

NIH Policy Manual

3006 - NIH Intramural Research Program (IRP) Research Misconduct Proceedings

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Transmittal Notice

1. Explanation of Material Transmitted: This revised chapter incorporates by reference as Appendix 1 the current edition of the *NIH Intramural Research Program Policies & Procedures for Research Misconduct Proceedings* (hereinafter “IRP RM Policy”). This chapter’s former title and content have been updated to ensure consistency with the current policies and procedures set forth in the IRP RM Policy.

2. Filing Instructions:

- Remove: 3006 – Policies and Procedures Relating to Possible Scientific Misconduct in the IRP at NIH, dated 02/15/1991
- Insert: 3006 – NIH IRP Research Misconduct Proceedings, dated 12/28/2021

3. PLEASE NOTE:

- For inquiries regarding the content of this chapter contact the Agency Intramural Research Integrity Officer (AIRIO), Office of Intramural Research (OIR), Office of the Director, NIH: AIRIO@nih.gov or 301-451-7764. Additional information on the handling of research misconduct allegations in the intramural research program (IRP) is located at the following URL: <https://oir.nih.gov/sourcebook/ethical-conduct/research-misconduct>
- For inquiries regarding the NIH Policy Manual contact the Management Operations Branch (MOB), Division of Compliance Management (DCM), Office of Management Assessment (OMA) at 301-496-4606, or navigate to the following URL: <https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx>.

A. Purpose

This manual chapter states the policies and references the procedures that will apply when research misconduct is alleged or suspected in the Intramural Research Program at the National Institutes of Health (NIH), U.S. Department of Health and Human Services (HHS).

B. Scope

Consistent with the NIH's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, [42 C.F.R. Part 93 \(the PHS Regulations\)](#), this chapter applies to alleged or actual research misconduct involving biomedical or behavioral research, research training, or activities that are related to research or research training, such as the operation of tissue and data banks and the dissemination of research information

1. carried out in NIH facilities by any person,
2. funded by the NIH IRP in any location, or
3. undertaken by NIH staff as part of official NIH duties or NIH training activities, regardless of location.

This chapter does not apply to authorship or collaboration disputes. It applies only to research misconduct that occurred within six years prior to the date the NIH or HHS receives the allegation, subject to the exceptions discussed in the PHS Regulations. To review NIH's policy for reporting allegations of criminal offenses, misuse of NIH grant or contract funds, or improper conduct by an NIH employee, please refer to Manual Chapter 1754. *Reporting Allegations of Criminal Offenses, Misuse of NIH Grant and Contract Funds, or Improper Conduct by an NIH Employee*.

C. Background

The research community and the community 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 the NIH. The process of reviewing allegations must be balanced by equal concern for protecting the integrity of the research as well as the careers and reputations of researchers. The NIH's responsibilities under the PHS Regulations are detailed in the [IRP RM Policy](#), included as Appendix 1 in this Policy Manual. All NIH staff are expected to report observed, apparent, or suspected research misconduct to the Agency Intramural Research Integrity Officer (AIRIO) and will cooperate with research misconduct proceedings.

D. Policy

This chapter and [IRP RM Policy](#) (found in Appendix 1) are intended to enable allegations of research misconduct to be processed fairly, confidentially, and promptly. Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. A finding of research misconduct by

NIH under the PHS Regulations and the IRP RM Policy requires that:

- a. there be a significant departure from accepted practices of the relevant research community;
- b. the misconduct be committed intentionally, knowingly, or recklessly; and
- c. the allegation be proven by a preponderance of the evidence.

E. Responsibilities

1. The Agency Research Integrity Liaison Officer (ARILO) oversees and coordinates the NIH's activities and policies related to research integrity in both intramural and extramural research supported by the NIH, and represents the NIH on matters of research integrity policy. The ARILO also serves as the Deciding Official for Investigations and findings of research misconduct. The NIH Principal Deputy Director for NIH currently serves as the ARILO.
2. The Deputy Director for Intramural Research (DDIR) is the Deciding Official for Inquiries.
3. The NIH Agency Intramural Research Integrity Officer (AIRIO) oversees and coordinates the NIH's activities and policies related to research integrity in the NIH IRP. As described in more detail in the [IRP RM Policy](#) (Appendix 1), the AIRIO assesses allegations of research misconduct, oversees Inquiries and Investigations, and is responsible for ensuring that the NIH complies with all [HHS Office of Research Integrity \(ORI\)](#) notice and reporting requirements. The AIRIO also has lead responsibility for ensuring that the NIH takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, research training, and related activities, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.
4. The NIH Institute, Center, or Office (ICO) Director assists the AIRIO and others, as needed, in the NIH research misconduct proceeding. At the close of the NIH proceeding, they assist with the implementation of administrative actions, if any, as directed by the Deciding Official or other appropriate NIH official.
5. NIH Institute, Center, and Office (ICO) Scientific Directors (SDs) and Deputy SDs, and other NIH officials as needed, are informed of the NIH research misconduct proceeding and may notify other NIH staff on an as needed basis to effectively manage agency resources and protect agency programs, consistent with applicable confidentiality requirements. Additional duties are described in the [IRP RM Policy](#).
6. NIH Staff are expected to report observed, apparent, or suspected research misconduct. NIH staff will cooperate with the AIRIO and other NIH officials in NIH research misconduct proceedings, including the review of allegations and the conduct of Inquiries and Investigations. NIH staff have an obligation to provide evidence relevant to research misconduct allegations to the AIRIO or other NIH officials. NIH staff who are responsible for research misconduct records must handle them in accordance with NIH Privacy Act System of Records Notice 09-25-0223.

F. Procedures

1. Procedures for NIH IRP research misconduct proceedings are set forth in detail in the [IRP RM Policy](#) (Appendix 1).
2. Allegations of research misconduct may be communicated through any means (*e.g.*, by written or oral statement) to an NIH or HHS official. Individuals who are uncertain whether they have evidence of, or have observed, research misconduct may discuss their concerns with, or seek advice from, individuals they trust, including the NIH Ombudsman, before bringing a formal complaint. The NIH encourages allegations to be communicated directly to the NIH Agency Intramural Research Integrity Officer (AIRIO), Office of Intramural Research, Office of the Director, NIH (AIRIO@nih.gov; 301-827-7745). Allegations of fraud, abuse, waste and misconduct can be made through the [Division of Program Integrity](#).
3. Confidentiality must be maintained in accordance with the PHS Regulations and the [IRP RM Policy](#).
 - a. Disclosure of the identity of Respondents and Complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and with implementation of its findings, as allowed by law. However, the NIH must disclose the identity of Respondents and Complainants to the [HHS Office of Research Integrity \(ORI\)](#) pursuant to an ORI review of research misconduct proceedings under the PHS Regulations.
 - b. Confidentiality must be maintained for any records or evidence from which research subjects might be identified, except as may otherwise be prescribed by applicable law. Disclosure is limited to those who have a need to know to carry out a research misconduct proceeding, or to implementing its findings. The disclosure of the identity of Inquiry or Investigation committee members and Inquiry or Investigation witnesses should be limited, to the extent possible, to those who need to know.
4. Following receipt of an allegation of research misconduct, the following procedures are initiated:
 - a. Assessment: The AIRIO will immediately assess the allegation to determine whether the allegation is:
 - I. sufficiently credible and specific so that potential evidence of research misconduct may be identified;
 - II. within the jurisdictional criteria of the PHS Regulations and the IRP RM Policy; and
 - III. within the definition of research misconduct in the PHS Regulations and the IRP RM Policy. If these criteria are met, an Inquiry is warranted.

- b. Inquiry: An Inquiry is the process of gathering information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an Investigation. The AIRIO will take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence (i.e., prepare a record of the proceeding), and sequester them in a secure manner. Under the PHS Regulations and the IRP RM Policy, an Investigation is warranted if the following criteria are met:
- I. there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of the PHS Regulations and the IRP RM Policy; and
 - II. the allegation may have substance, based on the preliminary information-gathering and preliminary fact-finding conducted by the Inquiry Committee.
- c. Investigation: An Investigation is the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct, which may include a recommendation for other appropriate actions, including administrative actions. In order to determine that a Respondent committed research misconduct, an Investigation Committee must find that a preponderance of the evidence established that:
- I. research misconduct, as defined in the IRP RM Policy, occurred;
 - II. the research misconduct is a significant departure from accepted practices of the relevant research community; and
 - III. the Respondent committed the research misconduct intentionally, knowingly, or recklessly.
- d. Decision by Deciding Official: Upon completion of an Investigation, the final Investigation Report is transmitted to the NIH Agency Research Integrity Liaison Officer (ARILO), who is the Deciding Official (DO) for Investigations. After a final decision has been reached, the AIRIO will notify the Respondent, Complainant, appropriate NIH officials, and the HHS Office of Research Integrity (ORI) in accordance with the PHS Regulations and the IRP RM Policy.
- e. Records Retention and Disposal: All records pertaining to this chapter must be retained and disposed of under the authority of [NIH Manual 1743, "Managing Federal Records," Appendix 4, Records Management Resources](#). These records must be maintained in accordance with current NIH Records Management and Federal guidelines. Contact your NIH Institute, Center, or Office (ICO) Records Liaison or the [NIH Records Officer](#) for additional information. As directed in NARA/OMB/NARA Memorandum ([M-19-21, Transition to Electronic Records](#)), to the greatest extent possible, all Federal records are created, retained, and managed in electronic formats, with the appropriate metadata tags, Integrity (ORI) in accordance with the HHS Regulations and the NIH RM Policy.

G. References

1. [NIH Policy Manual, Chapter 1743, Managing Federal Records,](#)
2. [NIH Policy Manual, Chapter 1754, Reporting Allegations of Criminal Offenses, Misuse of NIH Grant and Contract Funds, or Improper Conduct by an NIH Employee](#)
3. [NIH Intramural Research Program Policies & Procedures for Research Misconduct Proceedings](#)
4. [Public Health Service Policies on Research Misconduct, 42 CFR Part 93](#)
5. [Privacy Act of 1974, as amended, 5 U.S.C. 552a](#)
6. [NIH Privacy Act System of Records Notice 09–25–0223, NIH Records Related to Research Misconduct Proceedings, HHS/NIH \(77 Fed. Reg. 52043 \(Aug. 28, 2012\)\).](#)

H. Definitions

1. **Allegation** – A disclosure of possible research misconduct through any means of communication (*e.g.*, by written or oral statement) to an NIH or HHS official. In accordance with this Policy, allegations should be communicated to the AIRIO.
 - a. **Good Faith Allegation** – An allegation made by an individual having a belief in the truth of the allegation that a reasonable person in the individual’s position could have, based on the information known to the individual at the time.
 - b. **Bad Faith Allegation** – An allegation made by an individual with knowing or reckless disregard for information that would negate the allegation.
2. **Complainant** – A person who in good faith makes an allegation of research misconduct.
3. **Intentionally** – Purposefully acts to propose, perform, review research, or report research results that includes falsified, fabricated or plagiarized materials.
4. **Investigation** – The formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct, which may include a recommendation for other appropriate actions, including administrative actions. An Investigation must meet the criteria and follow the procedures of the PHS Regulations.
5. **Knowingly** – Uses falsified, fabricated, or plagiarized material to propose, perform, review research, or report research results knowing that the material has been falsified, fabricated or plagiarized.
6. **NIH staff** – NIH employees, as well as guest researchers, special government employees (SGEs), trainees, volunteers, former employees, contractors, and other persons engaged to perform a service in support of NIH.
7. **ORI** – The Office of Research Integrity – The office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS-supported activities.
8. **PHS Regulations** – The Public Health Service (PHS) Policies on Research Misconduct, 42 C.F.R. Part 93.

9. **Preponderance of the evidence** – Proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.
10. **Recklessly** - Uses falsified, fabricated or plagiarized materials to propose, perform, review research, or report research results without exercising the proper care or caution, and disregarding or showing indifference to the risk that the materials were falsified, fabricated or plagiarized.
11. **Research** – A systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.
12. **Research misconduct** – Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Specifically:
- a. **Fabrication** is making up data or results and recording or reporting them;
 - b. **Falsification** is 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;
 - c. **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit;
 - d. Research misconduct does not include honest error or differences of opinion.

A finding of research misconduct made under this Policy requires that: (a) there be a significant departure from accepted practices of the relevant research community; and (b) the misconduct be committed intentionally, knowingly, or recklessly; and (c) the allegation be proven by a preponderance of the evidence.

13. **Research record** – The record of data or results, both physical and electronic, that embody the facts resulting from scientific inquiry, including but not limited to, e-mails, research proposals, laboratory records, progress reports, abstracts, theses, oral and poster presentations, internal reports, journal articles, and any additional documents and materials obtained during the research misconduct proceeding.
14. **Respondent** – The person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding. There can be more than one Respondent in an Inquiry or Investigation.
15. **System of Records Notice** - An official public notice of an organization's system(s) of records, as required by the Privacy Act of 1974, that identifies: (i) the purpose for the system of records; (ii) the individuals covered by information in the system of records; (iii) the categories of records maintained about individuals; and (iv) the ways in which the information is shared.

Appendix 1

NIH Intramural Research Program Policies & Procedures for Research Misconduct Proceedings, available at the following URL:

https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/policy-nih_irp_research_misconduct_proceedings.pdf