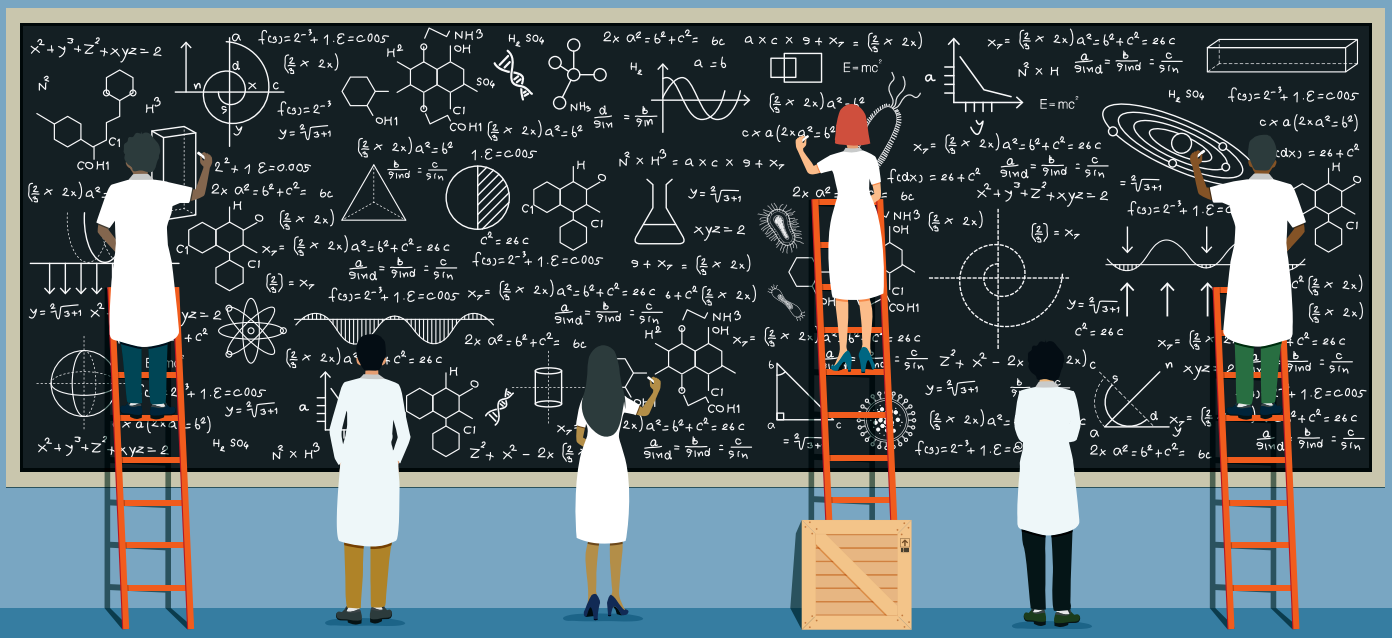

A QUICK GUIDE TO THE SCIENTIFIC INTEGRITY POLICY AT THE

National Institutes of Health (NIH)

Brought to you by
the Climate Science
Legal Defense Fund

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1 INTRODUCTION

A Quick Guide to the NIH Scientific Integrity Policy

Scientific integrity principles are indispensable to the missions and the functions of federal scientific agencies in the United States. Conducting sound and unbiased scientific research is essential to maintaining public trust in these agencies. For scientists employed at these agencies, understanding these principles—both how to abide by them, and what to do if they are violated—is a core job function.

Many scientific agencies adopted scientific integrity policies following a 2009 memorandum issued by President Obama, and a subsequent memorandum issued in 2010 by the White House Office of Science and Technology Policy. These policies clarify how individual agencies interpret scientific integrity. In many cases, a policy also describes how a scientist should report a loss of scientific integrity, how the agency will investigate such claims, and the rights of both a complainant and a person alleged to have committed a violation.

This guide examines the National Institutes of Health (NIH) scientific integrity policy. The guide is designed to help scientists working for or funded by NIH understand how the policy applies to them, what rights they have under the policy, and how they can avail themselves of these.

The NIH policy would be stronger if it provided more details and guidance for agency scientists. But it is still crucial for NIH scientists to know their rights and responsibilities concerning scientific integrity, and the policy's strengths and weaknesses.

While this guide helps NIH scientists understand the agency's scientific integrity policy, it is not a substitute for legal advice regarding a particular situation. The Climate Science Legal Defense Fund offers free, confidential consultations to scientists with questions about scientific integrity.

Contact us at
(646) 801-0853

Or send an email to
lawyer@csldf.org

2 SUMMARY

The National Institutes of Health Policies and Procedures for Promoting Scientific Integrity (referred to as the policy and SIP in this guide) has notable strengths. NIH funds external research and conducts research, and the policy is separated into two sections, so it is clear which provisions apply to which type of research.

NIH developed the policy so the public understands how the agency addresses scientific integrity. It focuses on disseminating NIH research and has detailed provisions to ensure that research findings are easily accessible to the public. It uses clear language, and serves a secondary purpose of bringing together all NIH policies without being overwhelming or confusing.

For internal or intramural research, the policy works with Guidelines and Policies for the Conduct of Research in the Intramural Research Program at the NIH (referred to in this guide as the guidelines).

For external or extramural research funded by NIH, the policy stands alone and does not work with another NIH set of guidelines.

The policy also has weaknesses. Sections are not numbered or sequentially labeled, making it difficult to navigate. The policy fails to define scientific integrity or describe procedures for investigating allegations of scientific integrity violations. While the policy links to a detailed, well-organized manual for investigating claims of research misconduct, it is unclear what would happen if there's a scientific integrity violation at the NIH that doesn't constitute research misconduct.

3 WHAT DOES THE POLICY GOVERN?

Research Misconduct

Extramural research. The policy defines research misconduct as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or reporting research results (defined in 42 CFR, Part 93). Research misconduct does not include honest errors or differences of opinion. According to the policy, the NIH and institutions that receive NIH funding must have policies and procedures for addressing research misconduct allegations.

The policy states that all NIH extramural staff members should receive biannual training on handling allegations of research misconduct properly.

Intramural research. The guidelines have the same definitions and information (guidelines, page 14).

Conflicts of Interest

Extramural research. NIH requires institutions that apply for or that receive funding under grants or cooperative agreements to address financial conflicts of interest under the requirements of 42 CFR, Part 50, Subpart F, Promoting Objectivity in Research.

The policy links to the regulation and provides a brief overview of what it contains. The regulation says that research design, conduct, and reporting should be free from bias involving an investigator's financial conflicts of interest. NIH defines an investigator as the project director, principal investigator, or any other person, regardless of title or position, responsible for the design, conduct, or reporting of research (SIP, page 7). The policy includes a link to the NIH Office of Extramural Research Financial Conflict of Interest website.

Intramural research. Intramural scientists are subject to the Standards of Ethical Conduct for Employees of the Executive Branch. NIH scientists are also 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 NIH institute or center has dedicated ethics officials to help scientists understand and comply with the ethics rules; the policy links to a list of these officials' names and contact information.

Political Interference

The policy does not address political interference.

Threats and Intimidation

The policy does not address threats, intimidation, or other forms of interference with research as violations of scientific integrity.

Use of Science in Agency Decision-Making

In addition to being a research institution and funder, NIH is a policymaking agency that develops policies around science management and safety, and future scientific inquiry directions. Policy issues fall under 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.

The policy contains an overview of the OSP's mission and its role serving diverse stakeholders, including the national and international scientific communities, patients, other federal agencies, and the public. The policy links to the OSP website, which has detailed information about the office and the programs it administers to promote sound policymaking (SIP, page 21).

Science Communication

Science communication is a cornerstone of the NIH policy. For both extramural and intramural research, the NIH Public Access Policy ensures the public has access to the published results of research funded and conducted by NIH.

The policy requires scientists to submit their final, peer-reviewed journal manuscripts resulting from NIH-funded or conducted research to a digital archive once a manuscript is accepted for publication. Papers must be made available to the public through the archive no later than 12 months after publication.

The NIH Office of Communications & Public Liaison (OCPL) makes the public aware of extramural and intramural research findings. The NIH information program includes ClinicalTrials.gov, a federal repository of data on research sponsored by NIH and other entities.

The policy states that the OCPL offers various mechanisms for direct public contact, and it recognizes the need for immediate, reliable responses to public inquiries (SIP, pages 9-10 and 16-17).

Timeliness: The results of extramural and intramural NIH research must be submitted to the NIH digital archive upon publication. The archive must make these papers available to the public within 12 months of their publication.

Press: The NIH policy has clear guidance for communicating with the media about intramural research: "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" (SIP, page 18).

Social media: The policy does not specifically address social media. It links to the digital communications page of the Department of Health and Human Services (HHS), NIH's parent agency, which contains a link to the HHS Social Media Policies web page.

Testifying before Congress: The policy doesn't refer to testifying before Congress, but Congress is referenced as one of the potential audiences for NIH communications. Federal law also protects the right to testify before Congress.

Right of scientists to review and/or correct agency communications: The NIH policy does not address whether scientists have the right to review agency communications that rely on their work or attribute them as authors or correct inaccuracies in agency communications.

Publishing and lecturing: The intramural research section says scholarly writing, lecturing, editing, and publishing are essential parts of research and professional development at NIH; the policy has a section titled Publication of Research Findings (SIP, page 15).

NIH has policies and procedures for the review, approval, and distribution of scientific, technical, and other professional information by individual employees, including intramural and extramural researchers and Office of the Director staff. Guidance is available for written, electronic, or oral presentations to ensure that NIH employees disseminate high-quality information.

Scientific and professional information presented by NIH employees is considered differently from the information presented in other professional settings, such as when scientists from universities or industry laboratories

speak in public forums. A clear distinction must be made between the presentation of scientific data and opinions that could be construed as an NIH position. The policy links to several additional webpages with guidance on the publication process (SIP, pages 16 and 17).

Scientific Societies: The policy does not mention scientific societies.

Opinion statements: In the intramural research section, the policy states that requirements may apply for certain types of communication with the press. These include communications related to official activities for NIH employees and disclaimers scientists should use when they are not speaking in an official capacity (SIP, page 18).

Hiring Practices

The policy emphasizes the hiring practices for intramural scientists to ensure that high productivity, equal opportunity, integrity, and safety standards are met (SIP, pages 11 and 12). The policy does not state that qualifications and expertise are the basis for hiring for scientific positions, but it links to the hiring guidelines in the Intramural Research Sourcebook, which has links to detailed criteria for hiring at NIH.

Federal Advisory Committees

According to the policy, NIH often seeks the assistance of Federal Advisory Committees (FACs) to guide policy discussions and engage key stakeholders with different perspectives on a proposed policy's impact. NIH currently maintains over 150 FACs; the FAC section of the policy (SIP, page 22) has an analysis of the use of these committees and guidelines for selecting FAC members and meetings. The NIH has an Office of Federal Advisory Committee Policy (OFACP), and the policy links to the OFACP website.

Human and Animal Research Subject Protections

The policy references animal and human research subject protection for both extramural and intramural research. For extramural research, the Office of Extramural Research maintains the Office of Laboratory Animal Welfare.

The intramural research section of the policy does not mention animal subject protections. But the section on research ethics links to Guidelines and Policies for the Conduct of Research in the Intramural Research Program at NIH, which discusses animal subject welfare.

The extramural research section references Human Subjects Protections (SIP, page 6). It states that both extramural and intramural research are subject to the HHS Office for Human Research Protections, which is responsible for applying 45 CFR, Part 46, Protections of Human Subjects.

For intramural research, the Guidelines and Policies for the Conduct of Research in the Intramural Research Program at NIH also describes human subject protections.

Whistleblower Protections

In the intramural research section, the policy defines the term whistleblower and explains how the concept

works in a scientific organization. The policy states that the federal government has enacted provisions to protect whistleblowers from retaliation.

The NIH Office of the Ombudsman Center for Cooperative Resolution can assist whistleblowers and provide a haven for scientists who might otherwise not report their concerns. This office allows NIH scientists and scientific personnel to speak with the NIH Ombudsman without fear of having their identities disclosed, and enables NIH ombudsmen to relay information between whistleblowers and those in authority. The ombudsman office's flexible nature allows whistleblowers more control over the process (SIP, page 12). The policy does not provide a link to the office or its contact information.

4 WHO DOES THE POLICY GOVERN?

The policy applies to NIH's Extramural Research Program, which constitutes nearly 80 percent of NIH's budget and funds more than 300,000 research personnel at more than 3,000 universities and research institutions. It also applies to research conducted by NIH scientists in its Intramural Research Program, which has more than 5,000 scientists working at 27 Institutes and Centers.

According to the policy, "[e]nsuring the integrity of science and science-based policymaking is at the heart of everything NIH does in fulfilling its mission" (SIP, page 2). However, the policy doesn't say what roles within its programs it applies to.

5 WHAT IS THE PROCESS FOR FILING A COMPLAINT?

This guide is not a substitute for legal advice about a specific situation. If you are considering filing a scientific integrity complaint, or are the subject of a complaint, please contact the Climate Science Legal Defense Fund or another attorney for advice about your situation.

What follows is general information about what the process of filing a complaint may entail.

The NIH policy does not have information about the process of filing a loss of scientific integrity complaint. The policy only references the rules that pertain to claims of research misconduct, which are described in the NIH Intramural Research Program Policies & Procedures for Research Misconduct Proceedings. These rules do not address scientific integrity violations, so it is unclear how the rules might apply to a scientific integrity complaint.

We discuss the processes for filing and addressing research misconduct claims at NIH because they demonstrate how claims of scientific integrity violations might be handled. Claims of research misconduct are addressed differently for extramural and intramural research and are discussed separately.

Extramural Research Misconduct

According to the policy, research misconduct for extramural research is as follows:

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

Institutions that receive NIH funding must have written policies and procedures for addressing research misconduct allegations.

The NIH and the Office of Research Integrity (ORI) also have procedures to address allegations of research misconduct. NIH extramural staff members should receive biannual training on how to handle research misconduct allegations correctly (SIP, page 8).

An institution that receives NIH funding will typically address an allegation of research misconduct through its own procedures. NIH generally allows grantees to correct wrongdoing before taking action unless public health or welfare considerations require immediate action. NIH findings of research misconduct may result in special award conditions or enforcement actions, depending on the circumstances (SIP, page 8).

Intramural Research Misconduct

The NIH Intramural Research Program Policies & Procedures for Research Misconduct Proceedings (referred to as the manual in this guide) describes the procedures for addressing intramural research misconduct at NIH. The manual is based on the Public Health Service (PHS) Policies on Research Misconduct, 42 C.F.R. Part 93, also known as the PHS regulations. NIH is part of PHS, the division of HHS concerned with public health.

The ORI has responsibility for addressing research integrity and misconduct issues.

Who can make a claim under the policy?

The manual does not specify who can make a claim.

Where and how can a scientist make a claim?

According to the manual, allegations of research misconduct may be communicated by written or oral means to NIH or HHS officials, and scientists are encouraged to directly communicate claims to the Agency Intramural Research Integrity Officer (AIRIO) (Manual § VI. A).

What should a complaint contain?

The manual does not say what a complaint should contain. It suggests that, where possible, the allegation should be sufficiently documented and include information about relevant parties, witnesses, dates, locations, publications, and the subject of the research in question (Manual § VI. A).

Is there a deadline for filing a complaint?

The provisions do not specify how long a person making a complaint, known as the complainant, has to file it after learning of alleged research misconduct.

6 WHAT HAPPENS AFTER A COMPLAINT IS FILED?

Who investigates?

The AIRIO investigates allegations of violations of scientific integrity. Their investigation has three phases: assessment, inquiry, and investigation. Section IV of the manual has definitions and explanations of the role of the AIRIO and other officials involved in the complaint proceedings.

Assessment

Once a formal complaint is received, the AIRIO will review the allegations and decide whether to initiate a formal inquiry. At this stage, the AIRIO must determine whether the allegation is credible and specific, including whether potential evidence of research misconduct can be identified, falls within the jurisdiction of the manual and the PHS regulations, and is within the definition of research misconduct in the manual and PHS regulations.

The AIRIO must initiate an inquiry if these criteria are met. There is no timeframe for the inquiry; the manual says only that the assessment period should be brief (Manual § VI.B). If an inquiry isn't initiated, the matter is closed, and the AIRIO may notify the complainant to resolve any questions concerning the assessment.

Inquiry

If the AIRIO determines an inquiry is warranted, they will immediately initiate the inquiry process, which is described in Manual § VII. The purpose of the inquiry is to conduct a preliminary review of the evidence and determine whether the allegation has enough substance to warrant an investigation. The AIRIO must make an effort to notify the respondent in writing and, if possible, verbally explain the inquiry process and advise the respondent that he or she may retain legal counsel.

The AIRIO should appoint an inquiry committee with three voting members who are federal employees; they can be employees of a different federal agency. The AIRIO should provide the respondent the names of the inquiry committee members and give the respondent seven days to object to a proposed member. The AIRIO may prepare a written charge for the committee, which will meet as necessary to evaluate the complaint. The

inquiry should be completed within 60 calendar days of its initiation, defined as the date of the first meeting of the inquiry committee.

The inquiry committee and the AIRIO must prepare a written draft inquiry report (Manual § VIII). The report should be provided to the HHS Office of the General Counsel for legal review, and the office can make appropriate modifications. The AIRIO will notify the respondent of the inquiry committee's decision and include a copy of the draft report. The NIH may choose to provide the complainant with a copy of the inquiry report. The respondent and complainant have 14 days to comment on the report. Based on their comments, the inquiry committee may revise the draft report or add a written reply to the comments before preparing a final version.

The final inquiry report will be delivered to the AIRIO, who then sends the final report to the Deciding Official (DO); the DO will determine whether an investigation is warranted (note that the Deputy Director for Intramural Research is the DO for inquiries).

The AIRIO must provide the ORI with a copy of the DO's decision within 30 days of the decision to launch an investigation. If the DO decides an investigation is not warranted, they must notify the respondent, the complainant, and anyone else with knowledge of the proceedings. The respondent may ask the AIRIO to take steps to restore the respondent's reputation (the steps are described in Manual § XIII(B)).

Investigation

If the DO decides an investigation is warranted, it must begin within 30 calendar days (investigations are addressed in Manual § IX). The AIRIO must inform the ORI Director of the decision to start an investigation and give the ORI a copy of the inquiry report. The AIRIO must notify the respondent in writing of the allegations being investigated, including any new allegations not addressed in the inquiry.

The AIRIO will appoint an investigation committee consisting of five voting members who should be federal employees; they may be employees of a different federal agency. The AIRIO will notify the respondent of the investigation committee members' names and allow the respondent to object to a committee member within seven calendar days.

The AIRIO will prepare a charge to the committee containing details of the allegation and the investigation process (Manual § IX. D. describes what this charge should include). One member will serve as the committee chair.

The investigation committee and the AIRIO must examine the evidence, take steps to ensure an impartial investigation, and interview each known respondent and complainant. Interviews should be recorded and transcripts prepared and entered into the record of the proceedings.

For a finding of research misconduct, there must be a significant departure from the relevant research community's accepted practices, the misconduct must have been committed intentionally, and a preponderance of the evidence must prove the allegation.

The NIH has the burden of proof for research misconduct findings. The respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest errors or differences of opinion. The respondent also has the burden of proof regarding any mitigating factors that lead to a decision to impose administrative actions.

The investigation must be completed within 120 days of its initiation, or the date the investigation committee first meets. This timeframe includes preparing the draft investigation report, providing the draft report to the DO for comment, review, and a final decision, and sending the final decision to the ORI.

The DO for investigations is the NIH Agency Research Integrity Liaison Officer, who oversees the NIH's intramural and extramural research integrity programs.

The investigation committee and the AIRIO will prepare the written draft investigation report, which should include all relevant details (found in Manual § X). A draft of the report will be sent to the HHS Office of the General Counsel for legal review. The AIRIO must provide the respondent with a copy of the draft report; the respondent has 30 days to submit comments.

The AIRIO will help the investigation committee finalize the draft investigation report, including considering respondent and complainant comments, and send the final report to the DO.

Is the confidentiality of the parties protected?

A complainant may bring an allegation anonymously or request that their name be withheld; in some cases, an inquiry and investigation can't proceed without identifying the complainant. There is no provision for protecting the respondent's confidentiality, but the proceedings for examining research misconduct accusations are clear about who should be notified at various stages.

Do the parties have a right to a hearing?

While there is no right to a formal hearing, both parties must be interviewed at the investigation stage. The interviews should be recorded, transcribed, and entered into the proceeding record.

Do the parties have a right to respond to the findings of the investigation?

Both parties have the right to submit comments on the draft inquiry report. Comments are attached to the final report, which is used to determine whether an investigation is warranted. If an investigation takes place, the respondent must receive a copy of the draft investigation report and have the opportunity to submit written comments, which will be considered and included in the final report. The complainant may receive and comment on the portions of the draft investigation report that address their role in the investigation. Their comments will be considered and included in the final report.

7 WHAT HAPPENS AFTER THE INVESTIGATION ENDS?

Once the final investigation report is sent to the DO, that person will determine in writing whether the NIH accepts the investigation report, its recommended findings and actions, and the suggested actions to take in response to this finding. The DO may issue a different decision than the committee recommends and may return the report to the committee for further fact-finding.

When a final decision is reached, the AIRIO will notify both the respondent and the complainant (if known) in writing. The AIRIO must submit a copy of the report to the ORI within 120 days, along with a statement of whether NIH accepts the findings, a statement of whether NIH found research misconduct and who committed it, and a description of pending or completed administrative actions against the respondent.

Once NIH makes a research misconduct finding and notifies the ORI, NIH must notify other relevant people and groups about it. The manual has sample language to use when responding to press inquiries about research misconduct (Manual § X. D).

Admission

The respondent has the opportunity to admit that research misconduct happened and that he or she committed the research misconduct any time during the research misconduct proceeding. If this occurs, the DO may terminate the NIH review of the allegation if the ORI approves the NIH acceptance of the admission and any proposed settlement.

The ORI will typically prepare a Voluntary Settlement Agreement for review by the respondent. The NIH proceeding is terminated once the agreement is approved and signed by the respondent and HHS (Manual § IV. E).

If a scientific integrity is found to have been compromised, who decides what the resolution/ remedy should be?

If the investigation report recommends a finding of research misconduct, the investigation committee can suggest administrative actions NIH should take, including actions against the respondent. The DO will refer to appropriate the NIH officials to decide what, if any, administrative actions to take.

Do the parties have the right to appeal if initial decision is not in their favor?

The respondent may submit comments for inclusion with the final investigation report, but they do not have the right to appeal the decision.

What are the penalties for misconduct?

The manual lists potential administrative actions (Manual § XII). These include, but are not limited to:

- Retraction or correction of all pending or published abstracts and papers that resulted from the research
- Removal of the responsible person from the project
- Letter of reprimand
- Special monitoring of future work
- Probation
- Suspension
- Salary reduction
- Initiation of steps leading to possible rank reduction or termination of employment

8 ADDITIONAL RELEVANT POLICIES AND RESOURCES

NIH Office of Extramural Research Financial Conflict of Interest website

Standards of Ethical Conduct for Employees of the Executive Branch

NIH Public Access Policy

NIH Office of Extramural Research Financial Conflict of Interest website

NIH Office of Science Policy website

HHS digital communications page

Intramural Research Sourcebook

Office of the Federal Advisory Committee Policy website

Guidelines and Policies for the Conduct of Research in the Intramural Research Program at NIH

9 REPRESENTATIVE CASES AND OUTCOMES

NIH does not address violations of scientific integrity, but summaries of research misconduct claims by NIH scientists and grantees are available on the HHS Office of Research Integrity case summaries webpage. The following examples are from the webpage.

Falsifying data is considered research misconduct. A researcher who reused and relabeled data to support different findings and falsified data was found to have committed research misconduct. The respondent agreed to have her research supervised for three years, exclude herself from serving in an advisory capacity to PHS, and request the retraction of papers containing the falsified data.

Falsifying laboratory records is considered research misconduct. A researcher fabricated data regarding mice behavior and laboratory entry logs and reported the fabricated data to his laboratory supervisors. The respondent agreed that if he received or applied for PHS support within two years, he would have his research supervised for one year. He also agreed to exclude himself from serving in any advisory capacity to PHS including, but not limited to, service on a PHS advisory committee, board, or peer review committee, or as a consultant for one year.

Widespread instances of research misconduct result in debarment. A researcher who recklessly caused and permitted 23 cases of research misconduct in grant applications, research papers, and posters was debarred from contracting or subcontracting with any United States government agency five years. The researcher was prohibited from serving in an advisory capacity to PHS including, but not limited to, service on PHS advisory committees, board, or peer review committees, or as a consultant for five years.

The Climate Science Legal Defense Fund produced this guide to help scientists understand their rights under federal agency scientific integrity policies. This guide concerns only U.S. laws, and nothing in it should be construed as legal advice for your individual situation.

CSLDF provides free counsel to scientists with legal questions pertaining to their work. Contact us at **(646) 801-0853** or email **lawyer@csldf.org** to arrange a free and confidential consultation with an attorney.

The Climate Science Legal Defense Fund (CSLDF) works to protect the scientific endeavor by helping defend climate scientists against politically and ideologically motivated attacks. CSLDF is a non-profit organization under section 501(c)(3) of the Internal Revenue Code.

This guide was made possible by the generous support of the Common Sense Fund, the Energy Foundation, the David and Lucile Packard Foundation, and CSLDF donors.

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