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

[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