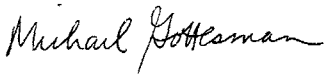
A Guide to the HANDLING OF RESEARCH MISCONDUCT ALLEGATIONS

National Institutes of Health
Office of the Director

Preface

Maintaining the highest ethical standards in the conduct of all research remains a goal of the entire scientific fellowship at the NIH. The American people and the international community of scientists demand no less. Any allegations of misconduct in research are addressed immediately, whether originating within or external to the NIH. The Public Health Service and the NIH developed guidelines for investigating allegations of research misconduct that ensure confidentiality, fairness, and prompt action to protect all parties in the proceedings. This Guide was prepared by the NIH Committee on Scientific Conduct and Ethics as a condensed aid for those with concerns about potentially questionable practices. It provides information on what constitutes research misconduct, whom to contact with concerns, and how the investigations process unfolds.



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January 2012

Overview

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 investigating allegations must be balanced by equal concern for protecting the integrity of the research as well as the careers and reputations of researchers.

This guide summarizes the *NIH Intramural Research Program (IRP) Policies & Procedures for Research Misconduct Proceedings* (Revised: 08/03/2010) (hereinafter "NIH Policy"). Because this guide is not intended to be comprehensive, the NIH Policy should be consulted regarding any questions concerning the handling of research misconduct allegations within the IRP. The NIH Policy is available at http://go.usa.gov/I9z

The NIH 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 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 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 they were 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.

Prepared by the NIH Committee on Scientific Conduct and Ethics

What is the scope of the NIH Policy?

The NIH Policy applies to alleged or actual research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) involving research:

1. carried out in NIH facilities by any person;
2. funded by the NIH IRP in any location; or
3. undertaken by an NIH employee or trainee as part of his or her official NIH duties or NIH training activities, regardless of location.

A person who, at the time of the alleged or actual research misconduct, was employed by, was an agent of, or was affiliated by contract, agreement, or other arrangement with NIH, is subject to the NIH Policy if, for example, he or she is involved in:

1. NIH- or Public Health Service (PHS)-supported biomedical or behavioral research;

2. NIH- or PHS-supported biomedical or behavioral research training programs;

3. NIH- or PHS-supported activities that are related to biomedical or behavioral research or research training, such as the operation of tissue and data banks and the dissemination of research information;

4. plagiarism of research records produced in the course of NIH- or PHS-supported research, research training or activities related to that research or research training; or

5. an application or proposal for NIH or PHS support for biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information (regardless of whether it is approved or funded).

The NIH Policy 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 the U.S. Department of Health and Human Services (HHS) receives the allegation, subject to the exceptions discussed in the PHS Regulations, 42 C.F.R. Part 93.

Allegations of research misconduct are handled through a three-stage process: Assessment of the allegations, Inquiry, and Investigation.

Allegation Assessment

The review of an allegation of research misconduct to determine whether an Inquiry is warranted.

What is the process?

Allegations of research misconduct may be communicated through any means 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 AIRIO (see the "Definitions" section below for contact information).

Where possible, the allegation should be provided, or subsequently documented, in sufficient detail to enable the NIH to assess it appropriately. This may include details such as relevant parties, witnesses, dates, locations, publications, and the subject matter of the research in question.

A person who makes an allegation of research misconduct may do so anonymously, or otherwise request that his/her name be withheld; however, in some cases, an Inquiry or Investigation may not be able to proceed without identifying and/or obtaining further information from the person who made the allegation (i.e., the Complainant).

If a person is unsure whether a suspected incident falls within the definition of research misconduct, he/she may contact or meet with the AIRIO to discuss the suspected research misconduct informally and confidentially, which may be presented as a hypothetical situation and/or anonymously. If the circumstances described by the individual do not meet the definition of research misconduct, the AIRIO

may refer the individual or allegation to other offices or officials with responsibility for resolving the problem. If the AIRIO concludes that the allegation meets the definition of research misconduct, he/she will proceed with an assessment.

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 NIH Policy;

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

If these criteria are met, an Inquiry is warranted. If no Inquiry is initiated, the matter shall be closed. If no Inquiry is initiated, the AIRIO may notify the Complainant, if known, and anyone else of whom the AIRIO is aware who has knowledge of the allegation, as appropriate, to resolve any questions that may exist concerning the status of the AIRIO's assessment.

Inquiry

The process of gathering information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an Investigation.

If the AIRIO determines that an Inquiry is warranted, he or she will immediately initiate the Inquiry process. 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.

At the time of, or before beginning, an Inquiry, the AIRIO will make a good faith effort to notify the Respondent in writing, if the Respondent is known. The AIRIO will attempt to provide to the Respondent a notification memo, signed by the AIRIO, which explains the nature of the allegation(s) of research misconduct, as well as a copy of the NIH Policy and/or related materials explaining NIH and PHS policies and procedures regarding research misconduct.

The AIRIO, in consultation with other NIH officials as appropriate, will appoint an Inquiry Committee, usually consisting of three voting members, as soon after the initiation of the Inquiry as is practical. The Inquiry Committee usually interviews the Respondent, the Complainant, if known, and key witnesses as well as examines relevant research records and materials. The scope of the Inquiry does not normally include conducting exhaustive interviews and analyses.

The Inquiry Committee and the AIRIO are responsible for preparing a written draft report for the Inquiry, which includes basis for recommending, or not recommending, that the allegations warrant an Investigation. An Investigation is warranted if the Committee determines: (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 NIH Policy; and (2) the allegation may have substance, based on the Committee's review 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.

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.

The purpose of the Investigation is to 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. The Investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations.

On or before the date on which the Investigation begins, the AIRIO must notify the Respondent in writing of the allegations to be investigated and provide the Respondent a copy of the Inquiry Report and a copy of, or reference to, the NIH Policy and the PHS Regulations. The AIRIO must also give the Respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the Inquiry or in the initial notice of the Investigation. If there is more than one Respondent, each should be notified separately.

The AIRIO, in consultation with other NIH officials as appropriate, will appoint an Investigation Committee, usually consisting of five voting members, as soon after the initiation of the Investigation as is practical.

The Investigation Committee and the AIRIO must:

- 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;

- take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical;
- 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; and
- 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 and the AIRIO are responsible for preparing a written draft report for the Investigation, which includes a statement of findings; i.e., for each separate allegation of research misconduct identified during the Investigation, includes a finding as to whether research misconduct did or did not occur. The AIRIO will assist the Investigation Committee in finalizing the draft Investigation Report, including ensuring that the Respondent's and Complainant's comments, if any, are included and considered, and transmit the final Investigation Report to the DO.

The DO will determine in writing: (1) whether the NIH accepts the Investigation Report, its 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. When a final decision has been reached, the AIRIO will notify both the Respondent and the Complainant, if known, in writing, as well as other parties, including ORI.[1]

[1]A description 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 are contained in the PHS Regulations, 42 C.F.R. Part 93. Additional information is also available on the ORI web site, http://ori.dhhs.gov/.

What are the roles of Complainants and Respondents?

The **Complainant** is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the research misconduct proceeding, including any Inquiry or Investigation.

During the Inquiry stage, the Complainant usually is interviewed and, when feasible, provided a copy of the transcript and an opportunity to correct errors in transcription. The NIH may choose to provide the Complainant the portions of the draft Inquiry Report that address the Complainant's role and statements in the Inquiry and give the Complainant an opportunity to submit comments.

During an Investigation, the Complainant is interviewed, if known, and subsequently provided a copy of the transcript and an opportunity to correct errors in transcription. The NIH may choose to provide the Complainant the portions of the draft Investigation Report that address the Complainant's role and statements in the Investigation and give the Complainant an opportunity to submit comments.

The Complainant may:

- consult with his/her own legal counsel or a non-lawyer personal adviser (who may not be a principal or witness in the case) and, subject to the AIRIO's prior approval, bring the counsel or personal adviser to interviews or meetings on the case. When a counsel or personal adviser is present at an Inquiry or Investigation Committee interview or meeting, his/her activities will be limited to advising the Complainant, as opposed to representing the Complainant before the Committee. The adviser or counsel should not direct questions to the Committee.
- request that an interpreter for him/her be present during an interview or meeting in the course of the research misconduct proceeding.

The **Respondent** is responsible for maintaining confidentiality and cooperating with the research misconduct proceeding, including any Inquiry or Investigation. The Respondent may:

- expect a good faith effort by the AIRIO to notify the Respondent of the allegation(s) in writing at the time of, or before beginning, an Inquiry and receive a copy of, or reference to, the NIH Policy and the PHS Regulations.
- have an opportunity, at both the Inquiry and Investigation stages, to object to a proposed committee member based upon a personal, professional, or financial conflict of interest. The Respondent must inform the AIRIO of any objections within seven (7) calendar days. The AIRIO will then determine whether a personal, professional, or financial conflict of interest exists that cannot be resolved and, as a result, necessitates replacement of the challenged committee member.
- be interviewed during the Inquiry and Investigation, be provided a transcript of each interview and an opportunity to correct errors in transcription, and have the transcript included in the record of the Inquiry and Investigation.
- consult with his/her own legal counsel or a non-lawyer personal adviser (who may not be a principal or witness in the case) and bring the counsel or personal adviser to interviews or meetings on the case. When a counsel or personal adviser is present before an Inquiry or Investigation Committee during an interview or meeting, his/her activities will be limited to advising the Respondent, as opposed to representing the Respondent before the Committee. The adviser or counsel should not direct questions to the Committee.
- consult with others who may assist Respondent in his/her defense, consistent with the responsibility to maintain confidentiality

within the bounds established under the PHS Regulations. Individuals who are consulted will be asked to sign a Confidentiality Statement provided by the AIRIO.

- request that an interpreter for him/her be present during an interview or meeting in the course of the research misconduct proceeding.
- have an opportunity to comment on the draft Inquiry Report and have his/her comments attached to the Report.
- be notified of the outcome of the Inquiry, and receive a copy of the final Inquiry Report.
- if there is to be an Investigation, be notified in writing of the allegations to be investigated within a reasonable time after the determination that an Investigation is warranted, but before the Investigation begins (which is to occur within 30 days after NIH decides to begin an Investigation), and be notified in writing of any new allegations, not addressed in the Inquiry or in the initial notice of Investigation, within a reasonable time after the determination to pursue those allegations.
- request that any witness who has been reasonably identified by the Respondent as having information on relevant aspects of the Investigation be interviewed during the Investigation, have the transcript provided to the witness for an opportunity to correct errors in transcription, and have the transcript included in the record of the Investigation.
- receive a copy of the draft Investigation Report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by the NIH and addressed in the final report.

- where no finding of research misconduct is made, request the AIRIO and other NIH officials to undertake, as appropriate, all reasonable and practical efforts to protect or restore the Respondent's reputation.

At any time during the 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.

Is the process confidential?

In accordance with the PHS Regulations, 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.

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.

Definitions

AIRIO – The NIH Agency Intramural Research Integrity Officer (AIRIO) is the NIH official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by the PHS Regulations, and warrant an Inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing Inquiries and Investigations in the intramural program; and (3) other responsibilities as described in the NIH Policy.[2]

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 the NIH Policy, allegations should be communicated to the AIRIO.

ARILO – The NIH Agency Research Integrity Liaison Officer (ARILO) is the NIH official responsible for overseeing the NIH's research integrity programs, both intramural and extramural.[3]

Assessment – The review of an allegation of research misconduct to determine whether an Inquiry is warranted is based on the following factors: whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; whether the allegation is within the jurisdictional criteria of the PHS Regulations; and whether the allegation falls within the definition of research misconduct in the PHS Regulations. The AIRIO is responsible for assessing allegations of research misconduct subject to the NIH Policy.

Complainant – A person who in good faith makes an allegation of research misconduct.

DO – Deciding Official – The Deputy Director for Intramural Research (DDIR) is the Deciding Official (DO) for Inquiries. The NIH ARILO is the Deciding Official who makes a final determination on findings of research misconduct by an Investigation Committee. The Deciding Official will not be the same individual as the AIRIO and should have no direct prior involvement in the allegation assessment, Inquiry, or Investigation.

Evidence – Any document (hard copy or electronic, including e-mail), tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

Inquiry – The process of gathering information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an Investigation. An Inquiry must meet the criteria and follow the procedures of the PHS Regulations.

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.

[2]The current AIRIO is Dr. Melissa Colbert, Bldg.2/Room 2E24, 301-827-7749, email:colbertmc@od.nih.gov.

[3]The current ARILO is Dr. Lawrence Tabak, Bldg.1/Room 126, 301-496-2433, email:Lawrence.tabak@nih.gov.

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.

ORI (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.

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.

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 the NIH 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.

Research misconduct proceeding – Any actions related to alleged research misconduct taken under the PHS Regulations and/or the NIH Policy including, but not limited to, allegation assessments, Inquiries, Investigations, ORI oversight reviews, hearings, and administrative appeals.

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 presentations, internal reports, journal articles, and any additional documents and materials obtained during the research misconduct proceeding.

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.

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