20852, (240) 747–7530, *mairi.noverr@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 19, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–20656 Filed 9–22–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

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

The meetings 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 Drug Abuse Special Emphasis Panel; Population Assessment of Tobacco and Health (PATH) Study.

Date: October 31, 2023.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shareen Iqbal, Ph.D., M.P.H., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 443–4577, *shareen.iqbal@nih.gov*.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; NIDA–K Alternate SEP.

Date: November 3, 2023.

Time: 12:00 p.m. to 1:45 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Marisa Srivareerat, Ph.D., Scientific Review Officer, Scientific Review Branch, Office of Extramural Policy, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 435–1258, *marisa.srivareerat@nih.gov*.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; NIDA Animal Genomics and Functional Validation/Characterization of Genes/Variants in SUD.

Date: November 27, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–4471, *ramadanir@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: September 20, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–20693 Filed 9–22–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 of Allergy and Infectious Diseases Special Emphasis Panel; Research and Development of Vaccines and Monoclonal Antibodies for Pandemic Preparedness (ReVAMPP) Centers for Flaviviridae and Togaviridae (U19 Clinical Trial Not Allowed).

Date: October 24–25, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F30, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Scott Jakes, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F30, Rockville, MD 20852, (240) 669–5931, *jakesse@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 20, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–20695 Filed 9–22–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

AGENCY: National Institutes of Health, HHS.

ACTION: Request for information.

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

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

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

Comments are voluntary and may be submitted anonymously. You may also voluntarily include your name and contact information with your response. Other than your name and contact information, please do not include in the response any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your response. After the Office of Science Policy (OSP) has finished reviewing the responses, the responses may be posted to the OSP website without redaction.

FOR FURTHER INFORMATION CONTACT: Tyrone Spady, Ph.D., Director of the Science Policy Coordination, Collaboration & Reporting Division, Office of Science Policy, at (301) 496–9838 or *SciencePolicy@od.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

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

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

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

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

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

Request for Information

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

1. Role and Responsibilities of the NIH SIO

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

Draft Scientific Integrity Policy of the National Institutes of Health

Purpose

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

Scientific Integrity at NIH

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

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

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

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

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

Effective Date and Policy Amendments

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

Applicability and Scope

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

Exceptions

This policy will be implemented consistent with applicable Federal law.

Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Director of Science Policy as the NIH SIO.

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

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

Roles and Responsibilities

Chief Scientist and Scientific Integrity Official

The CS shall:

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

The SIO shall:

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

NIH Scientific Integrity Council

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

The primary responsibilities of the Council are to:

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

Background on NIH Functions

Intramural Research

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

Extramural Research

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

NIH as a Policy Development Agency

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

Policy Requirements

Promoting a Culture of Scientific Integrity

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

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

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

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

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

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

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

I. Protecting Scientific Processes

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

It is the policy of NIH to:

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

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

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

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

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

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

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

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

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

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,

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

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

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

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

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

established laws, regulations, policies, and ethical considerations.[12]

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

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

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

II. Ensuring the Free Flow of Scientific Information

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

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

It is the policy of NIH to:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[19] This provision is further outlined in the United States Office of Government Ethics Standards of Conduct and 18 U.S.C. 208 as Applied to Official Social Media Use. Available at: *https://oge.gov/web/oge.nsf/News+Releases/EAE37A7DA3C38BF3852589470077533 9/$FILE/LA-23-03%20The%20Standards%20of%20Conduct%20and%2018%20U.S.C.%20%C2%A7%20208%20as%20Applied%20to%20Official%20Social%20Media%20Use.pdf.*

without scientific, legal, or security justification.

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

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

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

III. Supporting Policymaking Processes

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

It is the policy of NIH to:

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

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

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

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

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

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

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

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

IV. Ensuring Accountability

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

It is the policy of NIH to:

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

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

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

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

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

V. Protections

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

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

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

It is the policy of NIH to:

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

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

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

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

5. Comply with whistleblower protections, specifically:

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

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

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

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

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

VI. Professional Development for Government Scientists

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

It is the policy of NIH to:

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

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

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

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

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

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

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

VII. Federal Advisory Committees

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

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,

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

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

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

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

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

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

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

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

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

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

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

Addressing Scientific Integrity Concerns

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

1. Concerns about a potential loss of scientific integrity at NIH may be reported to the NIH SIO by any individual who has knowledge of the situation.

2. NIH employees are encouraged to seek an informal consultation with the NIH SIO or other relevant agency integrity officials to discuss whether a concern constitutes a potential loss of scientific integrity before submitting a formal complaint. Employees ultimately have the discretion to submit a formal complaint as they see fit.

3. The SIO will oversee an initial assessment of each reported concern and determine whether to request additional information from the complainant or others and to determine whether a formal investigation is warranted. Additionally, if any reported concern falls within the purview of existing OER, OIR, OMA, or OIG processes, those mechanisms will instead be utilized.

4. Should an investigation be opened, an investigation committee consisting of the NIH SIO and other agency integrity officials from the NIH Scientific Integrity Council will be convened to develop a factual record by exploring the allegation(s) in detail and consulting with subject matter experts, interviewing witnesses, and reviewing documentation as needed.

5. Once the investigation is complete, the NIH SIO will determine whether scientific integrity was lost and report findings to the appropriate management entity.

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

Handling Differing Scientific Opinions

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

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

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

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

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

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

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

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

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

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

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

resolution measures among NIH scientists. In general:

- A team member or group of team members with a differing opinion may engage with their colleagues to resolve the issue as soon as the difference of opinion is known. NIH recommends this type of internal discussion as a first step in most dispute resolution proceedings.
- A team may choose to consult a manager. First-level managers may defer to an appropriate higher-level manager if the first-level manager has a conflict of interest or cannot offer an impartial opinion for any reason.
- If the matter cannot be satisfactorily resolved by other means, a team may request assistance from OIR. The NIH SIO may be consulted if their assistance is requested or if there is a conflict of interest or perceived conflict of interest with relevant OIR staff.

Monitoring, Evaluating, and Reporting Scientific Integrity Activities and Outcomes

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

Related Policies and Statutes

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

Research Misconduct

- Federal Research Misconduct Policy: *https://www.federalregister.gov/documents/2000/12/06/00-30852/executive-office-of-the-president-federal-policy-on-research-misconduct-preamble-for-research*
- Public Health Service Policies on Research Misconduct: *https://www.ecfr.gov/current/title-42/chapter-I/subchapter-H/part-93*
- NIH Policy Manual Chapter 3006—NIH Intramural Research Program (IRP) Research Misconduct Proceedings: *https://policymanual.nih.gov/3006*
- NIH IRP Policies and Procedures for Research Misconduct Proceedings: *https://oir.nih.gov/system/files/media/file/2021-08/policy-nih_irp_research_misconduct_proceedings.pdf*

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

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

Public Access

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

Human and Animal Subject Protections

- Federal Policy for Protection of Human Research Subjects (the Common Rule): *https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html*
- Animal Welfare Act and Regulations: *https://www.aphis.usda.gov/animal_welfare/downloads/AC_BlueBook_AWA_508_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. 2302—Prohibited personnel practices: *https://uscode.house.gov/view.xhtml?req=29&f=treesort&num=125*
- Public Law 101–12—Whistleblower Protection Act of 1989: *https://www.govinfo.gov/content/pkg/STATUTE-103/pdf/STATUTE-103-Pg16.pdf*
- Public Law 103–424—Expansion of Whistleblower Protection Act of 1989: *https://www.govinfo.gov/content/pkg/STATUTE-108/pdf/STATUTE-108-Pg4361.pdf#page=3*
- Public Law 112–199—Whistleblower Protection Enhancement Act of 2012: *https://www.congress.gov/112/statute/STATUTE-126/STATUTE-126-Pg1465.pdf*
- 41 U.S.C. 4712—Enhancement of contractor protection from reprisal for disclosure of certain information: *https://uscode.house.gov/view.xhtml?req=(title:41%20section:4712%20edition:prelim)*
- Presidential Policy Directive 19—Protecting Whistleblowers with Access to Classified Information: *https://www.usda.gov/sites/default/files/documents/ppd.pdf*
- U.S. Office of Special Counsel: *https://osc.gov/*

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

Other Related Policies

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

Authorities

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

This policy is established in accordance with:

1. Public Law 111–358—The America COMPETES Reauthorization Act of 2010, section 103, as amended
2. Public Law 115–435—The Foundations for Evidence-based Policymaking Act of 2018
3. Public Law 106–554—The Information Quality Act of 2000
4. 67 FR 8451—OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies
5. 70 FR 2664—OMB Final Information Quality Bulletin for Peer Review
6. 65 FR 76260–76264—Federal Policy on Research Misconduct
7. Public Law 101–12—The Whistleblower Protection Act (WPA) of 1989, as amended
8. 41 U.S.C. 4712—The National Defense Authorization Act, Enhancement of contractor protection from reprisal for disclosure of certain information
9. 5 U.S.C. 13103 *et seq.*—The Ethics in Government Act of 1978, as amended, and 5 CFR parts 2634 and 2635, Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture and Standards of Ethical Conduct for Employees of the Executive Branch.
10. 18 U.S.C. 201–209—Statutes regarding Bribery, Graft and Conflicts of Interest
11. 5 CFR parts 5501 and 5502—Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services
12. 5 U.S.C. Ch. 10—The Federal Advisory Committee Act of 1972
13. 45 CFR part 73, Standards of Conduct
14. 5 CFR part 735, Employee Responsibilities and Conduct
15. HHS Protection of Human Subjects Regulation (45 CFR part 46).
16. PPD 19—Protecting Whistleblowers with Access to Classified Information, 2012
17. M–20–12—OMB Phase 4 Implementation of the Foundations for Evidence-Based Policymaking Act of 2018: Program Evaluation Standards and Practices
18. 42 CFR part 93—Public Health Service Policies on Research Misconduct
19. 10 U.S.C. 1034, made applicable to the Public Health Service Commissioned Corps through section 1129 of the Food and Drug Administration Safety and Innovation Act, Public Law 112–144, and implemented by Commissioned Corps Directive (CCD) 121.06
20. Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, Public Law 117–328, Division FF, title II, section 2321 (Jan 3, 2023)
21. Chips and Science Act, Public Law 117–167, title VI, subtitle D, section 10631 (Aug 9, 2022)

Dated: September 19, 2023.

Tara A. Schwetz,

Acting Principal Deputy Director, National Institutes of Health.

[FR Doc. 2023–20733 Filed 9–22–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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: Microbiology, Infectious Diseases and AIDS Initial Review Group; Microbiology and Infectious Diseases