Dated: October 16, 2024.

**Bruce A. George,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2024–24239 Filed 10–18–24; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Advisory Committee on Research on Women's Health.

The meeting will be open to the public as a virtual meeting. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*https://videocast.nih.gov/*).

*Name of Committee:* Advisory Committee on Research on Women's Health.

*Date:* December 9, 2024.

*Time:* 1:00 p.m. to 3:00 p.m.

*Agenda:* Briefing on the National Academies of Science, Engineering, and Medicine's (NASEM) Assessment of NIH Research on Women's Health.

*Place:* National Institutes of Health, 9000 Rockville Pike, Building 31, Bethesda, MD 20892 (In-Person and Virtual Meeting).

*Contact Person:* Vivian Ota Wang, Ph.D., FACMG, CGC, Deputy Director, Office on Research for Women's Health, Division of Program Coordination, Planning and Strategic Initiatives, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892, 240–550–9892, *otawangv@nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meetings. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://orwh.od.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: October 15, 2024.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2024–24238 Filed 10–18–24; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; U01 Cooperative Agreement for Clinical Trials in Hearing Disorders.

*Date:* November 12, 2024.

*Time:* 10:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate cooperative agreement applications.

*Address:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Sonia Elena Nanescu, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Suite 8300, Bethesda, MD 20892, (301) 496–8683, *sonia.nanescu@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: October 15, 2024.

**Victoria E. Townsend,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2024–24199 Filed 10–18–24; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Final Scientific Integrity Policy of the National Institutes of Health

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice of final policy.

**SUMMARY:** The National Institutes of Health (NIH) is issuing this Final NIH Scientific Integrity Policy to promote a continuing culture of scientific integrity at NIH. This 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:** This Final Policy is effective on December 30, 2024.

**FOR FURTHER INFORMATION CONTACT:** Jessica Tucker, Ph.D., Acting Deputy Director, Office of Science Policy, NIH, 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 support of our mission, 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 its continuing efforts to foster 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*). In this report, NIH outlines the various roles it plays 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 Final NIH Scientific Integrity Policy, which is in alignment with the guidance set forth in the Presidential Memorandum and the Final Scientific Integrity Policy of the U.S. Department of Health and Human Services (*https://www.hhs.gov/programs/research/scientificintegrity/index.html*). The Final NIH Scientific Integrity Policy articulates the procedures and processes in place at NIH that help maintain rigorous scientific integrity practices and outlines 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 (*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 Final NIH Scientific Integrity Policy outlines several new functions to further enhance existing practices and processes. For example, the Final NIH Scientific Integrity Policy includes a Federal definition of scientific integrity that is shared across the U.S. Government as outlined in the White House Framework. This alignment across the U.S. Government will help ensure consistency in guidance and language, lending clarity and uniformity to interagency efforts concerning scientific integrity. The Final NIH Scientific Integrity Policy also establishes the appointments of, and roles and responsibilities for, the positions of the NIH Chief Scientist (CS) and the NIH Scientific Integrity Official (SIO). The CS and SIO will have prominent and critical responsibilities in steering the NIH scientific integrity efforts, advising NIH leadership on scientific issues, and playing key roles in NIH adjudication efforts related to scientific integrity. The Final NIH Scientific Integrity Policy also includes NIH practices that will address important emerging topics in biomedical research, such as protecting against political interference.

**Overview of Public Comments**

NIH released its Request for Information on the Draft NIH Scientific Integrity Policy on September 25, 2023 (88 FR 65696: *https://www.federalregister.gov/documents/2023/09/25/2023-20733/request-for-information-on-the-draft-scientific-integrity-policy-of-the-national-institutes-of;* comment period closed on November 9, 2023). In response to the Draft Policy, NIH received 26 responses from interested parties, and the comments are publicly available at *https://osp.od.nih.gov/policies/scientific-integrity/.* The largest group of respondents reported no affiliation, followed by affiliation with professional societies, with a small percentage of respondents indicating affiliation with research institutions, industry, and advocacy coalitions. Respondents typically identified themselves as members of the public, while another sizeable section self-identified as scientific researchers. Remaining respondents identified as institutional officials, and smaller percentages self-identified as medical providers, government officials, and scholarly publishers. NIH considered all feedback in the development of the Final NIH Scientific Integrity Policy, and a discussion of the public comments on specific topics follows below.

**Discussion of Public Comments on the Draft NIH Scientific Integrity Policy**

*Policy Scope*

*Draft Policy:* The Draft NIH Scientific Integrity Policy explicitly outlined the categories of NIH employees and staff with defined roles and responsibilities when in the course of their official duties they propose, conduct, review, or communicate about science and scientific activities on behalf of NIH. It also stated that NIH has implemented separate policies for contractors, collaborators, awardees, and volunteers to uphold the principles of scientific integrity.

*Public Comments:* While commenters were generally supportive of the overall scope of the Draft NIH Scientific Integrity Policy, a few suggested clarifying how it might impact the extramural community, applicability to HHS officials and political appointees, and NIH employees engaging in program administrative roles.

*Final Policy:* The Final NIH Scientific Integrity Policy clarifies that the Policy applies to all NIH employees; Public Health Service Commissioned Corps officers assigned to NIH; NIH political appointees; NIH intramural clinical, research, and postdoctoral fellows; NIH intramural doctoral trainees; advisory committee members in their capacity as special Government employees; and all levels of employees managing scientific activities, engaging in program administrative roles, and using scientific information in decision making when in the course of their official duty activities they propose, conduct, review, or communicate about science and scientific activities on

behalf of NIH. Extramural investigators are not encompassed under this Policy unless they otherwise meet the qualifications of a covered individual (*e.g.,* membership on a Federal Advisory Committee in their capacity as a special Government employee); nevertheless, many individuals across the entire scientific enterprise have a role in supporting scientific integrity more broadly.

*Roles and Responsibilities of the Chief Scientist and the Scientific Integrity Official*

*Draft Policy:* The Draft NIH Scientific Integrity Policy proposed the appointments as well as roles and responsibilities for the positions of NIH Chief Scientist (CS) and NIH Scientific Integrity Official (SIO). It indicated that the CS and SIO will have prominent and critical responsibilities in steering NIH scientific integrity efforts, advising NIH leadership on scientific issues, and playing key roles in agency adjudication efforts related to scientific integrity.

*Public Comments:* While commenters were generally supportive of the establishment and proposed roles and responsibilities of the CS and SIO, a few suggested clarifying both roles and adding additional roles and responsibilities for other NIH leadership. Suggestions also included clearly defining the adjudication processes for losses of scientific integrity and ensuring adequate resources are allotted to the SIO and staff to implement the Policy and proactively seek out potential allegations of losses of scientific integrity.

*Final Policy:* The Final NIH Scientific Integrity Policy affirms the roles and responsibilities of the CS and SIO required by the 2021 Presidential Memorandum and includes some additional roles and responsibilities suggested by public comments. Detailed processes for adjudicating findings of loss of scientific integrity will be outlined in a NIH Manual Chapter and/or additional guidance. Additionally, NIH will ensure the SIO and other relevant agency offices and staff receive adequate support and resources to fulfill the functions outlined in the Policy.

*Roles and Responsibilities of the Scientific Integrity Council*

*Draft Policy:* The Draft NIH Scientific Integrity Policy proposed the establishment of a NIH Scientific Integrity Council comprising career employees from across NIH to be led by the NIH SIO. It indicated that the Council would 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.

*Public Comments:* Commenters were generally supportive of the establishment and proposed roles and responsibilities of the Council and suggested ensuring that it include a well-informed and a high-level group of experts on scientific integrity. Among the comments were suggestions for including desired areas of expertise for Council members, articulating a more explicit role of the Council in the adjudication process, and requiring the group to work with offices such as the NIH Tribal Health Research Office to consider any potential cultural implications. Additionally, a few commenters suggested that the NIH Scientific Integrity Council, the CS, and the SIO should consult with and/or include external experts to avoid potential conflicts of interest.

*Final Policy:* The Final NIH Scientific Integrity Policy describes desired expertise areas for Council members and affirms the roles and responsibilities of the Council. Processes for the role the Council will play in adjudicating findings of loss of scientific integrity will be outlined in additional implementation guidance. The Council will work with all pertinent NIH offices and seek public input when needed to ensure appropriate expertise on pertinent topics. All members of the Council, the CS, and the SIO will be expected to comply with existing conflict of interest policies and procedures.

*Promoting a Culture of Scientific Integrity*

*Draft Policy:* The Draft NIH Scientific Integrity Policy stated that diversity, equity, inclusion, and accessibility (DEIA) are integral components of the entire scientific process, and that 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 Draft Policy additionally noted that 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.

*Public Comments:* Several commenters expressed support for the inclusion of DEIA within scientific integrity principles. Several commenters noted the importance of mandatory training for all NIH employees, not just the sharing of information on scientific integrity.

*Final Policy:* The Final NIH Scientific Integrity Policy affirms the NIH stance that a strong culture of scientific integrity begins with ensuring a professional environment that is safe, equitable, fair, just, impartial, honest, and inclusive; DEIA are integral components of the entire scientific process. The Policy also states that scientific integrity training will be made available to all covered individuals, and some covered individuals may be required to complete role-specific training or refresher training as appropriate.

*Ensuring Free Flow of Scientific Information*

*Draft Policy:* The Draft NIH Scientific Integrity Policy affirmed NIH's commitment to the broad and equitable dissemination and promotion of rigorous and objective scientific information. It highlighted the role of the NIH Office of Communications and Public Liaison in disseminating objective and evidence-based research findings to the public and responding to public inquiries. It also reiterated that NIH scientists may communicate their scientific activities objectively without political interference or other inappropriate influence.

*Public Comments:* While commenters were generally supportive of the Draft NIH Scientific Integrity Policy provisions on ensuring the free flow of scientific information, a few noted that further delineation of scientists' ability to communicate with the media and public freely about their areas of expertise was needed and indicated that protection from potential bad faith attacks should be provided. Some commenters also suggested clarifying the differences between and processes for scientific technical review and media review.

*Final Policy:* The Final NIH Scientific Integrity Policy provides additional guidance on how NIH scientists may communicate scientific information while performing official duty activities and defines and protects against retaliation. The Final Policy reaffirms that NIH scientists and other covered individuals can communicate their personal or individual views to the media or the public in their personal capacities, including on social media, subject to the limitations of government ethics rules, HHS supplemental ethics regulations, social media regulations, and obligation to protect nonpublic information. The Final Policy also clarifies the requirements and

protections for scientific technical review processes.

*Protections*

*Draft Policy:* The Draft NIH Scientific Integrity Policy described NIH's commitment to prioritizing safe and respectful work environments as well as existing protections for employees to disclose 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. The Draft Policy also affirmed NIH's commitment to hiring and retaining candidates for NIH scientific and technical positions based on the candidate's scientific and technical knowledge, credentials, experience, and integrity.

*Public Comments:* Some commenters expressed the need for further protections for individuals who report allegations of loss of scientific integrity. Several commenters affirmed the importance of promoting DEIA with regard to the NIH workforce, grantmaking apparatus, and other activities and recommended further elaboration of specific groups who should be included and considered in efforts to promote diversity.

*Final Policy:* The Final NIH Scientific Integrity Policy describes protections from reprisal for individuals who report allegations of loss of scientific integrity, including whistleblower protections. The Final Policy also affirms NIH's commitment to promoting equity in the scientific workforce and includes a robust description of the types of demographic groups that will be considered regarding efforts to promote equity.

*Policy Implementation*

*Draft Policy:* The Draft NIH Scientific Integrity Policy proposed a delay between a final policy release and its effective date in order to communicate policy expectations to covered individuals and develop specific implementation details and plans. Expected implementation activities would include the establishment of an evaluation plan to regularly measure, monitor, and evaluate ongoing scientific integrity activities and outcomes. 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 would be published.

*Public Comments:* Several commenters requested that additional implementation details be added to the Policy, including information on the allegations reporting and appeals processes, applicable consequences, an evaluation plan, publication best practices, and plans for public input, including meaningful engagements to build trust with marginalized communities. Specifically, a comment noted that the annual report should include specific details regarding the allegation, the inquiry process, and the outcome of the investigation.

*Final Policy:* Consistent with other NIH policy development activities, additional implementation details will continue to be developed and publicly released. Given the bulk of implementation activities fall on NIH directly and not on our grantee institutions or contractors, NIH has chosen to enact a three-month implementation period. All implementation plans will comply with existing policies and regulations regarding conflicts of interest, whistleblower protections, etc. The Final NIH Scientific Integrity Policy notes that, for investigations that have been resolved, the annual report will include the types of corrective actions recommended by the investigation panel to restore scientific integrity, and the types of actions ultimately taken. Additionally, NIH will continue to seek input from the public, and the scientific integrity reporting process will also allow opportunities for public transparency. NIH is committed to promoting equity across the biomedical research enterprise and will consider additional methods to engage with communities historically underrepresented in biomedical research, including through existing robust outreach programs and initiatives.

*Additional Changes to Final Policy*

Some additional changes were made to the Final NIH Scientific Integrity Policy in response to public comments, for clarity, or to maintain consistency with the Final HHS Scientific Integrity Policy. Some of these additional changes include slight revisions to the definition of ''political interference,'' a new definition of ''retaliation,'' clarification of training requirements, and under ''Protecting Scientific Processes,'' a statement noting that early termination of extramural awards is prohibited except under certain specific circumstances.

**Concluding Points**

The Final NIH Scientific Integrity Policy builds upon and consolidates NIH's longstanding efforts to foster an organizational culture of scientific integrity, protect the integrity of the research process, communicate science with integrity, and safeguard scientific integrity. This Final NIH Scientific Integrity Policy is another step in ensuring that NIH's work as an institution maintains the highest standards of integrity and represents the best of the Nation's investment in biomedical research.

NIH looks forward to continuing to work 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.

The Final NIH Scientific Integrity Policy is set forth below.

**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**

In support of our mission, NIH funds extramural researchers throughout the country, conducts research within its intramural research program, and develops 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 decision making 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 at *https://www.hhs.gov/programs/research/scientificintegrity/index.html.* The majority of procedures regarding scientific integrity described herein are longstanding and foundational to NIH-supported research. The NIH Scientific Integrity Policy integrates existing and new practices under a single harmonized framework.

**Effective Date and Policy Amendments**

This policy goes into effect on December 30, 2024. This policy will be evaluated by NIH one year after its effective date and every two years thereafter. Proposals to amend this policy will be overseen by the NIH Scientific Integrity Official (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 officers assigned to NIH; NIH political appointees; NIH intramural clinical, research, and postdoctoral fellows; NIH intramural doctoral trainees; advisory committee members in their capacity as special Government employees; and all levels of employees managing scientific activities, engaging in program administrative roles, and using scientific information in decision making, are expected to adhere to this policy 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 entities who are not covered individuals, such as contractors, collaborators, extramural awardees, peer reviewers and volunteers, to uphold the principles of scientific integrity established by this policy while carrying out activities on behalf of NIH or within the scope of NIH support or engagement. The primary focus of this policy is on covered individuals' performance of official duty activities on behalf of NIH. Federal employees must adhere to the Standards of Ethical Conduct for Employees of the Executive Branch,[1] which delineates requirements (and certain restrictions) for Federal employees when acting on behalf of the Federal government.

**Exceptions**

This policy will be implemented consistent with applicable Federal law and Executive Orders.

**Definitions**

For the purposes of this policy, NIH adopts the following 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.

*Covered individuals* include all NIH employees; Public Health Service Commissioned Corps officers assigned to NIH; NIH political appointees; NIH intramural clinical, research, and postdoctoral fellows; NIH intramural doctoral trainees; advisory committee members in their capacity as special Government employees; and all levels of employees who manage scientific activities, engage in program administrative roles, and use scientific information in decision making when in the course of their official duty activities they propose, conduct, review, or communicate about science and scientific activities on behalf of NIH. NIH contractors, partners, permittees, lessees, grantees, extramural trainees and fellows (*i.e.,* those supported by NIH grants to non-NIH organizations), and volunteers who engage or assist in NIH scientific activities are not considered covered individuals but are strongly encouraged to uphold the principles of scientific integrity described in this policy while carrying out activities on behalf of NIH or within the scope of NIH support or engagement, particularly those described in the Protecting Scientific Processes, Ensuring the Free Flow of Scientific Information, Protections, and Professional Development sections of this policy; additionally, specific requirements may be incorporated into the terms of their engagement with NIH.

*Decision making* refers to (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.

*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 adherence to statutes, regulations, policies, and guidelines governing employee conduct.

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

[1] Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635) provide the basic guidelines for official duty activities, and NIH sets the policy for implementing the guidelines at the agency. Available at: *https://www.ecfr.gov/current/title-5/chapter-XVI/subchapter-B/part-2635.*

*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.[2] [3]

*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.

*Official duty activity* refers to activities performed by an employee as part of, or an extension of, regular official responsibilities.[4]

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

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

*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. Research misconduct does not include honest error or differences of opinion.[5]

*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.

*Retaliation* refers to, per 5 U.S.C. 2302(b)(8), taking or failing to take or threatening to take or fail to take a personnel action with respect to any employee or applicant for employment because of any disclosure of information that the employee or applicant reasonably believes evidences any violation of any law, rule, or regulation or gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety if such disclosure is not specifically prohibited by law and if such information is not specifically required by Executive Order to be kept secret in the interest of national defense or the conduct of foreign affairs. An employee or applicant is protected from retaliation for the disclosure of information the employee or applicant reasonably believes is evidence of censorship related to research, analysis, or technical information.[6] [7]

*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 and including multiple forms of evidence (*e.g.,* Indigenous Knowledge).

*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.[8]

*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.[9])

*Scientific Integrity Council* will assist the NIH SIO in iterative review, policy

[2] 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, security or legal review, review for compliance with existing policies, 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 (*e.g.,* 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.

[3] 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.

[4] The Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635) provide the basic guidelines for official duty activities, and NIH sets the policy for implementing the guidelines at the agency. Available at: *https://www.ecfr.gov/current/title-5/chapter-XVI/subchapter-B/part-2635.*

[5] 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.*

[6] Protection of Certain Disclosures of Information by Federal Employees. Available at: *https://home.treasury.gov/system/files/306/WPEA-2012-PL-112-199.pdf.*

[7] Prohibited personnel practices. Available at: *https://www.govinfo.gov/content/pkg/USCODE-2022-title5/pdf/USCODE-2022-title5-partIII-subpartA-chap23-sec2302.pdf.*

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

[9] 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.*

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 decision making. 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 Chief Scientist (CS) will:

1. Provide oversight of all NIH scientific integrity policies and procedures, including the periodic updates of those policies and procedures;
2. Engage in 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 the NIH or HHS Scientific Integrity Policies.

The Scientific Integrity Official (SIO) will:

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, and participate on the HHS Scientific Integrity 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 Assessment (OMA), and the HHS Office of the Inspector General (OIG) (*e.g.,* as related to waste, fraud, abuse, and illegal activities);
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 (*e.g.,* as related to waste, fraud, abuse, and illegal activities); and
9. Promote agency efforts regarding diversity, equity, inclusion, and accessibility.

*NIH Scientific Integrity Council*

The NIH SIO will establish and convene an NIH Council comprising career employees with expertise in ethics, research integrity, research misconduct, communications, whistle blower protections, and other relevant administrative areas from across 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 NIH SIO in adjudicating allegations of loss of scientific integrity (particularly related to political interference) in cases where such allegations fall outside of existing processes managed by OER, OIR, OMA, and OIG (*e.g.,* waste, fraud, abuse, and illegal activities);
6. In addition to being composed of relevant experts, confer with relevant offices (*e.g.,* Tribal Health Research Office, Chief Officer for Scientific Workforce Diversity, and Sexual and Gender Minority Research Office) when additional expertise is needed; and
7. Determine handling of investigation and adjudication proceedings from which the NIH 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, public access to the results of NIH-funded research, human subjects and research animal protections, the organization and management of 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 and discrimination.

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 will prominently post and maintain the NIH Scientific Integrity Policy on its website and will ensure 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. Scientific integrity training will be made available to all covered individuals, and some covered individuals may be required to complete role-specific training or refresher training as appropriate.

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 Decision Making Processes
IV. Ensuring Accountability
V. Protections
VI. Professional Development for Government Scientists, and
VII. Federal Advisory Committees

I. Protecting Scientific Processes

NIH has implemented a suite of complementary 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 such that it undermines impartiality, objectivity, nonpartisanship, or professional judgment. Further processes will be developed and documented to support this policy in an NIH Manual Chapter and/or additional guidance.

It is the policy of NIH to:

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

2. Prohibit inappropriate restrictions on resources and capacity that limit and reduce the availability of science and scientific products (*e.g.,* manuscripts for scientific journals, presentations for workshops, conferences, and symposia) outside of normal budgetary or priority-setting processes or without scientific, legal, or security justification.[10]

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

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, at a minimum, have (1) made a substantial contribution or provided editorial revisions that include critical intellectual content, (2) approved the final version, and (3) 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.[11]

6. Ensure independent review of scientific activities conducted by covered individuals as appropriate to ensure scientific integrity.[12]

7. Require that covered individuals comply with NIH policies and procedures for planning and conducting

[10] 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.*

[11] 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.*

[12] 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.*

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.[13]

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.[14]

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.[15]

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 NIH personnel 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.[16]

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.[17]

14. Prohibit the suspension or early termination of an extramural grant awarded by NIH except as consistent with applicable law and grants policies.[18] [19]

## 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 and rigorous research results, and their publication in reputable, peer-reviewed scientific journals. NIH's IRP researchers adhere to the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635)[20] and the 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.[21] Consistent with open science expectations, NIH will 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.[22] [23] [24] [25]

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

[13] 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.*

[14] 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.*

[15] 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.

[16] 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) at *https://www.congress.gov/117/plaws/publ328/PLAW-117publ328.pdf* and Chips and Science Act, Public Law 117–167, Title VI, Subtitle D, Section 10631 (Aug 9, 2022) at *https://www.congress.gov/117/plaws/publ167/PLAW-117publ167.pdf.* OSTP guidance and relevant HHS and NIH policies to implement this legislation are available at: *https://www.whitehouse.gov/wp-content/uploads/2024/02/OSTP-Foreign-Talent-Recruitment-Program-Guidelines.pdf* and *https://grants.nih.gov/policy/foreign-interference/requirements-for-disclosure.*

[17] 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) at *https://www.congress.gov/117/plaws/publ328/PLAW-117publ328.pdf* and Chips and Science Act, Public Law 117–167, Title VI, Subtitle D, Section 10631 (Aug 9, 2022) at *https://www.congress.gov/117/plaws/publ167/PLAW-117publ167.pdf.* OSTP guidance and relevant HHS and NIH policies to implement this legislation are available at: *https://www.whitehouse.gov/wp-content/uploads/2024/02/OSTP-Foreign-Talent-Recruitment-Program-Guidelines.pdf and https://grants.nih.gov/policy/foreign-interference/requirements-for-disclosure.*

[18] *https://grants.nih.gov/policy/nihgps/index.htm*

[19] 45 CFR 75.372. Available at: *h*ttps://www.govinfo.gov/content/pkg/CFR–2022-title45-vol1/pdf/CFR–2022-title45-vol1-sec75–372.pdf.

[20] Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635) provide the basic guidelines for official duty activities, and NIH sets the policy for implementing the guidelines at the agency. Available at: *https://www.ecfr.gov/current/title-5/chapter-XVI/subchapter-B/part-2635.*

[21] Per the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635), ''Employees shall not knowingly make unauthorized commitments or promises of any kind purporting to bind the Government.'' Available at: *https://www.ecfr.gov/current/title-5/chapter-XVI/subchapter-B/part-2635.*

[22] 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.*

[23] 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.*

[24] 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.*

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

media regarding their scientific activities and areas of expertise, subject to limitations of Government ethics rules (5 CFR part 2635). In communicating with the media, NIH scientists must seek advice from career NIH communications experts when acting in their official capacities.

4. Allow NIH scientists and other covered individuals to express their personal views and opinions to the media with appropriate written or oral disclaimers, including on social media, subject to the limitations of Government ethics rules, HHS supplemental ethics regulations, social media regulations, and obligation to protect nonpublic information.[26] NIH scientists and other covered individuals may name NIH as their employer as one biographical fact among several; however, their title and position cannot receive more prominence than any other biographical fact. They should not be sourced by the media as an NIH representative and 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.[27]

5. 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 valid scientific, legal, or security justification. Deviations from clearance policies or procedures that result in suppression, delay, or alteration of scientific and technological information without scientific, legal, or security justification may constitute violations of the NIH Scientific Integrity Policy and may be reported under the Addressing Scientific Integrity Concerns section in this document.

6. Prohibit NIH officials, including communications officers, from altering, or directing 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.

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

8. 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 will be given the option to review the scientific content of proposed communication documents prior to publication or public release.

9. 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. If NIH scientists whose work is represented in NIH social media identify any errors in those representations regarding their scientific activities and areas of expertise, NIH social media managers are responsible for making appropriate corrections.

10. When offering spokespersons in response to media requests, offer knowledgeable spokespersons who can, in an objective and nonpartisan manner, describe the relevant scientific or technological aspects of their work.

11. Ensure that NIH scientists may communicate their scientific activities objectively without political interference or other inappropriate influence consistent with HHS [28] and NIH [29] communication and media policies. Scientific products must adhere to relevant NIH technical review procedures.

## III. Supporting Decision Making Processes

NIH utilizes multiple mechanisms for ensuring transparency and accountability in developing policy and informing decision making. 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.[30] For example, as described in the Bulletin, when independent peer reviews of scientific information products are conducted by contractors, a conflict-of-interest review will 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

[26] Per the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635), ''Employees shall not knowingly make unauthorized commitments or promises of any kind purporting to bind the Government.'' Available at: *https://www.ecfr.gov/current/title-5/chapter-XVI/subchapter-B/part-2635.*

[27] 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.

[28] This provision is further outlined in the HHS Guidelines on the Provision of Information to the News Media. Available at: *https://www.hhs.gov/sites/default/files/media_policy.pdf.*

[29] 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.*

[30] 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.*

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 within 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 individuals 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 research 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 help 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. Corrective actions may include correction or retraction of published scientific work or related media releases, release of inappropriately suppressed scientific materials, monitoring or supervision of future scientific activities, or required validation of data sources.

2. Encourage and facilitate early informal or formal consultation between covered individuals 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 will 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 will document the necessary aspects for each step of the process as well as the roles of the 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 they 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.[31] Support scientists and researchers including, but not limited to, Black, Latino, Indigenous and Native American persons, Asian Americans and Pacific Islanders, and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, queer, intersex, and asexual (LGBTQIA+) 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.

2. Promote diversity, equity, inclusion, and accessibility in the scientific workforce and create and support the creation of safe workspaces that are free from harassment and discrimination.[32]

3. Protect from reprisal those individuals who report allegations in good faith of loss of scientific integrity. Efforts will be made to protect the privacy of individuals involved in allegations.

4. Prevent covered individuals 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. 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 retaliation 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

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

[32] This provision is further outlined in the NIH Policy Manual Chapter 1311 on Preventing and Addressing Harassment and Inappropriate Conduct and the NIH Sourcebook Addendum to BSC Policies and Procedures. Available at: *https://policymanual.nih.gov/1311* and *https://oir.nih.gov/sourcebook/processes-reviewing-nih-intramural-science/boards-scientific-counselors/addendum-policies-procedures.*

Corps officers through 42 U.S.C. 213a(a)(18) and implemented by Commissioned Corps Directive 121.06.

6. Ensure scientific integrity staff at NIH are protected by all applicable employee rights as required by law. An SIO or other scientific integrity staff may only be terminated or reassigned for reasons consistent with applicable law.

## VI. Professional Development for Government Scientists

A key aspect of the NIH effort to advance scientific integrity is encouraging NIH scientists and covered individuals to engage with the broader research community in maintaining the highest ethical standards and scientific norms, while adhering to the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635).[33] 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.[34]

2. Encourage the sharing of scientific activities, findings, and materials developed by covered individuals through appropriate avenues including digital repositories.[35]

3. Encourage covered individuals to participate in and present research at professional meetings including workshops, conferences, and symposia.[36]

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.[37]

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 covered individuals 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 will 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 FAC based on expertise, knowledge, and contribution to the relevant subject area.[38] [39] 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.[40] Ensure committee membership is fairly balanced in terms of points of view represented with respect to the functions to be performed by the FAC.[41] [42]

3. Comply with current standards governing conflict of interest as defined in statutes and implementing regulations.[43] [44]

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

[33] Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635) provide the basic guidelines for official duty activities, and NIH sets the policy for implementing the guidelines at the agency. Available at: *https://www.ecfr.gov/current/title-5/chapter-XVI/subchapter-B/part-2635.*

[34] This provision is further outlined in the NIH Public Access Policy. Available at: *https://sharing.nih.gov/public-access-policy.*

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

[36] 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.*

[37] 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.*

[38] 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.*

[39] 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.

[40] This provision is further outlined in the NIH Selection Criteria for NIH Advisory Committees. Available at: *https://ofacp.nih.gov/committees/selection_criteria.*

[41] 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.*

[42] General Services Administration 41 CFR part 102–3 Federal Management Regulation: Federal Advisory Committee Management. Available at: *https://www.regulations.gov/document/GSA-FMR-2022-0015-0010.*

[43] 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.*

[44] 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.*

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 (*e.g.,* as related to waste, fraud, abuse, and illegal activities).[45] 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.[46] As noted above, existing procedures under the purview of OER, OIR, OMA, and OIG (*e.g.,* as related to waste, fraud, abuse, and illegal activities) 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. Reporting can be done anonymously.

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 without reprisal.

3. The SIO will oversee an initial assessment of each reported concern and determine whether to request additional information from the complainant or others, as appropriate and feasible, 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 (including from the NIH Scientific Integrity Council, as appropriate) 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. Scientists can hold differing opinions without violating scientific integrity, and NIH encourages its scientists to respectfully express and engage with differing views as an integral part of the scientific process.[47] Differing scientific opinions are diverging views held by researchers who are substantively engaged in the science subject area. 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. 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.
- 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. For investigations that have been resolved, the report will include an aggregate summary of the types of corrective actions recommended by the investigation panel to restore scientific integrity, and a summary of the types of actions ultimately taken. 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, as appropriate. 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-*

[45] 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.

[46] 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 HHS Office of Special Counsel for information regarding retaliation based on whistleblowing. Further information can be found at: *https://www.edi.nih.gov/services/federal-EEO-complaint-process* 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.

[47] 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.*

*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://sharing.nih.gov/public-access-policy*
- 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. 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 U.S.C. part 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. 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 U.S.C. part 1034, made applicable to the Public Health Service Commissioned Corps through 42 U.S.C. 213a(a)(18) 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. part 4712—The National Defense Authorization Act, Enhancement of contractor protection from reprisal for disclosure of certain information
9. 5 U.S.C. 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 U.S.C. 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 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. 45 CFR part 46—HHS Protection of Human Subjects Regulation
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. part 1034, made applicable to the Public Health Service Commissioned Corps through 42 U.S.C. 213a(a)(18) and implemented by Commissioned Corps Directive (CCD) 121.06
20. Public Law No 117–328—Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, Division FF, Title II, Section 2321
21. Public Law No 117–167—CHIPS and Science Act of 2022, Title VI, Subtitle D, Section 10631

Dated: October 15, 2024.

**Lawrence A. Tabak,**

*Principal Deputy Director, National Institutes of Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer at (240) 276–0166.

**Project: State Opioid Response (SOR)/Tribal Opioid Response (TOR) Program Instrument (OMB No. 0930–0384)—Revision**

SAMHSA is requesting approval to modify its existing SOR/TOR Program Instrument by (1) broadening language from 'naloxone' to 'naloxone and other opioid overdose reversal medications' due to the availability of new FDA-approved non-naloxone overdose reversal medications; (2) broadening language from 'fentanyl test strips' to 'drug checking technologies as directed by SAMHSA due to the availability of new drug checking technology, including test strips for other emerging substances; (3) adding five questions to collect treatment and recovery support data that were previously reported biannually in the performance progress reports; (4) adding one question to collect data on clients who received contingency management for the treatment of stimulant use disorder; (5) adding a sub-recipient entity inventory table to collect expenditure data for each grant sub-recipient in response to the Consolidated Appropriations Act, 2023 (42 U.S.C. 300x–52(a)); (6) combining four questions with similar themes into two questions for clarity; (7) removing question 12 because it is comprised of more than one question with several different ideas, making it unsuited for this instrument; and (8) adding one question at the request of the Office of National Drug Control Policy (ONDCP) to collect information on Congressionally mandated and programmatic activities, and to comply with reporting requirements. The program-level information is collected quarterly for questions 1 to 13b, and annually for the sub-recipient entity inventory table, and entered and stored in SAMHSA's Performance Accountability and Reporting System (SPARS), which is a real-time, performance management system that captures information on the SAMHSA-funded substance use and substance use disorder prevention, harm reduction, treatment, and recovery support services, and mental health services delivered in the United States. Continued approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Modernization Act of 2010 reporting requirements that quantify the effects and accomplishments of its discretionary grant programs.

The SOR/TOR programs are authorized under the Further Consolidated Appropriations Act, 2024, Division D, Title II, and section 1003 of the 21st Century Cures Act [Public Law 114–255] (42 U.S.C. 290ee–3a), as amended. SAMHSA anticipates 189 recipients (states, territories, and tribal entities) will participate in these grant programs. Grantee-level data will include information related to: reported