, or NAMs, are based on human biology rather than the biology of nonhuman animals. This key difference gives NAMs important human- and clinical-relevant advantages over more traditional animal-based research methods, including the ability to model ancestry and other critical demographic characteristics.[2,3,4] The use of NAMs also contributes to animal use reduction and replacement efforts, in line with the aforementioned laws, regulations, policies, and ethical considerations. The human-relevance of research approaches is therefore an important scientific integrity issue that should be addressed in the Policy, its implementation, and within the broader culture of scientific integrity at the NIH by driving scientific processes that stimulate such human-relevant approaches.

Accordingly, we recommend that the "*I. Protecting Scientific Processes*" section in the Policy be amended as follows:

> 10. Require that research conducted by covered individuals involving the participation of human subjects and the use of non-human animals is conducted in accordance with applicable, established laws, regulations, policies, and ethical considerations, **and is of maximum relevance to human health.**

To enforce this policy, scientific integrity staff should work with the Center for Scientific Review (CSR) to ensure if grant proposal objectives can be met using human subjects, biospecimens, clinical data, or NAMs, the use of animals for such studies should not be permitted. This process can be developed under the scope of the Scientific Integrity Council to "measure, monitor, and evaluate ongoing scientific integrity activities and outcomes" as outlined in the Policy.

II. Ensuring the Free Flow of Scientific Information

We enthusiastically agree that open and timely communication of science plays a valuable role in building public trust and understanding of research. However, the ways that scientific activities and findings are communicated need to be revised, and the NIH has a central role in updating guidance and policies on all scientific records, including publication and awards. This could be facilitated by the Scientific Integrity Council's review and clarification of the NIH-wide Policy on Manuscript and Abstract Clearance and clear descriptors to the web form to include the following:

> 1) When animals are used in research intending to inform human health, it should be clearly communicated in the title of the manuscript that the findings are from animals.
>
> 2) Abstracts should be included in the clearance approval of manuscripts, and the use of animals should be explicitly stated.

These changes are consistent with the ARRIVE guidelines, yet researchers do not always comply, and publications do not always catch or enforce noncompliance with these guidelines. We welcome the recent notice encouraging award recipients to include the ARRIVE Essential 10 Checklist in all publications reporting on the results of vertebrate and cephalopod research (NOT-OD-23-057)[5] but recommend that the NIH makes this a requirement for all award recipients.

Furthermore, we, many other scientists, and the public, remain concerned about the reliability of the scientific record when so much NIH-funded research has and continues to use animals to inform human

health. Scientific integrity requires consideration of whether the findings can be recapitulated in humans, and analysis of whether and how results translate to humans. Raising such questions can stimulate innovation and should encourage more funding for the development of NAMs.

Reproducibility is a cornerstone of the scientific method, ensuring that findings replicate and building confidence in evidence. The NIH has taken important steps toward addressing the growing reproducibility crisis, including through the efforts of the Advisory Committee to the Director (ACD) Working Group on Enhancing Rigor, Transparency, and Translatability in Animal Research and the subsequent ACD Working Group on Catalyzing the Development and Use of Novel Alternative Methods to Advance Biomedical Research, as well as resources provided by the Office of Extramural Research (OER) on enhancing reproducibility through rigor and transparency. These efforts and resources, while important for fostering scientific integrity, could further be bolstered by specific policies in the Scientific Integrity Policy. This could be achieved, for example, by requiring awardees to comply with appropriate reporting guidelines—not only ARRIVE, but also guidelines for *in vitro* approaches, such as GCCP 2.0[6], GIVIMP[7], and RIVER[8]. These and other requirements that promote reproducibility and therefore foster scientific integrity should be formally incorporated into the Policy.

Moreover, to uphold the free flow of scientific information and protect the integrity of the scientific processes we recommend that the foundation of NIH's mission be amended to include the generation of reliable, rigorous, research results, and their publication in reputable, peer-reviewed scientific journals *regardless of impact factor*. The heavy reliance on publications and journal impact factors when evaluating grants is an inappropriate influence that should be addressed in the Policy.

2. Responsibilities of the NIH Scientific Integrity Council

As described in the Policy, the Scientific Integrity Council will assist the NIH Scientific Integrity Official in iterative review, policy development, and priority setting to ensure that the existing policies and procedures are responsive to issues that arise in the scientific integrity space. As described above, the relevance of NIH-funded research to human health is a scientific integrity issue; the Scientific Integrity Council should therefore further develop policies and set priorities to ensure responsiveness human-relevance integrity issues. To ensure that a well-informed and high-level group of experts supports scientific integrity at NIH, the Council should consist of human-relevant science expertise and should ensure that other scientific integrity staff and NIH leadership are adequately informed about human-relevant science and its relation to scientific integrity.

In addition, the Council should work with OER and CSR to ensure study sections, award recipients, trainees, and the broader scientific community are well-informed about human-based science and its role in scientific integrity. The Council should further work with CSR to ensure the proper evaluation of animal- and nonanimal-based projects and to ensure that continuously funded projects with limited human relevance and/or clinical impact are reevaluated and unfunded where necessary.

3. NIH as a Policy Development Agency

The Policy describes the role of the NIH in developing sound and comprehensive policies when promoting biomedical research. Important issues such as biosafety, human subjects' protection, and genomic data sharing are mentioned in the draft policy, however, to address long-standing challenges of

translation in biomedical research we recommend that the issue of reducing and replacing animal models and the publication integrity transparent reporting should be included in the final policy document.

III. **Supporting Policy-Making Processes**

The Policy describes a number of ways in which NIH works to maintain transparency and accountability in the policy drafting process. Following the Administrative Procedure Act (5 USC Subchapter II) the NIH policy procedures would increase public trust and evidence scientific policy accountability by removing the phrase "as appropriate" from the following sentences so that the agency is not perceived as creating loopholes for their dissemination and engagement efforts. We also recommend that all **draft** policy proposals, in addition to final policies, be published on the Federal Register. This would be in line with how other federal agencies conduct their policy-making processes utilizing the Federal Register:

1) The development of science policy at NIH generally follows procedures set forth under the Administrative Procedure Act (5 USC Subchapter II) at https://www.archives.gov/federalregister/laws/administrative-procedure, where applicable, and draft policy proposals are routinely issued through the NIH Guide and the Federal Register, to obtain early feedback into policy proposals.
2) Final policies are also issued through the NIH Guide and the Federal Register and incorporated into the NIH Grants Policy Statement and NIH Policy Manual.

[1] https://www.hhs.gov/sites/default/files/draft-hhs-scientific-integrity-policy.pdf

[2] Franzen N, van Harten WH, Retèl VP, Loskill P, van den Eijnden-van Raaij J, IJzerman M. Impact of organ-on-a-chip technology on pharmaceutical R&D costs. *Drug Discov Today*. 2019;24: 1720–1724. doi:10.1016/j.drudis.2019.06.003

[3] Ingber DE. Human organs-on-chips for disease modelling, drug development and personalized medicine. *Nat Rev Genet*. 2022; 1–25. doi:10.1038/s41576-022-00466-9

[4] Loewa A, Feng JJ, Hedtrich S. Human disease models in drug development. *Nat Rev Bioeng*. 2023; 1–15. doi:10.1038/s44222-023-00063-3

[5] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-057.html

[6] https://www.altex.org/index.php/altex/article/view/2376

[7] https://www.oecd-ilibrary.org/environment/guidance-document-on-good-in-vitro-method-practices-givimp_9789264304796-en;jsessionid=lcFblMGZO8qR-_Hk2btN6Zt0lMML8oWdMBQ0gGcK.ip-10-240-5-51

[8] https://osf.io/preprints/metaarxiv/x6aut/

Submit date: 11/9/2023

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

Name: Abigail Echo-Hawk

Name of Organization: Urban Indian Health Institute

Type of Organization: Nonprofit research organization

Role: Scientific researcher

Comment:

Uploaded File:

UIHI-Comments-on-NIH-Draft-Scientific-Integrity-Policy.pdf

Abigail Echo-Hawk, MA
Director, Urban Indian Health Institute
Executive Vice President, Seattle Indian Health Board

November 9, 2023

Lyric Jorgenson
National Institutes of Health Office of Science Policy
Bethesda, MD 20892

Submitted electronically via: https://osp.od.nih.gov/comment-form-draft-scientific-integrity-policy-for-the-national-institutes-of-health/

RE: Request for Information on the DRAFT Scientific Integrity Policy of the National Institutes of Health

Dear Acting Director Jorgenson,

Urban Indian Health Institute (UIHI) submits the following comments and recommendations to the National Institutes of Health (NIH) Office of Science Policy regarding the draft Scientific Integrity Policy. I am thankful to NIH for accepting these comments on its draft policy and request that the recommendations below be implemented in the final version to contribute to the betterment of American Indian and Alaska Native (AI/AN) communities. I hope that NIH will be transparent in its policy revision process and allow the review of future edits to this draft.

Background on Urban Indian Health Institute
UIHI is the research division of Seattle Indian Health Board,[1] a public health authority, and one of twelve Tribal Epidemiology Centers in the country – the only one with a national purview. UIHI conducts research and evaluation, collects and analyzes data, and provides disease surveillance for Tribes and the 41 UIOs nationwide. In 2021, UIHI released *Data Genocide*,[2] a report card grading U.S. States' quality of COVID-19 racial data highlighting the nation's inability to accurately collect, report, and analyze race and ethnicity data which drives health inequity. In response, UIHI has engaged with federal, state, and local public health agencies and policymakers to improve the collection and reporting of surveillance data on AI/AN.

UIHI's expertise in data access and exchange informed the Government Accountability Office report titled, *Tribal Epidemiology Centers: HHS Actions Needed to Enhance Data Access*.[3] Through these types of exchanges, UIHI continues to be a leader in the development, implementation, evaluation, dissemination, and translation of Indigenous evaluation and research to reduce diseases, risk factors, and health disparities. I submit the following recommendations regarding NIH's draft Scientific Integrity Policy to enhance the quality of research which is often used in policy decision-making.

- **Mandate trainings under *Promoting a Culture of Scientific Integrity* to ensure the policy is applied to the fullest extent possible.** The National Science and Technology Council's report *Protecting the Integrity of Government Science*[4] suggests that agencies

[1] SIHB is one of 41 Indian Health Service-designated Urban Indian Organizations in the Urban Indian Health Program, as defined by Section 4 of the Indian Health Care Improvement Act, and a Health Resources Service Administration 330 Federally Qualified Health Center.
[2] Urban Indian Health Institute. (2021). Data Genocide of American Indian and Alaska Natives in COVID-19 Data. Retrieved from: https://www.uihi.org/projects/data-genocide-of-american-indians-and-alaska-natives-in-covid-19-data/
[3] United States Government Accountability Office. (March 2022). Tribal Epidemiology Centers: HHS Actions Needed to Enhance Data Access. Retrieved from: https://www.gao.gov/assets/gao-22-104698.pdf
[4] National Science and Technology Council. (2022). Protecting the Integrity of Government Science. Retrieved from: https://www.whitehouse.gov/wp-content/uploads/2022/01/01-22-Protecting_the_Integrity_of_Government_Science.pdf

should "mandate scientific integrity training for everyone in federal agencies who plays a role in conducting, managing, communicating, or making use of science in decision-making". NIH's draft policy states that new employees "will receive scientific integrity information or training", but this is not sufficient. Simply providing information does not replace the need for training. The policy should mandate trainings in addition to providing information to new employees, not simply present them as a potential alternative.

- **Clarify administrative processes regarding allegations of deviation from the policy in the IV. Ensuring Accountability Policies #3 and #4.** NIH should clarify the processes surrounding allegations of deviation from scientific integrity. President Biden's *Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking*[5] calls for procedures to be published that establish "an administrative process for reporting, investigating, and appealing allegations of deviation from the agency's policy". While the draft policy published by NIH states that it is NIH policy to provide clear guidelines on this matter, such guidelines are not actually included in the draft policy. The officially adopted Scientific Integrity Policy should include detailed guidelines consistent with the President's memorandum.
- **Expand the II. Ensuring the Free Flow of Scientific Information Policy #9 to include tribes.** To ensure the free flow of information to sovereign nations, the NIH policy must be adjusted to state "Ensure that scientific information is accurately represented in responses provided by NIH to Congressional inquiries, tribal inquiries, testimony, and other requests.
- **Modify the II. Ensuring the Free Flow of Scientific Information Policy #11 to include a list of violations and applicable consequences.** Transparency with the public should be maximized and NIH should publish, as part of its Scientific Integrity Policy, a list of actions which violate the policy to achieve this. Under this policy, NIH should also publish a detailed protocol for filing a complaint and conducting an inquiry to follow should a violation from the list occur. Additionally, the policy should include a requirement for a report to be published detailing the allegation, the inquiry, and the outcome of the inquiry. The protocol and report requirements could be similar to the ones in the Department of the Interior Departmental Manual.[6]
- **Require the NIH Scientific Integrity Council to work with the NIH Tribal Health Research Office, when appropriate.** With the Scientific Integrity Council general responsibilities including to 'ensure that existing policies and procedures are responsive to issues that arise in the scientific integrity space' it is imperative for the Council to work in collaboration with the NIH Tribal Health Research Office when issues arise that involve tribes, tribal organizations, urban Indian organizations, and American Indian and Alaska Native communities. This is especially important as NIH career employees are not experts on AI/AN communities and allows for further cultural considerations.
    - **Utilize a Tribal Consultation and Urban Confer when an issue arises that goes beyond the knowledge and capabilities of the NIH Scientific Integrity Council and the Tribal Health Research Office.** With the Council responsible to 'review, assess, and revise the NIH Scientific Integrity Policy as needed' we would like to recommend that NIH implement a Tribal Consultation or Urban Confer when an issue involves tribes or AI/AN populations. This can address research misconduct allegations to heighten awareness on issues that involve AI/AN populations. Indian Health Service is the only

[5] The White House. (2021). Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. Retrieved from: https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/.

[6] Department of the Interior. (2014). Department of the Interior Departmental Manual. Retrieved from: https://www.doi.gov/sites/doi.gov/files/uploads/305_dm_3_final_revised_si_policy_12-16-14.pdf

federal agency with an existing Tribal Consultation AND Urban Confer policy.[7,8] An urban confer does not impede on the rights of sovereign tribes but rather supports the trust and treaty obligations to AI/AN populations residing in urban areas.

- **When necessary, consider cultural implications.** To address the long-standing and inter-generational knowledge carried within tribes and American Indian and Alaska Native populations, the NIH Scientific Integrity Policy must consider cultural implications by adapting policies and protocols when necessary. This would align with the NIH Office of Equity, Diversity, and Inclusion's stated goals to "identify and eliminate discrimination from the agency's personnel policies, practices, and working conditions" and "promote the understanding and appreciation of an inclusive and diverse workplace culture".[9] For example, under definitions for research and science NIH should honor the existence of Indigenous research and evaluation methods to ensure that allegations are not raised against scientists and researchers who use these methods in compliance with the Scientific Integrity Policy. This upholds the wellbeing of Indigenous communities.

Thank you for your consideration and action on the comments contained herein. If I can provide any additional information or answer any questions, please contact me using the information below.

Sincerely,

Abigail Echo-Hawk (Pawnee), MA
Director, Urban Indian Health Institute
Executive Vice President, Seattle Indian Health Board
AbigailE@uihi.org

[7] Indian Health Service. (2006). Tribal Consultation Policy. Retrieved from: https://www.ihs.gov/IHM/circulars/2006/tribal-consultation-policy/
[8] Indian Health Service. (n.a.). Conferring with Urban Indian Organizations. Retrieved from: https://www.ihs.gov/ihm/pc/part-5/p5c26/
[9] National Institutes of Health Office of Equity, Diversity, and Inclusion. (n.a.). Advancing racial equity. Retrieved from: https://www.edi.nih.gov/people/resources/advancing-racial-equity

Submit date: 11/9/2023

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

Comment:

November 9, 2023

Tara A. Schwetz, PhD

Acting Principal Deputy Director, National Institute of Health

9000 Rockville Pike,

Bethesda, MD 20892 USA

Re: Request for Information on the DRAFT Scientific Integrity Policy of the National Institute of Health.

via website: https://www.federalregister.gov/documents/2023/09/25/2023-20733/request-for-information-on-the-draft-scientific-integrity-policy-of-the-national-institutes-of

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 National Institute of Health's (NIH) draft scientific integrity policy. AADOCR recognizes and applauds NIH's effort to preserve scientific integrity throughout all NIH activities, establish key roles and responsibilities for those who will lead the agency's scientific integrity program, and establish relevant reporting and evaluation mechanisms. To respond to this request for comments, AADOCR engaged its Science Information Committee and its Board of Directors.

Scientific integrity is an essential tenet of every scientific study and discovery1. It provides certification that the data can be verified, repeated, and reproduced1. It is especially critical in the biomedical research space where scientific innovation and research discoveries contribute to life saving and quality of life improving measures. Therefore, AADOCR would like to congratulate NIH on a very detailed and comprehensive draft policy that aims to foster scientific integrity so as to ensure that scientific findings are objective, credible, and readily available to the public, and that the development and implementation of policies and programs is transparent, accountable, and evidence based. The additions to the policy on the roles and responsibilities of the Scientific Integrity Officer and the responsibilities of the Scientific Integrity Council are clear, logical, and necessary. Additionally, the inclusion of prohibitions against political interference is a socially responsible addition in all areas where it was introduced.

AADOCR would like to provide considerations for two specific areas of the policy:

- Page two of the policy document defines the NIH Mission as "to seek fundamental knowledge about the nature and behavior of living systems and apply that knowledge to enhance health, lengthen life, and reduce illness and disability". However, as the mission is currently under review to be potentially revised to "to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to optimize health and prevent or reduce illness for all people" AADOCR supports considering finalizing the scientific integrity policy only upon the confirmation of the new NIH Mission.
- The roles and responsibilities of the Chief Scientist was introduced on page 10 of the policy document. However, the definition of the term Chief Scientist provided on page 5, describes the Chief Scientist as the Principal Deputy Director. This indicates that the roles and responsibilities of the Chief Scientist will be carried out by the Principal Deputy Director. The introduction of a new title (Chief Scientist) to an existing position where that position is retained may be confusing to the public and policy makers. Some may make the incorrect assumption that Presidentially-appointed, Senate-confirmed NIH Director is the NIH Chief Scientist. Therefore, AADOCR supports considering, in lieu of a new title, providing clarification that the role of the Principal Deputy Director also includes the responsibilities listed under Chief Scientist within the policy document - oversight of all NIH scientific integrity policies and procedures. In the event that the Chief Scientist role would eventually evolve to an individual that is separate and apart from the Principal Deputy Director, AADOCR supports the consideration of "Deputy Director for Scientific Integrity" as a potential title for this employee. This is bolstered by the need to be sensitive to appropriation of and lack of respect for the Native American culture with the title "Chief" in creating a new position. [AADOCR recognizes the need to examine our own titles in this regard.]

AADOCR appreciates the opportunity to provide comments on NIH's draft scientific integrity policy and stands ready to work with NIH through an inclusive process to safeguard scientific integrity.

If you have any further questions, please contact Dr. Makyba Charles-Ayinde, Director of Science Policy, at mcayinde@iadr.org.

Sincerely,

Christopher H. Fox, DMD, DMSc — Chief Executive Officer

Alexandre Vieira, DDS, MS, PhD — President

1Diaba-Nuhoho P et al. (2021). Reproducibility and Research Integrity: The Role of Scientists and Institutions. BMC Research Notes. 14(451).

2Bohanon M. (2022). DEI Expert Lee Bitsóí Explains Why 'Chief' Should Be Eliminated from Diversity Titles. Retrieved from: https://www.insightintodiversity.com/words-matter-dei-expert-lee-bitsoi-explains-why-chief-should-be-eliminated-from-diversity-titles/. Accessed on November 1, 2023.

Uploaded File:

AADOCR-Response-to-Draft-Scientific-Integrity-Policy.pdf

Email: mcayinde@iadr.org

November 9, 2023

Tara A. Schwetz, PhD
Acting Principal Deputy Director, National Institute of Health
9000 Rockville Pike,
Bethesda, MD 20892 USA

Re: Request for Information on the DRAFT Scientific Integrity Policy of the National Institute of Health.

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Sincerely,

Christopher H. Fox, DMD, DMSc
Chief Executive Officer

Alexandre Vieira, DDS, MS, PhD
President

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[1]Diaba-Nuhoho P et al. (2021). Reproducibility and Research Integrity: The Role of Scientists and Institutions. BMC Research Notes. 14(451).
[2]Bohanon M. (2022). DEI Expert Lee Bitsóí Explains Why ‘Chief’ Should Be Eliminated from Diversity Titles. Retrieved from: https://www.insightintodiversity.com/words-matter-dei-expert-lee-bitsoi-explains-why-chief-should-be-eliminated-from-diversity-titles/. Accessed on November 1, 2023.