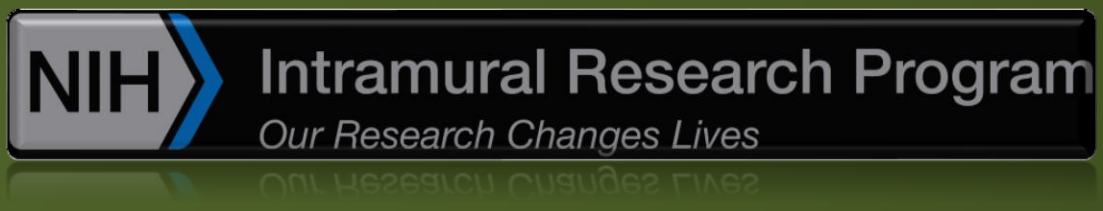
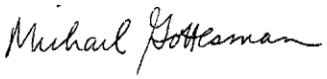


A Guide to the

HANDLING OF RESEARCH MISCONDUCT ALLEGATIONS

Preface

The research we do in the NIH intramural research program (IRP) leads to important discoveries that sustain and improve human health. Public trust in our research could be diminished if its integrity is questioned. The IRP has robust policies and practices that guide how we examine research results that are suspected to be contaminated with data falsification, fabrication, or plagiarism. A peer process is used for performing inquiries and investigations of possible research misconduct, and this process delves deeply into the questioned research and the research record, in order to verify that the research has integrity, while also ensuring confidentiality, fairness, and prompt attention. All researchers in the IRP should know about the research misconduct process, should stand ready to report suspect data, and should assist with an investigation if asked to. Mentors and supervisors are encouraged to ensure that laboratory personnel are appropriately trained on the responsible conduct of research, and that personnel know where to seek help when they have questions about the integrity of the laboratory's research results. This Guide provides information on what constitutes research misconduct, whom to contact with concerns, and how the process of investigation unfolds. This Guide was prepared to assist in responsible conduct of research training, because the IRP is committed to protecting the integrity of our research and maintaining public trust in the research results.



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The research community and the community at large expect intellectual honesty in the formulation, conduct, and reporting of scientific research. Allegations of research misconduct are taken seriously by the National Institutes of Health (NIH) Intramural Research Program (IRP). 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. These Guidelines summarize relevant provisions from the NIH IRP Policies & Procedures for Research Misconduct Proceedings (referred to as the "Policy"). The Policy is intended to enable allegations of research misconduct to be processed fairly, confidentially, and promptly. The Policy 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 Intramural Research Program (IRP) in any location; or

3. undertaken by NIH staff as part of official NIH duties or NIH training activities, regardless of location.

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Specifically:

1. **Fabrication** is making up data or results and recording or reporting them;

2. **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;

3. **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research misconduct does not include honest error or differences of opinion. A finding of research misconduct made under the PHS Regulations and the 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.

All NIH staff are expected to report observed, apparent, or suspected research misconduct. **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 parties involved are known as the **Respondent** (the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding), the **Complainant** (the person who in good faith makes an allegation of research misconduct), the NIH

Agency Intramural Research Integrity Officer (AIRIO; the NIH official responsible for assessing allegations of research misconduct and overseeing Inquiries and Investigations), and the **Deciding Official** (DO; the NIH Deputy Director for Intramural Research is the DO for Inquiries and the NIH Principal Deputy Director is the DO for Investigations).

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.

Upon receiving an allegation of research misconduct, the AIRIO will immediately assess the allegation to determine whether the allegation is:

1. sufficiently credible and specific so that potential evidence of research misconduct may be identified;

2. within the jurisdictional criteria of the PHS Regulations and the Policy;

3. within the definition of research misconduct in the PHS Regulations and the Policy.

If these criteria are met, an **Inquiry** proceeding is warranted. The purpose of the Inquiry is to conduct an initial review of the available evidence to determine whether to conduct an Investigation. It is not for the purpose of reaching a final conclusion as to whether research misconduct has, or has not, occurred.

The Inquiry Committee usually interviews the Respondent, the Complainant, if known, and key witnesses as needed, as well as examines relevant research records and materials. The Inquiry Committee will evaluate the evidence, including testimony obtained during the Inquiry. After consultation with the AIRIO and, if necessary, the Office of the General Counsel, the Committee will decide whether or not to recommend that an Investigation is warranted, because:

1. 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 Policy; and

2. The allegation may have substance, based on the preliminary information-gathering and preliminary fact-finding conducted by the Committee during the Inquiry.

The AIRIO will transmit the final Inquiry Report and any comments to the DO, who will determine whether an Investigation is warranted and document that decision in writing. The Inquiry is completed when the DO makes this determination.

If an **Investigation** is warranted, an Investigation Committee will develop a factual record by exploring the allegation(s) in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. An Investigation Committee and the AIRIO will:

1. use diligent efforts to ensure that the Investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations;

2. take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical;

3. interview each Respondent, each Complainant, if known, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation, including witnesses identified by the Respondent.

4. pursue diligently all significant issues and leads discovered that are determined relevant to the Investigation, including any evidence of additional instances of possible research misconduct, and continue the Investigation to completion.

The Investigation Committee must consider if (a) there was a significant departure from accepted practices of the relevant research community; and (b) the misconduct was committed intentionally, knowingly, or recklessly; and (c) the allegation was proven by a preponderance of the evidence. The Investigation is to be completed within 120 days of its initiation, including conducting the Investigation, preparing the report of recommended findings, providing the draft Report for comment, and review and final decision by the DO. The DO, who will determine in writing: (1) whether the NIH accepts the Investigation Report, its recommended findings, and any recommended NIH actions; and (2) the appropriate NIH actions to be taken, if any, in response to accepted findings of research misconduct.

If the DO determines that research misconduct is substantiated by the Investigation findings, he/she will decide what, if any, NIH **administrative actions** should be taken. The administrative actions must be consistent with applicable personnel rules and regulations and may include, for example:

1. **retraction or correction** of all pending or published abstracts and papers emanating from the research where research misconduct was found (though earlier corrective action may be appropriate for publications);

2. removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment; or

3. other action appropriate to the research misconduct.

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. **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 implement its findings.

If NIH makes a finding of misconduct at the conclusion of an NIH research misconduct proceeding, NIH may make a **disclosure** to research collaborators of the Respondent, professional journals, other publications, news media, professional societies, other individuals and entities, and the public. The disclosure may include information concerning the research misconduct finding and the need to correct or retract research results or reports that have been affected by research misconduct, unless NIH determines that release of the specific information in the context of a particular case would constitute a clearly unwarranted invasion of personal privacy.

At any time during the NIH research misconduct proceeding, the Respondent has the opportunity to **admit that research misconduct occurred** and that he/she committed the research misconduct. With the advice of the AIRIO and/or other NIH officials, the Deciding Official may terminate the NIH's review of an allegation that has been admitted, if the NIH's acceptance of the admission and any proposed settlement is approved by ORI.

The **Office of Research Integrity** (ORI) is the office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS-supported activities. The DO will send a final Investigation Report to ORI. Comprehensive descriptions of ORI's authority to review and respond to an allegation of research misconduct or a research misconduct proceeding and HHS' authority to take administrative action in response to a research misconduct proceeding and related matters are contained in the PHS Regulations. Additional information is also available on the ORI web site. Following a final finding of no research misconduct, including ORI concurrence where required by the PHS Regulations, the AIRIO must, at the request of the Respondent and as appropriate, undertake all reasonable and practical efforts to **restore the Respondent's reputation**.

The NIH IRP Policy is intended to enable allegations of research misconduct to be processed fairly, confidentially, and promptly. **Fairness** allows all of those who become involved in research misconduct proceedings 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 the allegations. A prompt response to an allegation helps to **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. Allegations of research misconduct that prove to be untrue, even if made in good faith, can damage careers and have a chilling effect on research. 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.

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