NIH Policies and Procedures for Promoting Scientific Integrity

NATIONAL INSTITUTES OF HEALTH
OFFICE OF THE DIRECTOR

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CONTENTS

LIST OF COMMONLY USED ABBREVIATIONS AND ACRONYMS

APA	Administrative Procedure Act
CFR	Code of Federal Regulations
CMO	Committee Management Officer
COR	Contracting Officer Representative
DDIR	Deputy Director for Intramural Research
FAC	Federal Advisory Committee
FACA	Federal Advisory Committee Act
FCOI	Financial Conflict of Interest
HHS	U.S. Department of Health and Human Services
IC	NIH Institute or Center
LoC	Library of Congress
NIH	National Institutes of Health
OAMP	NIH Office of Acquisition and Management Policy
OCPL	NIH Office of Communications & Public Liaison
OER	NIH Office of Extramural Research
OFACP	NIH Office of Federal Advisory Committee Policy
OGE	U.S. Office of Government Ethics
OHRP	HHS Office for Human Research Protections
OIG	HHS Office of Inspector General
OIR	NIH Office of Intramural Research
OLAW	NIH Office of Laboratory Animal Welfare
ORI	HHS Office of Research Integrity
OSP	NIH Office of Science Policy
OSTP	The White House Office of Science and Technology Policy
PHS	Public Health Service

PHSA   Public Health Service Act

SGE   Special Government Employee

I. INTRODUCTION

What Is Scientific Integrity?

Scientific integrity, in this context, refers to maintaining the quality and objectivity of the research activities that the National Institutes of Health (NIH) funds and conducts, such that they are sound and worthy of the public's confidence. NIH's commitment to sound, objective science also strengthens the public's trust in policy decisions informed by scientific data. 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 of policies based on science is conducted with appropriate transparency.

Purpose of This Document

On March 9, 2009, President Obama issued a memorandum to the heads of executive departments and agencies regarding scientific integrity. President Obama's memorandum ordered the Director of The White House Office of Science and Technology Policy (OSTP) to develop recommendations designed to uphold scientific integrity throughout the executive branch. On December 17, 2010, the Director of OSTP issued that guidance to the heads of the executive departments and agencies. Most, if not all, of the requirements set forth by OSTP were already in place at NIH but were located in multiple locations throughout the NIH Web site. Thus, this document consolidates summaries of and references to existing NIH policies and procedures so that interested members of the public can easily access vital information regarding NIH's commitment to scientific integrity.

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 the burdens of illness and disability. NIH accomplishes this mission by funding research through its Extramural Research Program and through research conducted by NIH scientists in its Intramural Research Program.

NIH is the Nation's largest single funder of biomedical research. Nearly 80 percent of the NIH budget goes to extramural research, and NIH funds more than 300,000 research personnel at over 3,000 universities and other research institutions throughout the United States and abroad.

NIH is also a research center with over 5,000 scientists working at many of its 27 Institutes and Centers (ICs). These scientists conduct applied and basic biomedical research within the laboratories and clinics of NIH's intramural facilities.

Ensuring the integrity of science and science-based policymaking is at the heart of everything NIH does in fulfilling its mission. NIH strongly supports appropriate degrees of transparency in the preparation and identification of the scientific and technological information that it uses for policymaking. NIH's goal is to maintain integrity in the conduct of the science that the public funds and to assure the public of the credibility of our scientific findings.

In addition to the requirements of the U.S. Department of Health and Human Services (HHS) and Federal-wide requirements, NIH has numerous policies and procedures in place to help ensure and optimize scientific integrity in both the Intramural and Extramural Research Programs. NIH also serves as a policymaking institution for its own research. Aside from internal policymaking, NIH participates in a wide range of trans-Federal policy development in areas such as clinical research, biotechnology, and biosecurity.

The primary purpose of this document is to make more readily available to the public the policies that NIH follows to help ensure the highest degree of scientific integrity in the research we conduct and fund and in the policies we make.

II. NIH AS A FUNDER OF RESEARCH

NIH is the Nation's largest single funder of biomedical research. NIH seeks to ensure the quality and integrity of the research it funds by developing, implementing, coordinating, and overseeing policies and procedures that provide priorities and standards for the critical processes involved in issuing and monitoring research conducted under NIH awards. By developing and implementing program policies and procedures centrally, NIH enhances consistency across all NIH ICs and extramural business areas.

The NIH extramural research continuum is depicted in Figure 1 below. NIH follows many policies, procedures, and laws to help ensure that scientific integrity is maintained throughout the funding and conduct of peer-reviewed extramural research.
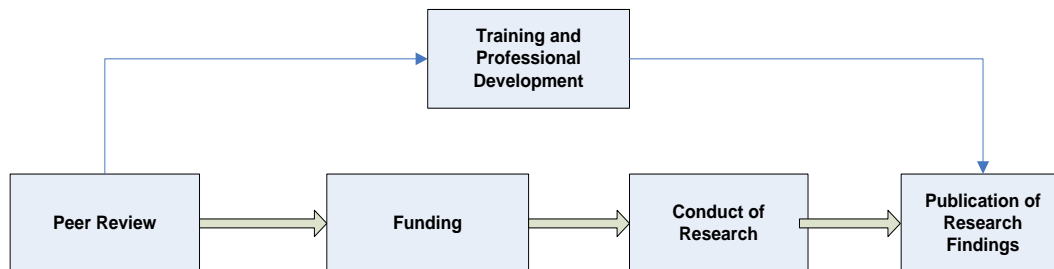

Figure 1: NIH Extramural Research Continuum

Peer Review

Peer-review groups at NIH generally are subject to the requirements of the [Federal Advisory Committee Act](#) (FACA), except for charter renewal (Public Health Service Act [PHSA] 492, 42 USC 289a). This means that the process by which grant applications are reviewed is transparent; all meetings are advertised and monitored by a Federal official; the criteria used to evaluate applications and membership are public information; and meeting records are filed with the Library of Congress (LoC).

Even though the privileged and confidential nature of information within applications necessitates meeting closures in accordance with NIH peer-review regulations (42 Code of Federal Regulations [CFR], Section 52h.6(b)), the public may request or access summary meeting minutes from LoC and access funded research using the [NIH RePORT](#) database.

The NIH Office of Extramural Research (OER) develops and oversees the implementation of policy for the NIH peer-review process. This two-tiered system involves initial peer review for scientific and technical merit and subsequent review by advisory councils or boards in the ICs 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.

Scientific integrity is the cornerstone of the NIH peer-review process and is exemplified in its core values: (1) expert assessment; (2) transparency; (3) impartiality; (4) fairness; (5) confidentiality; (6) integrity; and (7) efficiency. These core values drive NIH to seek the highest level of ethical standards and form the foundation for the laws, regulations, and policies that govern the NIH peer-review process. To help ensure scientific integrity in the initial peer-review process, OER has developed a policy for managing conflict of interest, the appearance of conflict of interest, prejudice, bias, or predisposition. That policy can viewed at:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-120.html

To increase transparency, HHS policy also requires that grant applications be evaluated according to the review criteria specified in the Funding Opportunity Announcement be used in the evaluation of applications submitted for that announcement. In addition, the rosters of all NIH study sections and descriptions of all funded grants are made available to the public on the OER Web site.

NIH clearly delineates the roles of extramural staff members to avoid conflicts. Thus, no member of the NIH extramural staff may serve as a reviewer on an NIH review panel, and no member of the NIH review staff may participate in review functions and portfolio management in the same scientific area. Furthermore, input from individual extramural research staff into the process is restricted: an individual may not participate in both an application's initial peer review and advisory council review.

Funding

The NIH Office of Acquisition and Management Policy (OAMP) helps ensure **scientific integrity in the award process for contracts and acquisitions** in accordance with the HHS Acquisition Regulation, Subpart 307.71. OAMP requires that the operating division involved in the award fully describe the acquisition strategy, funding approach, plans for full and open competition (or justification if limiting competition), and proposal evaluation criteria. In addition, in an effort to enhance competition, market research must be performed to identify prospective sources in addition to known sources. If it is best to limit competition, the requirement must satisfy stringent statutory authorities, and a justification must be approved to permit other than full and open competition.

Similarly, OER ensures scientific integrity throughout the NIH grants process, including different types of awards (e.g., cooperative agreements, research training awards). The mission of OER is to provide the corporate framework for NIH research administration, including leadership, policy, oversight, and the tools and guidance needed to administer and manage NIH grants policies and operations. OER policies for grants administration are specified in the NIH Grants Policy Statement and the NIH Guide for Grants and Contracts.

General Standards of Extramural Research Conduct

NIH requires grantees to establish safeguards to prevent employees, consultants, members of governing bodies, and others who may be involved in grant-supported activities from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private or financial gain for themselves or others, such as those with whom they have family, business, or other ties. These safeguards must be reflected in written **standards of conduct**. The grantee is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and in the case of financial conflict of interest, informing the IC chief grants management officer if the infraction is related to an NIH award. The grantee must promptly report issues involving potential criminal violations, such as misappropriation of Federal funds, to the HHS Office of Inspector General (OIG). The grantee is not required to submit its general standards of conduct to NIH for review or approval. However, a copy must be made available to each of its officers, each employee and consultant working on the grant-supported project or activity, each member of the governing board, if applicable, and, upon request, to NIH.

If a suspension or separation action is taken by a grantee against a project director, principal investigator, or other senior key personnel under an NIH grant, the grantee must request prior approval of the proposed replacement as specified in Administrative Requirements, Changes in Project and Budget, Prior Approval Requirements of the NIH Grants Policy Statement.

An integral element of ensuring the integrity of NIH-sponsored research is adherence to specific requirements that foster the safe and ethical conduct of research. These are articulated in terms and conditions that must be agreed to by institutions receiving NIH funding. When an NIH grantee fails to materially comply with the terms and conditions of award, including confirmed instances of research misconduct, NIH may take one or more actions, depending on the severity and duration of the noncompliance. NIH will undertake such action in accordance with applicable statutes, regulations, and policies. Generally, NIH will afford the grantee an opportunity to correct the deficiencies before taking action unless public health or welfare concerns require immediate action. However, even if a grantee takes corrective action, NIH may take proactive actions to protect the Federal Government's interests, including placing special conditions on awards or precluding the grantee from obtaining future awards for a specified period, or may take action designed to prevent future noncompliance, such as closer monitoring.

If a grantee fails to materially comply with the terms and conditions of award, NIH may take action to wholly or partially suspend the grant, pending corrective action, or may terminate the grant for cause. The regulatory procedures that pertain to suspension and termination are specified in 45 CFR, Sections 74.61, 74.62, and 92.43. A grant also may be terminated, partially

or totally, by the grantee or by NIH with the consent of the grantee. If the grantee decides to terminate a portion of a grant, NIH may determine that the remaining portion of the grant will not accomplish the purposes for which the grant was originally awarded. In any such case, NIH will advise the grantee of the possibility of termination of the entire grant and allow the grantee to withdraw its termination request. If the grantee does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire grant for cause. NIH also may decide to withhold support of a noncompeting continuation award in a current competitive segment. This postaward decision may be appealed by the grantee.

The policies and procedures found at the following Web links apply to research conducted, or proposed to be conducted, in facilities by any person funded by the NIH Extramural Research Program:

http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_ch8.htm#_Suspension,_Termination

Title 42, Part 52: Grants for Research Projects

Title 45, Part 74: Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations and Commercial Organizations

Title 45, Part 92: Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments

Animal Welfare

OER's Office of Laboratory Animal Welfare (OLAW) coordinates Public Health Service (PHS) regulations, policies, and procedures regarding the use of animals in research throughout the Federal Government. The NIH peer-review system evaluates justifications for the use of vertebrate animals in grant applications and descriptions for their use in research; any concerns raised during peer review must be resolved to the satisfaction of OLAW and the NIH program staff before an award can be issued. In addition, OLAW evaluates reports of noncompliance with PHS policy and conducts compliance oversight of PHS-supported animal care and use programs. OLAW provides oversight of all NIH-supported research activities that involve animals through its guidance and interpretation of the Public Health Service Policy on Humane Care and Use of Laboratory Animals.

More information about OLAW can be found at:

http://grants.nih.gov/grants/oer_offices/olaw.htm.

Human Subjects Protections

The HHS Office for Human Research Protections (OHRP) provides leadership in the **protection of the rights, welfare, and well-being of human subjects involved in research conducted or supported by HHS**. OHRP helps ensure this by providing clarification and guidance,

developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and sociobehavioral research.

In implementing the regulations of 45 CFR, Part 46, "Protections of Human Subjects," the NIH grants process includes numerous checkpoints to ensure compliance with PHS regulations and policy for human subjects protections. An NIH grant application that contains inadequate or unacceptable plans for protecting human subjects will not receive NIH funding. The NIH peer-review system evaluates the adequacy of protections for human subjects in each grant application and research and development contract proposal, and any concerns raised by reviewers must be resolved to the satisfaction of OER and program staff members before an award can be issued.

In addition, NIH requires education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or noncompeting awards for research involving human subjects. Recently, OER launched the online tutorial "Protecting Human Research Participants" (http://phrp.nihtraining.com/users/login.php), which is designed for those involved in the design and/or conduct of research involving human participants. The training module is also available in Spanish.

Training in the Responsible Conduct of Research

Since1989 NIH has required that institutional training grant applications include a description of activities related to instruction about **responsible conduct of research**. The scientific community has responded by developing innovative courses, workshops, research projects on instruction in the responsible conduct of research, and instructional materials.

The NIH OER Research Training Web site (http://grants.nih.gov/training/extramural.htm) includes additional information on instruction in the responsible conduct of research and links to the HHS Office of Research Integrity (ORI) (http://ori.hhs.gov/), instructional materials, and examples of programs regarded as good models for instruction in the responsible conduct of research (http://bioethics.od.nih.gov/researchethics.html). Additional resources regarding the responsible conduct of research can be found at:

http://grants.nih.gov/training/responsibleconduct.htm.

Conflicts of Interest

NIH requires institutions that apply for or receive funding under grants or cooperative agreements (except Phase I SBIR/STTR applicants) to address **financial conflicts of interest** (FCOI) by complying with the requirements of 42 CFR, Part 50, Subpart F, Promoting Objectivity in Research. These regulations were revised in 2011, and institutions are required to comply with the updated regulations as of August 24, 2012. The requirements under the FCOI

regulations promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of research funded under NIH or other PHS grants or cooperative agreements will be free from bias resulting from investigator FCOI. "Investigator" is defined in the regulations to mean the project director, principal investigator, or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS or who is proposed for such funding, which may include, for example, collaborators or consultants.

Information regarding the FCOI requirements, including links to the regulations and frequently asked questions, is available on the NIH Office of Extramural Research's FCOI Web site at:

http://grants.nih.gov/grants/policy/coi/.

Research Misconduct

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results, according to "Public Health Service Policies on Research Misconduct," 42 CFR, Part 93.

- **Fabrication** is defined as making up data or results and recording or reporting them.

- **Falsification** is defined as 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.

- **Plagiarism** is defined as appropriating another person's ideas, processes, results, or words without giving appropriate credit.

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.

- The allegation must be proven by a preponderance of the evidence.

Research misconduct does not include honest error or differences of opinion. All institutions receiving PHS funding must have written policies and procedures for addressing allegations of research misconduct. NIH and ORI have specific procedures in place to address allegations of research misconduct. In addition, all NIH extramural staff members receive training biannually in the proper handling of allegations of research misconduct.

NIH identification of findings of research misconduct may result in special award conditions and/or enforcement actions, depending on the specific circumstances involved. Therefore, a

grantee's failure to comply with the terms and conditions of award, including confirmed instances of research misconduct, may cause NIH to take one or more actions, depending on the severity and duration of the noncompliance. NIH will undertake any such action in accordance with applicable statutes, regulations, and policies. Additional information related to NIH's process for the handling of research misconduct allegations involving the extramural research community can be found at:

http://grants.nih.gov/grants/research_integrity/index.htm.

Fraud, Waste, and Abuse

Any individual who becomes aware of the existence (or apparent existence) of fraud, waste, or abuse related to NIH grants or grant funds should consider contacting:

- The grantee institution's Office of Sponsored Research, Compliance Office, or other responsible office
- The NIH chief grants management officer listed in the Notice of Award for the IC that funded the grant
- The Division of Grants Compliance and Oversight, Office of Policy for Extramural Research Administration, OER (DGCO/OPERA/OER)

In addition, allegations of criminal offenses should be reported to the HHS OIG Hotline.

OIG has authority within HHS to conduct criminal investigations. Further allegations of noncriminal misuse of grant funds and grantee conflict of interest should be reported to the NIH Office of Management Assessment (http://oma.od.nih.gov/). The policies and procedures available at the following Web link apply to research conducted, or proposed to be conducted, in facilities by any person funded by the NIH Extramural Research Program:

http://grants.nih.gov/grants/policy/nihgps_2011/index.htm

NIH requires that none of the funds made available in the governing appropriations act may be used to disseminate deliberately false or misleading scientific information.

This information can be found in Section 4.2.3, Dissemination of False or Deliberately Misleading Scientific Information of the NIH Grants Policy Statement.

Public Accessibility

Research Results

The NIH Public Access Policy (http://publicaccess.nih.gov/policy.htm) helps ensure that the public has **access to published results** of NIH-funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH-funded research to the digital archive PubMed Central® upon acceptance for publication. To help advance science and

improve human health, the policy requires that these papers be made available to the public on PubMed Central® no later than 12 months after publication.

The NIH Office of Communications & Public Liaison (OCPL) makes the public aware of individual IC clearinghouses, toll-free telephone numbers, and other contact information through the "Quickfinder" publication, a list of IC-based information resources. Another cornerstone of the NIH information program is ClinicalTrials.gov, a Federal repository of information about research sponsored by NIH and other entities. Although many ICs offer specialized trial searches through individual databases, ClinicalTrials.gov is a central repository for international research involving humans.

General NIH Information

OCPL offers a variety of mechanisms for direct public contact and recognizes the need for immediate, reliable responses to public inquiries, but by way of policy, does not offer personalized medical advice or product endorsements. Public inquiries that arrive via an online form on the NIH home page or by email (NIHinfo@od.nih.gov) are fielded by OCPL's Editorial Operations Branch. Staff members respond daily to requests for information; OCPL has set a goal of responding to each inquiry within 48 hours of receipt.
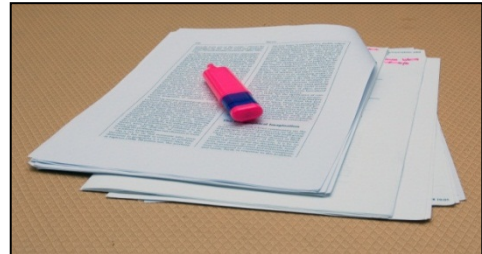
Patients seeking medical advice are directed to their primary health care practitioners. Records of inquiries submitted to NIHinfo@od.nih.gov are kept for approximately 1 year. General information on NIH activities can be found at the following Web links:

NIH "A-Z" Health Information and NIH Publications List:
http://health.nih.gov/see_all_topics.aspx and http://nihpublications.od.nih.gov/

"Contact NIH":
http://www.nih.gov/about/contact.htm

"Quickfinder":
http://www.nih.gov/about/quickfinder.pdf

ClinicalTrials.gov:
http://www.clinicaltrials.gov/

Selected NIH Education and Awareness Campaigns:
http://www.nih.gov/icd/od/ocpl/resources/campaigns/

Biennial Report of the Director, NIH, including the Health Communication and Information Campaigns and Clearinghouses section:
http://report.nih.gov/biennialreport/

III. NIH AS A RESEARCH INSTITUTION

The NIH Intramural Research Program conducts research, training, and technology transfer within its own laboratories and clinics. To help ensure the high quality and integrity of its intramural programs, NIH develops and implements NIH-wide policies and review standards for intramural research, training, and technology transfer.

The NIH intramural research continuum is outlined in Figure 2 below. Scientific integrity begins with the staffing process, which seeks to ensure that the scientists hired to conduct research at NIH are of the highest caliber. In addition, NIH has a wide variety of policies and procedures that help ensure scientific integrity throughout the conduct of research and the eventual publication of research results. Most importantly, NIH maintains a culture of scientific integrity by employing an overarching program of training and professional development for all scientists conducting research at NIH.
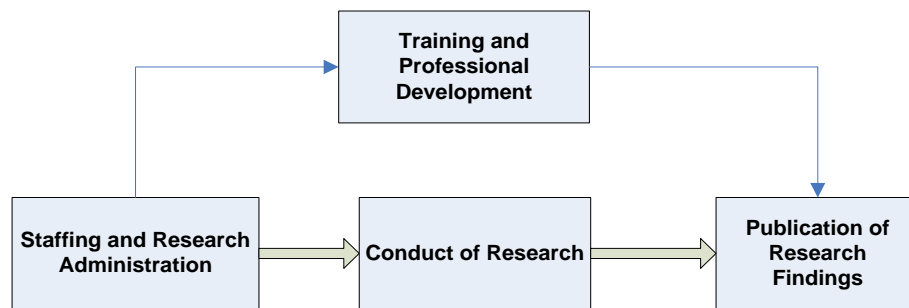

Figure 2: NIH Intramural Research Continuum

Staffing and Human Resource Administration

Hiring Practices

The NIH Office of Intramural Research (OIR) is actively involved in the hiring of new scientists at NIH. The selection of new senior investigators, tenure-track investigators, senior scientists, and senior clinicians is considered one of the most important functions of the Intramural Research Program. 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, the NIH Deputy Director for Intramural Research (DDIR) must approve all searches for these individuals. The DDIR also provides hiring guidelines in the Intramural Research Sourcebook (https://oir.nih.gov/sourcebook).

Prior to a new search, the IC sends to the DDIR for approval a brief memorandum (with appropriate attachments) describing the general procedures that will be used for searches to fill vacancies. It is recognized that these general procedures may differ, even in principle, depending on the seniority and the nature of the desired or necessary expertise of the individual being sought. Specific information is sent to the DDIR regarding such matters as the names and

credentials of the proposed chairperson and members of the search committee, specific instructions contemplated for the committee, a draft of the vacancy announcement and where it will be placed, and any other pertinent information.

It is anticipated that the DDIR will designate an additional member of the search committee and work with the IC to modify the search plan when that seems advisable. Once a candidate is selected, a report about the search, including the number of applicants, as well as the name of the selected individual, is sent to the DDIR for approval (https://oir.nih.gov/sourcebook).

Whistleblower Protections

The term "**whistleblower" refers to the act of reporting wrongdoing to stop illegal or unethical behavior**. When an organization's employees and scientific staff report such behavior, they draw attention to activities that undermine both the institutional mission and the public trust. Scientists and scientific staff members can play an instrumental role by surfacing latent problems so that they can be addressed. Scientists and scientific staff members will be reluctant to come forward, however, if they believe they may be subject to retaliation for having done so. The Federal Government has enacted whistleblowing provisions designed to encourage the reporting of personnel and safety violations while protecting Federal employees from acts of reprisal.

The NIH Office of the Ombudsman, Center for Cooperative Resolution, plays a crucial role in assisting whistleblower scientists. The Office of the Ombudsman provides a safe haven for scientific whistleblowers who otherwise might not report their concerns. Scientists and scientific personnel can speak with the NIH Ombudsman without fear of having their identities disclosed. NIH ombudsmen are able to shuttle information between whistleblowers and those in authority, helping to surface issues of scientific misconduct, the improper use of human and animal subjects, and other system-wide problems. Furthermore, the flexible nature of the Ombudsman Office allows scientific whistleblowers more control over the process.

Standards of Integrity and Objectivity in Research

Research Ethics

The progress and excellence of NIH research depend on NIH's vigilance in **maintaining the highest quality of conduct in every aspect of science**. OIR has developed a set of general principles for the ethical conduct of research, published as the "Guidelines for the Conduct of Research in the Intramural Research Program at NIH" (https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-

conduct_research.pdf). These Guidelines define specific core areas critical for high-quality, ethical research. Individuals who are directly involved in the research activities of the NIH Intramural Research Program must read, understand, and incorporate the principles in the Guidelines into everyday practice.

The Responsible Conduct of Research policy requires one-time training (http://researchethics.od.nih.gov/) in the core areas and yearly followup using research ethics case discussions on specific themes encountered in research. These sessions review real-world case studies that engender discussions of scientific integrity. Case studies are archived, can be reviewed at any time, and can be accessed at https://oir.nih.gov/sourcebook/ethical-conduct/responsible-conduct-research-training

Research Misconduct

OIR, the research community, and the public at large rightly expect adherence to exemplary standards of intellectual honesty in the formulation, conduct, and reporting of scientific research. Allegations of research misconduct are taken seriously by NIH. The process of investigating allegations must be balanced by equal concern for protecting the integrity of research as well as the careers and reputations of researchers.

The online resource NIH Intramural Research Program Policies & Procedures for Research Misconduct Proceedings (NIH Intramural Policy) is intended to enable allegations of research misconduct to be processed fairly, confidentially, and promptly. Fairness allows all who become involved in research misconduct cases to have the opportunity to participate appropriately in addressing the relevant issues and seeks to protect innocent participants from adverse consequences. Confidentiality helps protect innocent people who are incorrectly or unjustly accused and those who bring allegations. A prompt response to an allegation helps minimize any harm to the public that could result if research misconduct is found and allows those who are incorrectly accused to clear their names without going through a long process. Fair, confidential, and prompt treatment of research misconduct allegations is important and also fosters an institutional climate supportive of honest, good-faith reporting of possible research misconduct.

The NIH Intramural 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 NIH Intramural Research Program 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.

Policies and procedures relating to allegations of potential misconduct in the Intramural Research Program at NIH, available via the Web link above, also have been summarized in the online resource "A Guide to the Handling of Research Misconduct Allegations" (http://sourcebook.od.nih.gov/ResEthicsCases/NIH%20Misconduct2.pdf).

Conflict of Interest

Avoiding financial and other conflicts of interest are important for NIH, where the trust and protection of research participants are vital to our mission to improve public health. 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 subject to the requirements found in [5 CFR Part 2636](), [5 CFR Part 2640](), [5 CFR Part 2641](), [5 CFR Part 5501,]() and [5 CFR Part 5502](). Each IC has dedicated ethics officials available to help NIH scientists understand and comply with the applicable ethics rules. A list of these officials' names and contact information is found at: [https://ethics.od.nih.gov/contacts.html](). Additional information on the ethical conduct laws, regulations and policies can be found at: [http://ethics.od.nih.gov/default.htm](). In addition, OIR, working with the NIH Ethics Office, has prepared a guide to assist clinical investigators in avoiding real or perceived financial and nonfinancial conflicts of interest, which is available at: [https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-conduct_research.pdf]()

Professional Development

NIH trainees have a single primary supervisor, but other individuals also may function as mentors for specific aspects of training and career development. It is the responsibility of the primary supervisor to serve as a role model and provide a rich research environment in which the trainee has the opportunity to acquire both the conceptual and technical skills of the field. In this setting, the trainee is provided with clear expectations and undertakes a significant piece of research, usually chosen as the result of discussions between the mentor and the trainee. To provide a meaningful, high-quality training experience, the mentor monitors and guides the trainee's progress closely and interacts personally with the trainee on a regular basis to give timely feedback regarding research findings and progress.

Mentoring is adapted to the needs and career stage of each individual trainee. Mentors are particularly diligent to involve trainees in research and related activities that contribute to their careers, including participation in intramural or extramural collaborations, encouragement of presentations at scientific meetings, and networking. Mentors provide trainees with timely and realistic appraisals of their performance and with advice regarding career opportunities and advancement.

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 investigators to share information about their official and professional activities, NIH seeks to advance scientific knowledge and contribute to its employees' professional education.
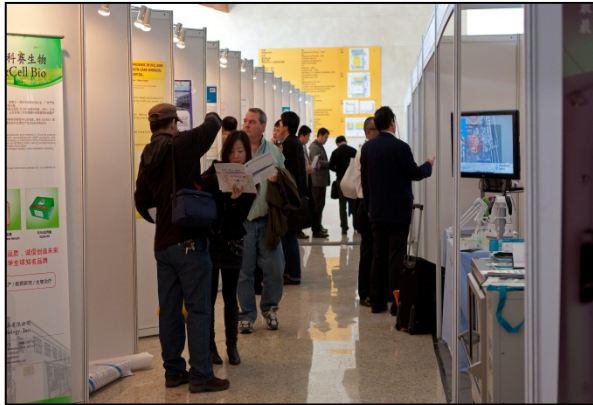
Ordinarily, scientific research results or other professional findings by NIH intramural scientists are reported via either publication in a scientific or professional journal or as a presentation at a professional organization's meeting. Sometimes NIH provides "breaking news" to the public on research findings prior to publication in scientific journals and prior to peer review by journals of an important public health finding, such as publication of the results of a clinical trial result that has immediate health implications.

Professional Collaborations

The NIH Office of the Ombudsman also has resources aimed at fostering successful professional development for scientists and researchers. 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. The Office offers a range of professional development services designed to help researchers (1) identify and prevent problems arising from scientific collaborations and (2) address interpersonal conflicts involving scientists or others they manage. Because the Office is a confidential resource that is unaffiliated with any institute or department, scientists and fellows are able to identify and address their sensitive coaching needs without disclosing them to their supervising investigator or scientific director. In addition, as a consequence of working with many scientists over time to resolve scientific and interpersonal disputes, the Office of the Ombudsman is able to identify likely problems that a researcher may encounter when working collaboratively with other scientists. These potential issues, and concrete strategies for addressing them, are contained in *Collaboration and Team Science: A Field Guide*, a book written by the Office of the Ombudsman together with an intramural scientist. The Office of the Ombudsman also helps scientific collaborators think critically about the nature of their collaborations through its online resource *Questions for Scientific Collaborators: A Collaborative Agreement Template*, which helps foster proactive decision making. The following resources and documents on conflict resolution are available for use by NIH scientists and research staff members:

http://ombudsman.nih.gov/

Collaboration & Team Science: A Field Guide

Sample Partnering Agreement Template

Workplace Conflict

General Guidelines for Authorship Contributions (PDF)

OAMP also offers professional development opportunities for the NIH scientific Contracting Officer Representative (COR) community. NIH COR staff members are responsible for the award and administration of contracts. The COR staff must meet Federal Acquisition Certification.

In addition, one of the general business competencies established by HHS relates to integrity and honesty in the activities as a COR.

Publication of Research Findings

Publication Policies

OIR has established policies and procedures for the review, approval, and distribution of scientific, technical, and other professional information by individual employees (including intramural, extramural, and NIH Office of the Director staff members). Guidelines are available for written, electronic, or oral presentations, which reiterate the many quality control measures embedded in the scientific process, and at NIH, to help ensure that the information disseminated by NIH employees is of the highest quality. Scientific and professional information presented by NIH employees must be considered differently from information presented in other professional settings (such as when scientists from universities or industry laboratories present information in public forums). A clear distinction must be made between the presentation of scientific data and the presentation of opinion that may be construed as the position of NIH. Publication policies can be found at the following Web links:

http://publicaccess.nih.gov/nih_employee_procedures.htm

http://sourcebook.od.nih.gov/oversight/non-peer-reviewed-instruct.htm

http://sourcebook.od.nih.gov/oversight/pub-clear.htm

NIH is committed to maximizing both the quality and effectiveness of NIH publications and audiovisuals while providing an orderly basis for review without hampering the free flow of information. OCPL also supports existing quality control measures found in the scientific process and works with the scientific staff to help ensure that peer-reviewed, research-based information disseminated by NIH employees is of the highest quality, recognizing that (1) information presented by NIH employees is considered and treated differently from that presented in other professional settings and (2) there is a clear distinction between the presentation of scientific data and opinion.

OCPL has developed an NIH-wide editorial policy and a policy for using the NIH name and logo for science and health information materials produced by NIH ICs (http://health.nih.gov/editorialpolicy.aspx). OCPL policies also guide the production and

dissemination of staff scientific publications and health materials designed for the public at large. The Office also reviews and clears all proposed NIH publications and public health campaign materials through HHS to ensure accuracy and adherence to Federal Government publication standards. Of equal importance is guidance for use of the NIH name and logo to help ensure consistency and accountability in the use of logos both within and outside the agency.

OCPL's Editorial Operations Branch maintains **guidelines for submission and clearance of NIH publications**. Publications designed for wide public dissemination must undergo a series of internal approvals prior to printing. As a general policy, NIH publications may not include advertising. The clearance process follows a number of clear, prescribed steps. Speeches or journal publications, as well as letters to the editor from NIH directors or associate directors, are reviewed for editorial suggestions or policy implications. In some cases, material may be subject to a number of levels of review, including HHS review, especially when current policy issues are involved. Additional guidance for specific NIH publications, such as the *NIH Record*, is posted on the publication Web site at http://nihrecord.od.nih.gov/.

The NIH policy and procedures to be followed in the preparation, review, approval, and distribution of documents issued by NIH and its components can be found at:

http://oma.od.nih.gov/manualchapters/management/1183/.

The NIH policy and procedures for the review, approval, and **distribution of scientific, technical, and other professional information** by individual employees can be found at:

http://oma.od.nih.gov/manualchapters/management/1184/1184.pdf.

The Plain Writing Act of 2010 was signed into law on October 13, 2010. The law requires Federal agencies to use "clear Government communication that the public can understand and use" and sets down several requirements for Federal agencies. NIH's "clear communication" policies, including plain-language requirements, can be found at the following Web links:

http://www.nih.gov/clearcommunication/

http://www.nih.gov/clearcommunication/plainlanguage.htm

http://plainlanguage.nih.gov/CBTs/PlainLanguage/login.asp

http://www.hhs.gov/open/recordsandreports/plainwritingact/index.html

http://www.plainlanguage.gov

The 1998 Amendment to Section 508 of the Rehabilitation Act requires that all **Web site content** be equally accessible to people with disabilities. This applies to Web applications, Web pages, and all attached files. The OCPL staff collaborates with IC and HHS counterparts as well as with Federal partners and the Office of the Chief Information Officer in an effort to ensure

that NIH meets Section 508 requirements and achieves Government-wide Section 508 goals. Information regarding 508 compliance can be found at the following Web links:

http://www.hhs.gov/web

http://www.hhs.gov/web/508/index.html

Media and Interview Requests

OCPL maintains clearance procedures for **interview requests, press releases, media availabilities, and teleconferences** and also serves as the point of contact for NIH policies governing video and photos during media sessions. OCPL serves as a central, coordinating media relations office and works closely with NIH's component communications offices and staffs and with HHS's Federal partners.

Public audiences for NIH communications include patients and their family members, nonprofit organizations, Congress, industry, the media, the scientific community (primarily through professional membership organizations), and the wider public that receives NIH communications through the NIH Web site, broadcast or print news outlets, and social media outlets. NIH seeks to be responsive to the media, recognizing that press inquiries about NIH-supported research are a high priority.

In general, NIH does not (1) participate in marketing efforts or for-profit activities, (2) comment on unfunded investigators or pending grants, or (3) contribute to ideological discussions. NIH employees may speak to members of the press about their work but are not required to do so. A number of specific requirements may apply, for example, those related to official duty activities for NIH employees and disclaimers to be used when scientists are not speaking in an official capacity. NIH also is committed to protecting the rights of patients and subjects used in photos and other media coverage while fulfilling NIH's communication mission and meeting continuous media deadlines.

HHS media relations guidelines and style guidelines for press releases can be found at the following Web links:

HHS Guidelines on the Provision of Information to the News Media:
http://www.hhs.gov/news/media_policy.html

HHS and HHS Agency Press Contacts:
http://www.hhs.gov/news/contacts/index.html

NIH **guidance material regarding media relations information** can be found at the Web links listed below.

Media Policies

NIH Media Contacts:
http://www.nih.gov/news/media_contacts.htm

HHS Center for New Media (resources, checklists, guidelines, policies, including new media at NIH):
https://www.hhs.gov/web/index.html

Authorization for Interviewing, Recording, Filming, and/or Photographing of Patients in the Clinical Center for External Media/Communications Purposes (Form NIH-549):
https://security.nih.gov/Documents/Guidelines%20for%20Photography%2C%20Filming%2C%20or%20Video%20Recording%20at%20the%20NIH.pdf

Publication Policies

NIH Policy on Scientific, Technical, and Other Professional Information Presented by NIH Employees: Review, Approval, and Distribution (including use of disclaimers, Section D3):
https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx

Office of Management and Budget and HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies and NIH Guidelines for Ensuring the Quality of Information Disseminated to the Public:
https://obamawhitehouse.archives.gov/omb/fedreg_final_information_quality_guidelines/

Intramural Research Sourcebook for Publications and Meeting Abstracts Clearance:
https://oir.nih.gov/sourcebook/submitting-research-publications/publication-abstract-clearance

Public Accessibility

Research Results

The NIH Public Access Policy (http://publicaccess.nih.gov/policy.htm) helps ensure that the public has **access to published results** resulting from research conducted by NIH. The policy requires scientists to submit final peer-reviewed journal manuscripts resulting from NIH-funded research to the digital archive PubMed Central® upon acceptance for publication. To help advance science and improve human health, the policy requires that these papers be made available to the public on PubMed Central® no later than 12 months after publication.

OCPL informs the public about individual IC clearinghouses, toll-free telephone numbers, and other contact information through the "Quickfinder" publication, a list of IC-based information resources. Another cornerstone of the NIH information program is ClinicalTrials.gov, a Federal repository of information about research sponsored by NIH and other entities. Although many

ICs offer specialized trial searches through individual databases, ClinicalTrials.gov is a central repository for international research involving humans.

General NIH Information

OCPL offers a variety of mechanisms for direct public contact and recognizes the need for immediate, reliable **response to public inquiries** but, as a matter of policy, does not offer personalized medical advice or product endorsements. Public inquiries that arrive via an online form on the NIH home page or by email (NIHinfo@od.nih.gov) are fielded by OCPL's Editorial Operations Branch. Staff members respond daily to requests for information; the Office has a goal of responding to each inquiry within 48 hours of receipt.

Patients seeking medical advice are directed to their primary health care practitioners. Records of inquiries submitted to NIHinfo@od.nih.gov are kept for approximately 1 year. General information on NIH activities can be found at the following Web links:

NIH "A-Z" Health Information and online publications:
http://health.nih.gov/see_all_topics.aspx
http://nihpublications.od.nih.gov/

"Contact NIH":
http://www.nih.gov/about/contact.htm

"Quickfinder" information resource:
http://www.nih.gov/about/quickfinder.pdf

ClinicalTrials.gov:
http://www.clinicaltrials.gov/

Selected NIH Education and Awareness Campaigns:
http://www.nih.gov/icd/od/ocpl/resources/campaigns/

Biennial Report of the Director, NIH, including the Health Communication and Information Campaigns and Clearinghouses section:
http://report.nih.gov/biennialreport/

IV. NIH AS A POLICY DEVELOPMENT AGENCY

NIH Office of Science Policy

In addition to being a research institution and the Nation's major funder of biomedical research, **NIH is also a policymaking agency that develops and participates in the development of policies regarding the management and safety of science, as well as future directions for scientific inquiry**. Spearheading the development and analysis of these policies is the NIH Office of Science Policy (OSP), which advises the NIH Director on science policy issues affecting the biomedical research community, NIH, and the public. OSP's mission is to promote progress in the biomedical research enterprise through the development of sound and comprehensive policies for the conduct and oversight of biomedical research. OSP accomplishes this mission by taking a leading role in the development of new research policies and programs in a variety of arenas, including the conduct and oversight of clinical research, biosafety, the societal impact of genomics research and data sharing, the ethical use of stem cells in research, and biosecurity in the life sciences.

OSP also serves as a focal point in the coordination of the activities of the 27 individual IC science policy offices. OSP staff members also take a leadership role in a variety of working groups that have been established to provide in depth analysis of science policy initiatives. The Director of OSP also serves as the NIH liaison to important Federal science policy partners such as the U.S. Food and Drug Administration and OHRP. The various interagency and intra-agency coordination activities provided by OSP help ensure that the NIH Director is provided with the most balanced and sound advice possible when considering science policy matters.

OSP's Role in Ensuring the Integrity of Science Policy Analysis

One of OSP's most critical roles in science policy development is identifying and analyzing the needs of a diverse set of stakeholders. These stakeholders often include the national and international scientific community, patients, other Federal agencies, and the public. To fulfill the needs of such a broad spectrum of stakeholders, OSP must be adept in analyzing complex scientific information and its potential impacts. OSP has developed several successful mechanisms for reaching out and consulting with stakeholders. Such mechanisms include holding public stakeholder meetings where interested parties can provide their perspectives on proposed policy matters. Other mechanisms include providing stakeholders with clear, accessible information on emerging policy issues through one of the Web sites that OSP maintains.

Additional information regarding OSP, and the programs that OSP administers to promote sound policymaking decisions, can be viewed at the following Web link:

http://osp.od.nih.gov/

In addition to the aforementioned policymaking activities, NIH frequently makes use of Federal Advisory Committees when seeking balanced and expert input on science policy matters.

Federal Advisory Committees

To develop sound, credible scientific polices, NIH often seeks the assistance of Federal Advisory Committees (FACs) to help guide policy discussions and engage key stakeholders to learn different perspectives regarding the proposed policy's impact. The development of science policy at NIH generally follows the Administrative Procedure Act (APA) to allow for the appropriate engagement of members of the general public.

The general process utilized by NIH in policy development is outlined below in Figure 3. Scientific integrity begins with ensuring that scientific input regarding a proposed policy is appropriate. This information, in conjunction with public input, is then used to craft sound, credible scientific policy. A hallmark of the policymaking process is NIH's commitment to transparency. In the case of policymaking, FACs are often used to provide crucial guidance to NIH. The advice from these committees, as well as input from the public is an integral element of NIH's ability to craft sound, credible, scientific policies.
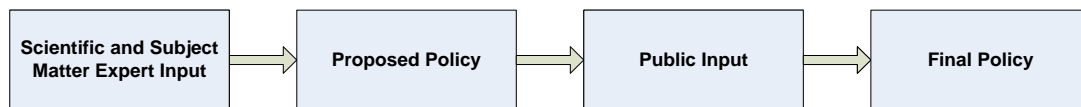
Scientific and Subject Matter Expert Input	→	Proposed Policy	→	Public Input	→	Final Policy

Figure 3: NIH Policy Development Process

Roles and Responsibilities of the NIH Staff in Managing Federal Advisory Committees

The Office of Federal Advisory Committee Policy (OFACP) is responsible for the oversight of all NIH FACs established and operated under the FACA. OFACP develops policies and provides guidance, resources, and training for NIH and serves as the central liaison to HHS on FAC management matters.

At NIH, each IC has a Committee Management Officer (CMO) or an agreement with a CMO service center to coordinate all operational committee management activities within its organization (A CMO service center is a committee management office in one IC that has a memorandum of agreement with other ICs to provide them with committee management services). The IC CMO or CMO service center prepares nomination slates and furnishes OFACP generated policy guidance and assistance to IC leadership and FAC members to ensure compliance with the FACA.

Every FAC has a designated Federal official or executive secretary that attends all committee meetings, ensures that the meeting proceeds according to the agenda, and maintains responsibility for meeting records, among other requirements.

Use of Federal Advisory Committee Members

The Federal Government recognizes the important roles played by FACs in developing effective policies and providing guidance on many issues. The influence and number of FACs have grown quickly, as have concerns within the Federal Government regarding FAC management, cost, and accountability. Since 1962 several Executive Orders and Federal acts have established guidelines for using such groups. Today, the principal Federal act that FACs must follow is the FACA.

NIH maintains over 150 chartered FACs, the largest number of any executive branch agency. The majority of these committees are either mandated or authorized by the PHSA. 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 through FACs.

Recruitment of Federal Advisory Committee Members

The nomination and selection of FAC members are major professional responsibilities of each FAC's manager. The selection process involves long-range planning and obtaining suggestions and information from many different sources. NIH draws on numerous resources to select suitable nominees for membership.

NIH utilizes four different types of FACs:

- Integrated/Initial Peer Review Groups
- Program Advisory Councils
- Boards of Scientific Counselors
- National Advisory Councils

More information regarding how NIH manages the different types of FACs can be found on the OFACP Web site: http://ofacp.od.nih.gov/. Additional information on the NIH selection criteria for FAC membership can be viewed at:
https://ofacp.od.nih.gov/committees/pdf/SelectionCriteria.pdf

Ethics Requirements for Special Government Employees

Members of FACs, with the primary exception of members of integrated/initial peer review groups, are almost always considered Special Government Employees (SGEs). An SGE is an officer or employee in the executive branch of the Federal Government who is appointed to perform temporary duties, with or without compensation, for a period not to exceed 130 days during any period of 365 consecutive days. The SGE nominee must complete the U.S. Office of Government Ethics (OGE) Form 450 (Confidential Financial Disclosure Report) before serving and attending meetings as a member. OGE Form 450 is reviewed by the IC CMO in consultation

with the FAC's executive secretary and the IC deputy ethics counselor to determine whether an actual or apparent conflict of interest exists.

As SGEs, FAC members are also subject to various additional ethics requirements and must take the course "Ethics Training for Special Government Employees," which covers financial disclosure, conflict of interest, and misuse of positions, among other topics. The ethics rules governing FAC members and SGEs can be found at:

http://ofacp.od.nih.gov/ethics/pdfs/SGETRAININGOCT2004.pdf.

Additional resources related to ethics requirements and avoiding conflicts of interest for SGEs can be found at the following links:

http://ofacp.od.nih.gov/ethics/ethics_training.asp

http://oma.od.nih.gov/manualchapters/management/1810-1/

Federal Advisory Committee Meetings and Public Transparency

Specific policies must be followed when conducting a FAC meeting, including the following:

- The meeting must be held at a reasonable time and in a manner or place **reasonably accessible to the public**, including **facilities that are readily accessible** to and usable by persons with disabilities.

- The meeting room or other venue must be large enough to accommodate FAC members, agency staff members, and a reasonable number of interested members of the public.

- Any member of the public may be permitted to file a written statement with the FAC.

- Any member of the public may speak to or otherwise address the FAC within limits established in advance by the committee.

- FAC meetings conducted in whole or part by teleconference, video conference, the Internet, or other electronic medium also must meet the above requirements.

FAC meetings must be announced at least 15 days prior through a notice published in the *Federal Register*. The *Federal Register* notice must include the name of the FAC; the time, date, and location of the meeting; a statement as to whether the meeting will be open to the public or closed (if closed, the reasons must be cited); and the contact information for the agency official responsible for the meeting.

The FACA requires that detailed minutes of each open meeting be kept and that they must include the names of the persons present; an accurate description of matters discussed and conclusions reached; copies of all reports received, issued, or approved by the FAC; and

certification by the FAC chair as to the accuracy of the minutes. The FACA also requires that a summary of each closed or partially closed FAC meeting be kept, including a summary of its activities that would be informative to the public.

Reports on Federal Advisory Committee Functions

Throughout the year, NIH contributes to the *Annual Comprehensive Review of Federal Advisory Committees* (https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/advice-and-guidance/the-federal-advisory-committee-act-faca-annual-comprehensive-review), which provides the public with detailed information about every FAC in the executive branch of the U.S. Government.

Transparency in the Policymaking Process

As described above, NIH often uses FACs to provide guidance on issues that NIH is weighing when developing sound, credible, scientific policies. When a FAC provides recommendations to NIH, these are taken under advisement and often are developed into a proposed policy for public review. These public policies are generally advertised broadly in accordance with the APA, which provides the framework for how Federal Government agencies communicate proposed policy matters to members of the public.

V. CONCLUDING STATEMENT

As the Nation's largest single funder of biomedical research and as a research institution employing over 5,000 investigators, it is of vital importance that the public trusts the research being funded and conducted by NIH. As shown throughout this document, NIH has extensive policies and procedures in place to help ensure that the highest degree of scientific integrity is maintained in the research that NIH funds and conducts. NIH consistently seeks innovative ways to further foster scientific integrity in everything it does. NIH has an unwavering commitment to scientific integrity, transparency, and public accountability that serves at the core of its mission.

We welcome any comments, suggestions, or concerns the public may have regarding the ways NIH seeks to ensure scientific integrity in the research it funds and conducts. A list of NIH contacts is provided below.

VI. CONTACT US

NIH staff members are always available to answer any questions the public may have regarding the research that NIH funds and conducts. Please find the appropriate contact information below for any questions or comments you may have.

For questions regarding this document or general questions regarding scientific integrity programs at NIH, please contact the NIH Office of Science Policy at SciencePolicy@mail.nih.gov or visit our Web site at www.osp.od.nih.gov.

For specific questions on programmatic issues, please contact the appropriate NIH entity:

General NIH Information nihinfo@od.nih.gov

NIH Office of Extramural Research http://grants.nih.gov/grants/oer.htm

grantsinfo@od.nih.gov

NIH Office of Intramural Research http://irp.nih.gov

IRPinfo@mail.nih.gov

NIH Office of Communications & Public Liaison http://www.nih.gov/icd/od/ocpl/index.html

olib@od.nih.gov

NIH Office of Federal Advisory Committee Policy http://ofacp.od.nih.gov/

spaethj@od.nih.gov

NIH Office of Management Assessment http://oma.od.nih.gov/

omainfo@mail.nih.gov

NIH Office of Acquisition and Logistics Management http://oalm.od.nih.gov/

Center for Cooperative Resolution/ NIH Office of the Ombudsman ombudsman.nih.gov

NIH Ethics Office http://ethics.od.nih.gov/