

# **NIH POLICIES & PROCEDURES FOR PROMOTING SCIENTIFIC INTEGRITY**

**NATIONAL INSTITUTES OF HEALTH**

**2022 Update**



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## SECTION I. SCIENTIFIC INTEGRITY AT NIH

The National Institutes of Health (NIH) is an Operating Division within the U.S. Department of Health and Human Services (HHS) whose mission 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.

### SCIENTIFIC INTEGRITY

*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.*

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](#). Over the past decade, this report has served as evidence of NIH's unwavering commitment in this area. In 2021, a new National Science and Technology Council (NSTC) Scientific Integrity Task Force was formed per the [Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking](#) to identify directions for strengthening Federal policies and practices. Findings from the Scientific Integrity Task Force are outlined in its 2022 report [Protecting the Integrity of Government Science](#). The report identifies regulations, policies,

principles, and best practices for ensuring 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—including political interference. The Presidential Memorandum also charged Federal agencies with updating their scientific integrity policies and procedures to ensure the Nation is responding to the emerging issues of our time. NIH is pleased to respond to this call and has updated its previous compendium to further advance its commitment to scientific integrity.

## SECTION II. EMERGING AND CROSS-CUTTING THEMES

Ensuring NIH's policies and procedures continue to evolve with changing scientific practices and shifting public values is imperative to upholding principles of scientific integrity. NIH acknowledges and recognizes that to be effective, scientific integrity policies must adapt with this changing landscape to ensure that our science, programs, and policies work to combat systemic inequities and injustices that violate public trust in our system.

***“In addition to being reaffirmed and expanded to all appropriate communities of practice, scientific integrity policies also need to be updated to address important, emergent issues of our time.”***

*- 2022 White House Scientific Integrity Task Force Report*

In accordance with the 2022 White House Scientific Integrity Task Force report, NIH is providing a summary of its current activities in response to the identified emerging themes. Note, recommendations attributed to the Task Force report listed below reflect consolidated and summarized themes for which NIH is providing a response. NIH will continue to enhance its response to the Task Force report and other elements of the Presidential Memorandum.

**Task Force Report:** Foster an organizational culture of scientific integrity.

**NIH Action:** NIH continues to agree that institutionalizing principles of scientific integrity is essential as evidenced through our longstanding commitment to fostering a culture of scientific integrity. NIH recognizes organizational culture starts with leadership at the highest levels. It has designated the NIH Principal Deputy Director as the NIH Chief Scientist (CS), and it has designated the Associate Director of Science Policy as the NIH Scientific Integrity Official (SIO). The CS will provide oversight of all NIH scientific integrity policies and procedures, including the periodic updates of those policies and procedures, and will promote scientific integrity across the NIH. The SIO will report to the CS on all matters involving scientific integrity, will provide a focal point for NIH scientific integrity allegations that fall outside of existing processes, and will provide regular reporting on NIH scientific integrity allegations and outcomes. The CS and SIO will engage and promote agency efforts regarding diversity, equity, inclusion, and accessibility. The NIH SIO will lead the NIH Scientific Integrity 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 SIO will also serve as the appointed NIH official on the HHS Scientific Integrity Council, which comprises integrity officials

from across HHS, and the newly chartered NSTC Subcommittee on Scientific Integrity. A primary purpose of the HHS Scientific Integrity Council is to ensure consistent implementation of the Scientific Integrity Policy at HHS.

**Task Force Report:** Protect the integrity of research processes.

**NIH Action.** 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 (COI), 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. These efforts are described in further detail throughout this document. 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.

#### **POLITICAL INTERFERENCE**

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

**Task Force Report:** Communicate science with integrity.

**NIH Action.** The communities that NIH interacts with represent the public's voice on a wide range of issues falling under the NIH mission. These interactions have proven essential to the development of responsible science programs and policies. 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. 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 NIH funds. NIH benefits from dynamic and interactive communications with the many communities it interacts with and remains committed to promoting and disseminating rigorous and objective scientific information broadly and equitably. Further, NIH is committed to ensuring that scientific information is accurately represented in responses to congressional inquiries, testimony, and other requests. These efforts are described in further detail throughout this report.

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 Intramural Research Program (IRP) researchers adhere to a [NIH-wide Policy for Manuscript and Abstract Clearance](#)

[Procedures](#) and follow established guidance to ensure transparency in research findings through [Processes for Authorship Dispute Resolution](#) if the situation arises.

**Task Force Report:** Safeguard scientific integrity.

**NIH Action.** NIH is firmly committed to establishing and formalizing additional procedures to identify and adjudicate allegations regarding compromised scientific processes or technological information. NIH has established several adjudication processes with distinct offices (i.e., the Office of Extramural Research ([OER](#)), the Office of Intramural Research ([OIR](#)), and the Office of Management Analysis ([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 subsequent sections of this report. The designation of an NIH SIO allows 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.

**Task Force Report:** Elevate issues of Diversity, Equity, Inclusion, and Accessibility (DEIA) as an integral component of the entire scientific process.

**NIH Action:** NIH is committed to instituting new ways of meaningfully integrating DEIA practices throughout the agency, and to identifying and addressing any policies and practices that may be detrimental to our workforce and our science. As a science agency, we know that bringing diverse perspectives, backgrounds, and skillsets to complex scientific problems enhances scientific productivity. NIH has long supported programs to improve the diversity of the scientific workforce with the goal of harnessing the complete intellectual capital of the Nation. These efforts, however, have not been sufficient and, as such, NIH has launched an effort to end structural racism and advance racial equity in biomedical research through a new initiative called [UNITE](#), which has already begun to identify short-term and long-term actions. The UNITE initiative focuses on three primary areas:

- Enhance research on health disparities, minority health, and health equity;
- Identify and address any internal policies, procedures, and structural norms that may be barriers to full equity within the NIH workforce; and
- Increase participation of individuals from diverse backgrounds, including those from underrepresented groups, within the extramural biomedical research workforce by improving access to training and support.

To signify the importance of DEIA in relation to scientific integrity, the NIH CS serves as a UNITE Co-chair. Ultimately, these efforts will bolster NIH's commitment to DEIA within the scientific workforce and promote racial equity on the NIH campus. NIH is also developing an NIH-Wide Strategic Plan for DEIA that will articulate NIH's vision for embracing, integrating, and

strengthening DEIA across all NIH activities to achieve the NIH mission. The Strategic Plan will capture activities that NIH will undertake to meet the vision of the Strategic Plan, and will be organized around accomplishments, needs, opportunities, and challenges in addressing DEIA in the NIH workforce, its structure and culture, and the research it supports.

**Task Force Report:** Extend scientific integrity principles and practices to new challenges stemming from emerging areas of research.

**NIH Action:** As a leader in biomedical innovation, NIH consistently works to develop proactive policies capable of rapidly and responsibly ushering in new and emerging science and technology. To institutionalize these activities, NIH has established numerous FACs to serve as public forums for the discussion of emerging science and technology. For example, the [Novel and Exceptional Technology and Research Advisory Committee](#) was created to address scientific, safety, ethical, and social issues associated with areas of emerging biotechnology research for which NIH requests advice or guidance.

Recognizing the growing interest in data-enabled science, NIH has taken steps to address scientific integrity issues associated with applications of artificial intelligence/machine learning (AI/ML) to large biomedical datasets. For example, NIH launched the Artificial Intelligence and Machine Learning Consortium to Advance Health Equity and Researcher Diversity ([AIM-AHEAD](#)) to mitigate the risk of creating and continuing harmful biases in how AI/ML is used, how algorithms are developed and trained, and how findings are interpreted. Addressing these issues upfront may allow NIH to help prevent or mitigate these harmful biases, which often disproportionately affect underrepresented communities. Another example of NIH's leadership in this space is the Bridge to Artificial Intelligence program ([Bridge2AI](#)). This program focuses on the generation of new “flagship” data sets and will identify or generate best practices for data acquisition that enable ML analysis. Bridge2AI brings together technological and biomedical experts with social scientists and ethicists to develop solutions on generating biomedical and behavioral data sets that are ethically sourced, trustworthy, well-defined, and accessible.

NIH will also implement a new [Data Management and Sharing Policy](#) to promote data stewardship and transparency, which complements other efforts aimed at ensuring NIH-supported research is rigorous and reproducible. NIH believes that these efforts must be maintained throughout the agency to ensure all Americans benefit from their investment in biomedical research.

**Task Force Report:** Develop and promulgate scientific integrity policies and practices for emerging modes of science.

**NIH Action.** NIH recognizes that the future of science relies on new and innovative methods and modes for conducting research. Fundamental to these approaches are robust collaborations between communities and scientists that respect individual preferences and cultural norms. NIH is working to institutionalize some of these practices through policy development. For instance, NIH recently implemented a [NIH Tribal Consultation Policy](#) to establish a mutually beneficial partnership between NIH and American Indian/Alaska Native Tribes that enables Tribes to provide meaningful input on the development of NIH policies with Tribal implications. NIH is also pioneering models for using existing relationships and fostering new ones, such as working closely

with community leaders and organizations to address the misinformation and mistrust that can slow the adoption and uptake of biomedical research. In one example, the NIH Community Engagement Alliance ([CEAL](#)) Against COVID-19 Disparities was established with the explicit goal of providing trustworthy and accurate information to find effective ways to deliver information to communities hardest hit by the COVID-19 pandemic. Another example is the NIH [All of Us](#) Research Program, which is piloting new methods for engaging research participants as partners in research by partnering with a diverse network of nearly 100 funded and unfunded community, professional, and grassroots organizations across the country to support engagement, outreach, and dissemination of information to diverse communities and populations. In addition to participant engagement, programmatic data is now available to researchers through a cloud-based analytics platform to ensure diversity across the research continuum. The program is taking active steps in researcher outreach and engagement, including raising awareness and facilitating access to programmatic data to researchers from diverse communities and institutions, bridging communities of researchers and participants, and fostering capacity building and collaboration between and within institutions, researchers, and communities. NIH intends to collect lessons learned from these initiatives to promote best practices for integrating principles of scientific integrity into other emerging modes of science as they arise.

### SECTION III. NIH AS A RESEARCH FUNDER

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.

*Extramural Peer Review.* The NIH peer review process forms the cornerstone of the NIH extramural research mission and seeks to ensure that applications submitted to the NIH are evaluated by scientific experts in a manner free from inappropriate influence. The core values of NIH peer review are expert assessment, transparency, impartiality, fairness, confidentiality, security, integrity, and efficiency. These values drive NIH to seek the highest level of scientific and ethical standards, and form the foundation for the laws, regulations, and policies that govern the NIH peer review process. The NIH dual peer review system is mandated by statute in accordance with section 492 of [42 U.S.C 289a \(Public Health Service Act\)](#) and [Federal regulations](#) governing "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects."

Peer review at NIH is a two-tiered system involving initial peer review for scientific and technical merit and subsequent review by National Advisory Councils or Boards that are considering applications for funding. Both levels of the NIH peer review process involve the consistent application of standards and procedures that produce fair, equitable, informed, and unbiased examinations of grant and cooperative agreement applications to NIH. This two-tiered system described in [42 CFR Part 52h](#) and mandated by the [NIH Reform Act of 2006](#) is extended by policy to other types of applications submitted to NIH.

OER oversees the development and implementation of policies that ensure applications submitted to the NIH are evaluated fairly, equitably, timely, and free of bias. All NIH employees involved in the peer review process are subject to the [Standards of Ethical Conduct for Employees of the Executive Branch](#) and the [Principles of Ethical Conduct for Government Officers and Employees](#). HHS policy also requires that grant applications be evaluated according to the review criteria specified in the Funding Opportunity Announcement used for application submission. NIH also routinely reminds participants and the communities that NIH interacts with in the NIH peer review process of Federal statutes, regulations, and NIH policies regarding peer review security and confidentiality; their responsibilities for abiding by those rules; and possible actions that NIH (in coordination with other offices) may take and consequences that may ensue from a violation of those rules (see [Maintaining Security and Confidentiality in NIH Peer Review: Rules, Responsibilities and Possible Consequences](#)). Maintaining security and confidentiality in the NIH peer review process is essential for:

- Safeguarding the free exchange of scientific opinions and evaluations without fear of reprisal;
- Protecting trade secrets or other proprietary, sensitive, and/or confidential information;
- Providing reliable input to the agency about research projects to support;
- Safeguarding the NIH research enterprise against the misappropriation of research and development to the detriment of national or economic security; and
- Maintaining public trust in science.

Managing real or apparent conflict of interest (COI) is a long-standing priority for NIH. Accordingly, NIH has developed a variety of policies and procedures to manage COI and the appearance of COI, as well as mitigate against the risk of prejudice, bias, or predisposition on the part of individuals participating as reviewers (see [Managing COI in NIH Peer Review of Grants and Contracts](#)). NIH clearly delineates roles and responsibilities to avoid potential COI (i.e., NIH extramural staff may not simultaneously participate in review functions and programmatic functions, extramural individuals may not participate in both an application's initial peer review and National Advisory Council review).

#### **NIH RePORT**

*NIH Research Portfolio Online Reporting Tools (RePORT) provide access to reports, data, and analyses of NIH research activities including information on NIH expenditures and the results of NIH-supported research.*

NIH also employs strong measures of transparency to promote scientific integrity by publicly sharing rosters of NIH peer review committees and descriptions of funded grants (see [OER Web site](#) and [NIH RePORTER](#), respectively). Except for certain types of information that may be considered proprietary or private information that cannot be released, most grant-related information submitted to NIH by the applicant or recipient in the application or post-award phase is considered public information once an award is made and therefore subject to possible release to individuals or organizations outside NIH (see [NIH Grants Policy](#)

[Statement \(GPS\) Section 2.3.11 Availability and Confidentiality of Information](#)).

*Extramural Research Funding.* Transparency in NIH research funding policies is essential to upholding principles of scientific integrity and NIH utilizes two major mechanisms to achieve this goal:

- The [NIH GPS](#) makes available, in a single document, the policy requirements that serve as the terms and conditions of NIH grant awards. When a grantee accepts an award, they become bound to the requirements outlined in the NIH GPS (except where the notice of award states otherwise) and
- The [NIH Guide for Grants and Contracts](#) (NIH Guide) is the official publication for NIH biomedical and behavioral research grant policies, guidelines, and funding opportunity announcements. Notices of policy changes published in the NIH Guide can supersede information in the NIH GPS. Compliance with these policy updates also becomes a term and condition of award, and NIH incorporates these notices into the annual update of the NIH GPS.

When the award is a contract, as opposed to a grant or other mechanism, NIH Acquisition Staff are bound by the Federal Acquisition Regulation ([FAR](#)), HHS Acquisition Regulation ([HHSAR](#)), and HHS- or NIH-issued policy, guidance, instruction or procedure. The contract is a legally binding document awarded for a product or service in support of or for scientific or technological findings, data, information, conclusions, or technical results. The award requires frequent reporting throughout the life of the contract and NIH ensures integrity throughout the contract process. For competitive/noncompetitive awards, the agency issues requests for proposals and utilizes a technical review committee or the peer review process to evaluate proposals. Also, the agency requires Offeror representations and certifications, including certifications that the research will be reviewed and approved by the Institutional Review Board (IRB) and [P.L. 93-579 \(Privacy Act of 1974\)](#) adherence, as appropriate. The contract is also monitored by the Contracting Officer and/or Contract Specialist and Contracting Officer's Representative.

Under contracts, apparent or actual COI are examined and addressed throughout the life of a contract. The COI examination begins prior to award, and is considered during the acquisition planning phase, the peer review process, and throughout negotiations, up to source selection. The peer review committee is screened for possible conflicts; and if any conflicts are identified, steps are taken to mitigate those conflicts so that the proposals are evaluated in an unbiased manner. Furthermore, institutions and investigators must adhere to the Financial COI (FCOI) requirements of [45 CFR 94.4](#), Responsibilities of Institutions regarding Investigator financial COI of [42 CFR 50.604](#), and provide annual reports to NIH for any NIH-funded research projects. Additionally, there are applicable FAR addressing COI; for example, agencies are required to include [FAR 52.203-16](#) in certain solicitations and contracts to prevent personal COI if the contractor is performing services closely associated with inherently Governmental functions.

*Access to Extramural Research Information and Results.* NIH is committed to improving public access to the results of the research it supports and conducts. To this end, NIH has promulgated policies to ensure public access to NIH-funded data, publications, and research results. Note, policies described below are also applicable to researchers within the IRP (see **SECTION IV. NIH AS A RESEARCH INSTITUTION**).

- The [NIH Policy for Data Management and Sharing](#), effective January, 2023, requires researchers to prospectively plan for how scientific data will be preserved and shared through submission of a Data Management and Sharing Plan.
- [The NIH Genomic Data Sharing Policy](#) sets forth expectations that ensure the broad and responsible sharing of large-scale human or non-human genomic data.
- The [NIH Policy on Dissemination of NIH-funded Clinical Trial Information](#), which complements Section 402(j) of the Public Health Service Act (as amended by Section 801 of the Food and Drug Administration Amendments Act (FDAAA) of 2007, ) and the Final Rule for Clinical Trials Registration and Results Information Submission, [42 CFR Part 11](#), establish the expectation that researchers conducting clinical trials, funded in whole or in part by NIH, ensure that their clinical trials are registered at, and that summary results information is submitted to, NIH's ClinicalTrials.gov registry and results databank for public posting.
- The [NIH Public Access Policy](#) requires the submission of final peer-reviewed journal manuscripts that arise from NIH-funded research to the digital archive [PubMed Central®](#) (PMC) upon acceptance for publication to make research findings available to the public for free on PMC no later than 12 months after publication.

*Research Participants Protections in Extramural Research.* The NIH grants process includes numerous checkpoints to ensure compliance with all applicable HHS policies, funding requirements, laws, and regulations, such as [45 CFR Part 46](#) (of which, subpart A is widely referred to as the 'Common Rule'). NIH also widely disseminates relevant information about policies and regulations relevant for human subjects protections through a variety of mechanisms, such as training sessions, and provides additional resources to assist researchers in understanding the required elements related to human subjects protections when submitting a grant application. Importantly, the NIH peer review system evaluates the adequacy of protections for human research participants in each grant application and research and development contract proposal. Any concerns raised by reviewers must be resolved to the satisfaction of the relevant program and contracting staff members before an award can be issued. In addition, before funds are awarded for research involving human subjects, NIH requires education on the protection of human research participants for all investigators and individuals identified as key personnel. As an additional resource for the NIH community, the [NIH OER Policies and Regulations – Human Subjects](#) website includes NIH's human subjects policies and applicable regulations and the related requirements for staff on NIH-funded projects.

*Use of Animals in Extramural Research.* The NIH Office of Laboratory Animal Welfare ([OLAW](#)) within OER was established to ensure the humane care and use of animals in Public Health Service (PHS)-supported research, testing, and training. OLAW provides guidance and interpretation of the [PHS Policy on Humane Care and Use of Laboratory Animals](#), supports educational programs, and monitors compliance with the Policy by Assured institutions and PHS funding components to ensure the humane care and use of animals in PHS-supported research, testing, and training, thereby contributing to the quality of PHS-supported activities. Importantly,

institutions must have an [Animal Welfare Assurance](#), which represents legally binding institutional commitment to the PHS, and is necessary to receive PHS funds. Prospective NIH awardees must describe their proposed use of vertebrate animals in grant applications and contract proposals which are subsequently evaluated during NIH peer review. Any concerns raised during this process must be resolved to the satisfaction of OLAW and NIH program staff before an award can be issued. As a resource for the NIH community, the [OLAW Policy](#) website includes a full list of OLAW's policies, regulations, and guidance that protect animals used in research, training, and testing.

NIH also routinely engages communities it interacts with in discourse about the conduct of animal research. For instance, the NIH Director charged the Advisory Committee to the Director ([ACD](#)) to make recommendations to enhance the reproducibility and rigor of animal research focused on improving experimental design, optimizing translational validity, enhancing training, and increasing the transparency of research studies involving animal models. The ACD then established a working group with the overarching goal to allow all communities that NIH interacts with to have full confidence in the quality and applicability of research findings from animal studies, and to ensure that animal subjects are used with appropriate consideration of ethics and harm-benefit analysis. NIH also actively engages external partners, such as the [National Academies of Science, Engineering, and Medicine](#), to ensure the agency is positioned to proactively address any animal research issues.

*Training in the Responsible Conduct of Research.* Education in the responsible conduct of research is a fundamental element of research training. NIH requires that all trainees, fellows, participants, and scholars receiving support through any NIH training or career development award, research education, or dissertation grant must receive instruction in responsible conduct of research (see [FY 2022 Updated Guidance: Requirement for Instruction in the Responsible Conduct of Research](#)). The scientific community has responded to this call by developing innovative courses, workshops, and research projects on instruction in the responsible conduct of research. As an additional resource for the community, the [NIH OER Research Integrity](#) website includes information on instruction in the responsible conduct of research, links to instructional materials, and examples of programs regarded as good models for instruction in the responsible conduct of research. NIH also maintains a set of [Frequently Asked Questions \(FAQs\)](#) on the responsible conduct of research.

*Safe and Respectful Work Environments.* 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. All NIH funding recipients are expected to provide safe and healthy working conditions for their employees and to foster work environments conducive to high-quality research as outlined in [NIH GPS Section 4. Public Policy Requirements, Objectives and Other Appropriation Mandates](#). NIH encourages all

institutions receiving NIH funds to have rigorous policies and related procedures for their employees, contractors, trainees, and fellows who engage in agency-funded activities.

NIH does not tolerate harassment or discrimination of any kind anywhere NIH-funded activities are conducted. Accordingly, the [NIH Anti-Harassment and Policy Guidance](#) establishes numerous systems, policies, and procedures to ensure NIH-supported research activities are managed and conducted in accordance with all Federal laws, regulations, and policies protecting the rights and safety of individuals working on NIH-funded projects. In May 2022, NIH implemented a general provision in the that mandates the NIH Director to require NIH-funded institutions to report to NIH when individuals identified as principal investigator or key personnel in an NIH notice of award are removed from their position or are otherwise disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions. The passage of this bill into law is an important milestone in support of NIH's vital commitment to eliminating harassment in biomedical research.

*Adjudicating Extramural Research Misconduct.* Research misconduct is defined through the PHS Policies on Research Misconduct, [42 CFR 93.103](#) as:

- ***Fabrication:*** making up data or results and recording or reporting them;
- ***Falsification:*** manipulating research materials, equipment, or processes or changing or omitting data or results such that the research is not accurately represented in the research record; and
- ***Plagiarism:*** the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

NIH has specific procedures in place to address allegations of research misconduct and all NIH extramural staff receive annual training in the proper handling of allegations of research misconduct. NIH refers allegations of extramural research misconduct to the HHS Office of Research Integrity ([ORI](#)), which has the authority to oversee investigations into research misconduct. A finding of research misconduct requires the following:

- There must be a significant departure from accepted practices of the relevant research community;
- The misconduct must be committed intentionally, knowingly, or recklessly; or
- The allegation must be proven by a preponderance of the evidence.

When a NIH funding recipient institution finds, learns of, or suspects research misconduct that impacts or might impact the conduct or performance of a NIH-supported project(s), whether at the recipient organization or at a third-party subrecipient organization, the recipient must work with NIH to assess the effect on the ability to continue the project, as originally approved by NIH. NIH may take action(s) to protect the health and safety of the public, including research participants, to promote the integrity of the PHS supported research and research process, and to conserve public funds. When a recipient fails to comply with the terms and conditions of award, NIH may take one or more enforcement actions including disallowance of costs, withholding of

further support, or suspension or termination of the grant. These actions are described in the [NIH GPS Section 8.5 Specific Award Conditions and remedies for noncompliance \(specific award conditions and Enforcement Actions\)](#). As an additional resource, the [NIH OER Research Integrity](#) website includes additional information related to NIH's process for the handling of research misconduct allegations involving the extramural research community.

## SECTION IV. NIH AS A RESEARCH INSTITUTION

Scientific integrity begins with our workforce. Accordingly, NIH has numerous policies in place to ensure NIH hires staff for their scientific and technical expertise and that the IRP is a welcoming and inclusive workplace (and not that hiring guidelines can be found in the [NIH Intramural Sourcebook](#)). The 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 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](#) is an official mechanism of issuing NIH-wide policy and all Manual Chapter issuances.

*Hiring Practices.* The selection of new senior investigators, tenure-track investigators, senior scientists, and senior clinicians is considered an important function of the IRP. To help ensure that overall standards of high productivity, equal opportunity, integrity, matters of safety, and many other general aspects of the research establishment are met throughout NIH, nationwide, highly advertised searches are conducted with a carefully vetted search committee to ensure the best candidate is selected. Search committee members must have appropriate expertise, accomplishment, professional standing, and ethical reputation to enable them to judge the caliber and fit of each candidate for the scientific, administrative, and other professional duties of the position being filled. The NIH Deputy Director for Intramural Research (DDIR) and OIR Senior Staff review and approve the membership of all search committees and all search processes for candidates. The DDIR may also recommend additional search committee members. Once a candidate is selected, a report about the search, including the number of applicants, as well as the name, credentials, and demonstration of professionalism and dedication to mentoring a diverse workforce by the selectee, is sent to the DDIR for approval. Hiring guidelines are outlined in the [NIH Intramural Sourcebook – Search and Selection](#).

*Review and Evaluation of Intramural Programs.* Intramural research at NIH is reviewed by committees of scientists from outside NIH. Policies and procedures for the outside scientific review and evaluation of intramural research at NIH by Boards of Scientific Counselors (BSCs) and the review of the Scientific Directors' scientific and administrative leadership by National Advisory Councils or Boards, as assisted by *ad hoc* subcommittees, are outlined in [NIH Manual Chapter 3005 – Review and Evaluation of Intramural Programs](#). The BSCs comprise individuals with outstanding scientific credentials who are committed to providing rigorous, objective reviews

to assist in evaluating the quality of the intramural research programs. BSC evaluations are also distributed to the DDIR, the appropriate NIH ICO Director, and the ICO Scientific Director. The BSC also reports annually to the ICO National Advisory Council or Board.

Managing real or apparent COI in the IRP is as vital to the integrity of the biomedical research enterprise as it is in the extramural program. As members of the executive branch of the U.S. Government, NIH intramural scientists are subject to the [Standards of Ethical Conduct for Employees of the Executive Branch](#). In addition, NIH scientists are also subject to numerous Federal regulations and requirements to safeguard scientific integrity in intramural research activities, including:

- [5 CFR Part 2634 – Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture](#)
- [5 CFR Part 2636 – Limitations on Outside Earned Income, Employment and Affiliations for Certain Noncareer Employees](#)
- [5 CFR Part 2640 – Interpretation, Exemptions and Waiver Guidance Concerning 18 U.S.C. 208 \(Acts Affecting a Personal Financial Interest\)](#)
- [5 CFR Part 2641 – Post-Employment COI Restrictions](#)
- [5 CFR Part 5501 – Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services](#)
- [5 CFR Part 5502 – Supplemental Financial Disclosure Requirements for Employees of the Department of Health and Human Services](#)

Each NIH ICO employs ethics officials who are assigned to assist NIH researchers in understanding and complying with ethics rules. Additional information on the ethical conduct laws, regulations and policies can be found at the [NIH Ethics Program website](#).

*Avoiding Interference in Intramural Research and Data Collection.* The Presidential Memorandum emphasizes that scientific integrity policies should “ban improper political interference in the conduct of scientific research and the collection of scientific or technological data; prevent the suppression or distortion of scientific or technological findings, data, information, conclusions, or technical results[...].” [NIH Manual Chapter 1184 – Preparation and Clearance of Scientific, Technical, and Public Information Presented by NIH Employees or Produced for Distribution by NIH](#) is consistent with these principles, in stating that there are many quality control measures embedded in the scientific process that ensure high quality information is produced and disseminated by NIH, and that the agency expects that publications or presentations by its employees be prepared in accordance with professional and ethical standards. Further, published material should be objective, and supporting data should have full, accurate, and transparent documentation. Failure to follow this policy may be construed as improper conduct that is injurious to the integrity of HHS, or NIH, under [NIH Manual Chapter 1754 – Reporting Allegations Of Criminal Offenses, Misuse of NIH Grant And Contract Funds, or Improper Conduct By An NIH Employee](#), and may be reported to NIH as a matter of employee misconduct.

The IRP is committed to facilitating and maintaining productive and collaborative relationships with foreign scientists and institutions while protecting the U.S. from exploitative relationships. Researchers in the IRP are directed to the [NIH Intramural Sourcebook – Guide for NIH Intramural Principal Investigators to Navigate International Interactions and Avoid Inappropriate Foreign Interference with Their Research](#) (and as updated) which addresses:

- Deciding whether to invite a foreign scientist to work or train in an IRP laboratory;
- Invitations to establish, oversee, or advise research programs in foreign countries;
- Writing letters of reference for foreign scientists; provisions of material support for foreign research activities; and
- Establishing collaborations with scientists from other countries.

IRP researchers must disclose all relevant information when providing their supervisor with a document for approval that entails a foreign activity or institution. Supervisors should solicit input from appropriate ICO support staff (such as the IC Deputy Ethics Counselor, Ethics Coordinator, or Ethics Specialist) and must carefully consider whether the information provided in one

#### **NIH INTRAMURAL DATABASE**

*NIH intramural research projects are summarized in the NIH Intramural Annual Report. Annual reports since 1998 can be searched in the NIH Intramural Database (NIDB).*

document, in the context of other approved activities, might lead to a perception (or reality) of undue foreign influence. Critical to this process is articulating how the proposed activity benefits the NIH. IRP researchers and trainees from foreign countries may work at NIH under several appointment authorities, but are required to follow policies and procedures outlined in the NIH Manual Policy such as [NIH Manual Chapter 2300-308-1 – Guest Researcher/Special Volunteer Programs](#) and [NIH Manual Chapter 2300-320-3 – NIH Intramural Visiting Fellow Program \(VFP\) Policies](#).

*Scientific Disagreements.* At the foundation of the NIH mission is the generation of reliable, rigorous, research data, deposited in established repositories, and the sharing of research results, published in reputable, peer-reviewed scientific journals. Resolution of scientific disagreements through subsequent evidence-based publications is the norm. Scientific disagreements that are based on doubts about the integrity of the research, such that research misconduct may have occurred, may be addressed by contacting the agency Intramural Research Integrity Officer.

Some scientific disagreements are not related to the research findings as much as to authorship issues or other considerations. The IRP uses a manuscript clearance process, managed by each IC, that can often resolve these types of disagreements. The manuscript clearance process is described in the and entails the submission of a clearance form and subsequent routing of approval through the IC Scientific Directors. Appeals of an IC decision that a manuscript may not be submitted are adjudicated by the DDIR or the IC Director. It is expected that members of each research group, laboratory, and branch will freely discuss and resolve questions of authorship, including the order of authors, before and during the course of a study. Further, each author has the responsibility to review and support their contributions to the manuscript and be willing to support the general conclusions and integrity of the study submitted (originally or in revision) for publication. NIH

has policies for resolution of authorship disputes, using a four-tiered process involving discussion, mediation, the option for peer review of the publication and/or authorship, and if unsuccessful, a final decision by the IC Scientific Director or the DDIR. This process is outlined in detail in the [NIH Intramural Sourcebook – NIH IRP Authorship Conflict Resolution Process](#).

*Access to Intramural Research Information and Results.* The principles guiding scientific integrity regarding access to research information and results in the IRP are the same as outlined in **SECTION III. NIH AS A RESEARCH FUNDER**. In addition, IRP staff must also adhere to the policies, procedures, and guidelines related to the creation, maintenance, and disposition of Federal records (see [NIH Manual Chapter 1743 – Managing Federal Records](#)). The IRP must also comply with the [Records Management Schedule and Storage](#), which includes retention of research records related to planning, development, oversight, and execution of biomedical research projects and programs performed by NIH research staff, contractors, or under collaborative research and development agreements. These records span the project lifecycle and include, but are not limited to, final plans and protocols; clearances and authorizations; and experimental, observational, and control data generated in such research, including laboratory notebooks and the products of research such as articles, reports, and data sets required to:

- Facilitate data analysis, publication, collaboration, and peer review;
- Demonstrate compliance with accepted policies and standards for the conduct of good science;
- Validate and reproduce research outcomes;
- Support intellectual property claims; and
- Defend against allegations of research misconduct and malpractice.

*Research Participant Protections in Intramural Research.* Several of the numerous NIH intramural policies and procedures governing human research, including participant protections, are outlined in the [NIH Manual Chapter 3014 – NIH Intramural Human Research Protection Program](#). The [NIH Office of Human Subjects Research Protections \(OHSRP\)](#) carries out the day-to-day operations and regulatory oversight of intramural human subjects research activities and promotes the protection of the rights, safety, and welfare of these human participants. Within OHSRP, the NIH Intramural IRB (NIH IRB) reviews human subjects research conducted by NIH intramural investigators. OHSRP also promotes the NIH's research mandate by supporting the IRP in reviewing, administering, and managing human subjects research activities; developing NIH policies and procedures consistent with Federal law, regulation, and policy; organizing and conducting educational activities for NIH human subjects researchers, NIH research staff, and the NIH IRB; and overseeing quality assurance and quality improvement activities to ensure NIH IRB compliance with Federal regulations and policies.

*Use of Animals in Intramural Research.* Policies and procedures governing use of animals in research are outlined in the [NIH Manual Chapter 3040-2 – Animal Care and Use in the Intramural Research Program](#). The NIH Office of Animal Care and Use (OACU) ensures that NIH intramural research programs and facilities for animal care and use are in compliance with Federal regulatory requirements and standards and maintain full accreditation.

*Training in the Responsible Conduct of Research.* The progress and excellence of NIH research depends on NIH's vigilance in maintaining the highest quality of conduct in every aspect of science. OIR has developed the [Guidelines and Policies for the Conduct of Research in the Intramural Research Program at NIH](#) to define specific core areas critical for high-quality, ethical research. Individuals who are directly involved in the research activities of the IRP must read, understand, and incorporate the principles in the Guidelines into everyday practice. NIH trainees are also expected to adhere to this guidance and the [Guidelines for Non-FTEs \(Trainees\) for NIH-Related Activities, Outside Activities, and Awards](#). OIR has also developed a [Summary Guidance Table](#) to illustrate various outside activities in which trainees are often engaged and whether those activities are permitted. Trainees are also required to document official duty activities, using a [Trainee Review Form](#) that has been signed by their NIH advisor.

Training and education in the responsible conduct of research should occur not only during undergraduate or graduate studies in science, but throughout one's scientific career. All NIH intramural researchers who have direct and substantive involvement in proposing, performing, reviewing, or reporting research, or who receive research training, are required to participate in ongoing responsible conduct of research instruction including:

- One-time training in the core areas through an online training module;
- Participation in an annual research ethics case discussion on specific themes encountered in research; and
- For NIH trainees, a one-time in-depth workshop on responsible conduct of research.

The full IRP Responsible Conduct of Research Training Policy can be found in the NIH [Intramural Sourcebook – Responsible Conduct Research Training](#).

*Professional Development.* 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.

*Safe and Respectful Work Environments.* Researchers in the IRP are entitled to work in an environment that is safe and healthy. NIH is committed to actively promoting a comprehensive and effective Occupational Safety and Health Program to support the development,

implementation, maintenance, and improvement of occupational safety and health practices that reflects the NIH policy to:

- Provide the highest practical degree of safety and health for employees in all activities of the NIH;
- Minimize losses in property damage and human resources due to accident, injury, or illness; and
- Comply with [P.L. 91-596 \(The Occupational Safety and Health Act of 1970\)](#), [Executive Order 12196](#), and other regulations, standards, and guidelines governing the occupational safety and health of HHS employees.

The roles, responsibilities, and function of the program are outlined in the [NIH Manual Chapter 1340 – NIH Occupational Safety and Health Management Program](#) and additional workplace safety policies and procedures can be found at the [NIH Division of Occupational Health and Safety](#) website.

NIH has also taken direct actions to foster a safe and inclusive workplace that is free of harassment, which is also described in **SECTION II. EMERGING AND CROSS-CUTTING THEMES** and **SECTION III. NIH AS A RESEARCH FUNDER**. OIR strictly adheres to the [NIH Anti-Harassment and Policy Guidance](#) and oversees IRP hiring policies and procedures to ensure that high standards of productivity, equity, integrity, safety, and transparency are upheld. OIR also works to incorporate inclusive excellence into all its policies, practices, procedures, and operations in order to cultivate a diverse and inclusive workforce that can most efficiently pursue the NIH mission. IRP staff are encouraged to engage the [NIH Civil Program](#) to report any workplace concerns involving any uncivil behavior, including, but not limited to, harassment, sexual harassment, inappropriate conduct, intimidation, bullying, or any other unproductive, disruptive, and/or violent behavior. If an investigation by the Civil Program finds evidence of uncivil behavior by a Federal employee, NIH management could take corrective action, including, but not limited to, written counseling, reprimand, suspension, demotion, or removal from one's position and/or separation from the Federal Service. Such actions may also be considered when making administrative decisions related to funding, staffing, and other resources. If the offender is a Government contractor, corrective and/or disciplinary action will be the responsibility of the contracting company and negative performance may be recorded in the Contractor Performance Assessment Reporting System (CPARS), if warranted.

*Adjudicating Intramural Research Misconduct.* OIR, the research community, and the broader public rightly expect adherence to exemplary standards of intellectual honesty in the formulation, conduct, and reporting of scientific research. Allegations of research misconduct in both the extramural and intramural programs are taken seriously by NIH. Policies and procedures that apply when research misconduct is alleged or suspected in the IRP are outlined in the [NIH Manual Chapter 3006 – NIH Intramural Research Program \(IRP\) Research Misconduct Proceedings](#). The NIH Policy applies to alleged or actual research misconduct involving research carried out by any person in an NIH facility or who is funded by the IRP in any location or undertaken by an NIH employee or trainee as part of his or her official NIH duties or NIH training activity regardless of location.

*Institutional Oversight.* The [P.L. 97-255 \(Federal Managers' Financial Integrity Act of 1982\)](#), implemented through [OMB Circular A-123, Management's Responsibility for Enterprise Risk Management and Internal Control](#), requires that managers take systematic and proactive measures to assess the adequacy and controls in programs and operations, identify needed improvements, take corresponding corrective actions, and report annually on management controls. The DDIR is responsible for initiating, evaluating, and assuring that IC reporting offices are effectively carrying out their responsibility for IRP management controls, including: (1) Program and Project Management; (2) Health and Safety of IRP Personnel; (3) Recruitment, Appointment, Retention and Evaluation of Scientific and Technical Personnel; (4) COI; and (5) Technology Transfer. This is accomplished through an annual survey completed by each ICO's intramural Scientific Director addressing these and other areas of risk and evaluated by OIR. The Medical Executive Committee ([MEC](#)) provides institutional oversight of hospital and clinical operations at the NIH Clinical Center. MEC membership consists of various Clinical Directors of IRP clinical research programs and other senior medical and administrative staff. The MEC advises the Clinical Center CEO and develops policies governing standards of clinical care in the Clinical Center. When approved by the CEO, the recommendations of the committee become operating policies of the hospital. MEC represents and acts for the medical staff and other clinical professionals in the Clinical Center, oversees credentialing and privileging of the medical staff, and enforces the rules and policies of the Clinical Center.

## **SECTION V. NIH AS A POLICY DEVELOPMENT AGENCY**

NIH promotes progress in the biomedical research enterprise through the development of sound and comprehensive policies. The NIH Office of Science Policy ([OSP](#)) works across the biomedical research enterprise to ensure NIH policy evolves in tandem with rapidly advancing science and technology. Utilizing our diverse backgrounds and collective expertise in science policy, OSP develops, analyzes, and implements forward thinking policies to promote the responsible conduct of research. OSP also conducts horizon scanning and provides advice to the NIH Director and the United States Government on issues of future importance. To achieve these aims, we partner with the diverse communities NIH interacts with that includes researchers, policymakers, ethicists, research participants, legal scholars, and importantly the American public. While many of the policies addressed in this section impact NIH as a research institution or as a funder, OSP serves as the lead on science policy issues that broadly impact the agency.

*Policy Development Process.* NIH utilizes multiple mechanisms for ensuring accountability in developing policy. The development of NIH-wide policies or policies for extramural research generally follows procedures set forth under the [5 U.S.C. Subchapter II \(Administrative Procedure Act\)](#), 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 partner engagement plan to promote broad dissemination and engagement in the policymaking process. NIH considers all comments submitted on draft policies 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 GPS and NIH Policy Manual, as appropriate. Policies are also posted to NIH websites with additional resources such as FAQs and other supplemental resources as needed. As a resource to the NIH community, the [NIH OSP](#) website provides further information about NIH policy development.

*Interagency Coordination.* NIH works across the Federal Government, as appropriate, to coordinate policy and program development, address pressing public health challenges, and identify gaps and areas of opportunity for future policy development. These efforts not only provide for Government-wide input, but institute additional checks and balances on the Federal policy development processes. Some efforts are established under formal mechanisms such as through the White House National Science and Technology Council. NIH strives to coordinate across all levels, including establishment of Joint Leadership Councils that are chaired by agency leadership through initiating staff-level working groups that identify common issues and propose policy solutions. OSP serves as a central coordinating body for NIH's interagency activities.

*Engaging Federal Advisory Committees.* Diverse and meaningful input is critical for informing the development of robust and comprehensive Federal policies. NIH utilizes multiple mechanisms for achieving these aims, including FACs, which are uniquely assembled to provide advice on a broad range of issues affecting Federal policies and programs. The NIH Office of Federal Advisory Committee Policy ([OFACP](#)) is responsible for the oversight of all NIH FACs established and operated under FACA and ensures appropriate management and internal controls are in place. OFACP develops and implements policies and procedures, provides guidance, resources, and training for NIH, and serves as the central liaison to HHS on FAC management matters. OFACP coordinates with the NIH Ethics Office, OER, and other NIH ICOs to ensure efforts are integrated and policies, guidelines, and systems remain current. Examples related to the integrity of the review process include confidentiality policies, service limits, and restrictions pertaining to Federally registered lobbyists. NIH also prohibits FAC service if there is evidence of integrity violations, undue foreign influence, or undeclared COI.

**FEDERAL ADVISORY  
COMMITTEE ACT (FACA)**

*5 U.S.C. 1001-1014 (FACA), was enacted in 1972 to ensure that Federal agencies seeking relevant, objective, consensus advice on a broad range of issues affecting Federal policies do so through a transparent and public mechanism.*

Each NIH ICO has a Committee Management Officer (CMO) or an agreement with a CMO service center to coordinate all operational committee management activities within its organization and serve as a liaison to OFACP. Each CMO is responsible for a range of duties, which include:

- Preparing nomination and appointment documentation for membership to FACs;
- Furnishing staff guidance, assistance, and leadership on the various facets of FAC activities;
- Establishing necessary controls and procedures to ensure compliance with FACA, applicable regulations, and NIH and HHS policies;

- Maintaining charter and membership records; and
- Coordinating and preparing required annual reports.

NIH maintains approximately 144 actively chartered FACs, the majority of which are mandated or authorized by the Public Health Service Act. This Act authorizes appropriate scientific and technical peer review of biomedical and behavioral research grant and cooperative agreement applications, research and development contracts, and research conducted at NIH (see [SECTION III. NIH AS A RESEARCH FUNDER](#)). Each FAC has a Designated Federal Officer (DFO), a Government employee who approves the agenda, attends and calls meetings to order, serves as chair when directed to do so by the agency head, and adjourns the meeting when such adjournment is in the public interest or in the best interest of the Government, among other requirements. NIH utilizes four different types of FACs:

- ***Peer Review Groups:*** Provide scientific and technical merit review in accordance with the first level of peer review of research grant and cooperative agreement applications and contract proposals (also referred to as Integrated or Initial Review Groups and Special Emphasis Panels; please see Extramural Peer Review in [SECTION III. NIH AS A RESEARCH FUNDER](#));
- ***National Advisory Councils/Boards:*** Perform the second level of peer review of research grant and cooperative agreement applications and contract proposals; provide advice and recommendations on matters of significance to the policies, missions, and goals of the ICO they advise; provide recommendations on research conducted by each ICO's IRP; and serve as a forum whereby interested members of the public, in open session, may hear and comment on issues relevant to the overall mission of the ICO;
- ***Program Advisory Committees:*** Advise on specific programs, future research needs and opportunities, and management policy issues, and participate in the identification and evaluation of future extramural initiatives; and
- ***Boards of Scientific Counselors:*** Review and evaluate IRP research programs and investigators.

NIH has a robust process to protect the integrity of NIH's FAC processes and that appropriate expertise and representation is prioritized. Membership Balance Plans emphasize recruitment that is diverse in terms of racial, ethnic, and gender representation, and that all appointments shall be made free from all forms of discrimination on the basis of race, religion, color, national origin, age, physical or mental disability, genetic information, or sex (including pregnancy, sex stereotyping, gender identity, transgender status, and sexual orientation). Members are generally appointed as Special Government Employees (with the primary exception of members of peer review groups) and are required to disclose real or apparent conflicts related to their service (see [OGE Form 450 – Confidential Financial Disclosure Report](#)). Members are also subject to Government-wide statutes and regulations and must complete a web-based ethics training module, [Ethics Training for Special Government Employees](#), which covers financial disclosure, COI, and misuse of positions, among other topics. As a resource for the community, the [NIH Ethics](#) website contains more information about ethics rules for Special Government Employees; the [NIH OFACP](#) website contains additional information regarding NIH and FACs.

*Ensuring Information Quality and Public Dissemination.* It is NIH's goal to ensure and maximize the quality, objectivity, utility, and integrity of information that it disseminates to the public. NIH adheres to the standards of quality set forth in the [Office of Management and Budget Information Quality Guidelines](#) (OMB Guidelines), the [HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public](#) (HHS Guidelines), and the [NIH Information Quality Guidelines](#) (NIH Guidelines). NIH strives to provide information that is accurate, reliable, clear, complete, unbiased, and useful, and is committed to integrating the principle of information quality into every phase of information development, including creation, collection, maintenance, and dissemination.

There are many quality control measures embedded in the scientific process that ensure high quality information is produced and disseminated by NIH. OCPL issues guidelines for the review, approval, and clearance of professional scientific, technical information and products, destined for wide public distribution (see [NIH Manual Chapter 1184 – Preparation and Clearance of Scientific, Technical, and Public Information Presented by NIH Employees or Produced for Distribution by NIH](#)). All scientific content in proposed agency communications is reviewed by experts, including the scientists whose work the communications may be based upon. OCPL has also issued guidance to ensure NIH's brand is not used in a manner inconsistent with the agency's mission or commitment to objective science (see [NIH Manual Chapter 1186 – Use of NIH Names and Logos](#)).

NIH also encourages its scientists and staff to engage public partners in research, policy, and programmatic activities via the media. NIH adheres to the [HHS Guidelines on the Provision of Information to the News Media](#). OCPL serves as a central, coordinating media relations office and works closely with NIH ICOs and other Federal agencies to communicate accurate and timely information through the NIH website, news outlets, and social media. OCPL also supports the dissemination of peer-reviewed, published scientific discoveries and works through news media and coordinates with NIH ICO communication offices to ensure accuracy, effectiveness, and transparency of media products and interviews. In general, NIH does not participate in marketing efforts or for-profit activities, comment on litigation, comment on legislation except through appropriate executive and legislative branch channels, or disclose unfunded grant applications or internal deliberations on grants/applications. NIH subject matter experts are encouraged to speak to members of the press about their work but are not required to do so. NIH also is committed to protecting the rights of patients and participants in research including the use of their likeness in photos and other media coverage.

*Safe and Respectful Work Environments.* As emphasized in previous sections, 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 evidences 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 Office of Inspector General](#).

NIH adheres to Whistleblowing provisions designed to encourage the reporting of personnel and safety violations while protecting Federal employees from acts of reprisal. A Whistleblower complaint must allege four key elements:

- The employee engaged in activity protected by the Whistleblower protection law(s) (such as reporting a violation of law);
- The employer knew about, or suspected, that the employee engaged in the protected activity;
- The employer threatened to take or failed to take, or took or failed to take a personnel action against the employee; and
- The employee's protected activity motivated or contributed to the personnel action.

The [NIH Office of the Ombudsman's](#) Center for Cooperative Resolution provides a safe haven for Whistleblowers who otherwise might not report their concerns. The NIH Office of the Ombudsman is a confidential, neutral resource that provides informal assistance to scientists, clinicians, fellows, and scientific personnel in addressing laboratory and other work-related issues. NIH personnel can speak with the NIH Ombudsman without fear of having their identities disclosed. The NIH Ombudsman may recommend that Whistleblowers lodge formal complaints with the NIH SIO or other agency adjudicating office(s). More information related to Whistleblower Protections can be found on the [HHS OIG](#) website.

*Research Fraud, Waste, and Abuse.* All NIH employees and stewards of Federal funds have a responsibility to uphold scientific integrity. Any activities that may be criminal or improper should be reported appropriately. Employees of NIH grantee organizations who become aware of real or apparent fraud, abuse, or waste of financial assistance funds are also encouraged to make a report to NIH (i.e., Chief Grants Management Officer listed on the Notice of Award), the HHS OIG, the grantee institution's Office of Sponsored Research, Compliance Office, and/or any other responsible office. Examples of activities that may constitute grants or contracts fraud include, but are not limited to:

- Falsifying information in grant or contract proposals;
- Using Federal funds to purchase items that are not for Government use;
- Billing for work that was not performed;
- Misrepresenting a project's status to continue to receive Federal funds; and
- Improperly influencing Government employees during the award of a grant or contract.

OMA's Division of Program Integrity ([DPI](#)) is responsible for conducting reviews of allegations involving misuse of NIH grant or contract funds, grantee or contractor COI, and other misconduct or misuses of NIH resources by NIH employees or others doing business with NIH. NIH also maintains a dedicated email address, [NIHHotline@mail.nih.gov](mailto:NIHHotline@mail.nih.gov), and phone hotline, (301) 496-5586, for confidentially reporting information. Other types of allegations regarding research fraud, waste, and abuse can also be directly reported to the following NIH offices:

- **Research Misconduct:** OER, NIH; OIR, NIH; ORI, HHS

- ***Human Subject Matters:*** OHSRP, NIH; Office for Human Research Protections, HHS
- ***Animal Welfare Matters:*** OLAW, NIH; OACU, NIH
- ***Discrimination and Harassment:*** Office of Equity, Diversity and Inclusion, NIH Civil Program, NIH; Office of the Ombudsman, NIH
- ***Personnel Matters:*** Office of Human Resources, NIH
- ***Criminal Activities:*** OIG, HHS

Allegations of criminal fraud, waste, and abuse are under the purview of the HHS OIG. It is also important to note that during the allegation review process, DPI does not advocate on behalf of a specific complainant; instead, DPI seeks to identify violations of NIH or HHS policy, which are then addressed by appropriate NIH officials. As a resource to the community, the [NIH OMA DPI](#) website provides additional information regarding NIH policies and procedures for reporting allegations of misconduct or misuse of NIH funds.