A Guide to the Handling of

Scientific Misconduct Allegations in the Intramural Research Program at the NIH

Introduction

The scientific 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 scientific misconduct are taken seriously by the 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 procedures to be described are intended to permit allegations of scientific misconduct to be processed promptly, confidentially, and fairly. A prompt response to an allegation helps to minimize any harm to the public that could result if misconduct is found and allows those who are incorrectly accused to clear their names without going through a long process. Allegations of misconduct that prove to be untrue, even if they were made in good faith, can damage careers and have a chilling effect on research. Confidentiality helps protect both those who bring the allegations and innocent people who are incorrectly or unjustly accused. Fairness allows all of those who become involved in scientific misconduct cases to have the opportunity to participate appropriately in addressing the issue and seeks to protect innocent participants from adverse consequences.

These policies and procedures apply to research conducted, or proposed to be conducted, in NIH facilities by any person; or research funded by the NIH Intramural Research Program; or research conducted, or proposed to be conducted, by an NIH employee or trainee as part of his or her official NIH duties or NIH training activity in any facility.

The NIH IRP Policies and Procedures for Investigating Scientific Misconduct are available at

www1.od.nih.gov/oir/sourcebook/ethic-conduct/smpolicy.htm

May 2001 – prepared by the NIH Committee on Scientific Conduct and Ethics

Definitions

Scientific misconduct or misconduct in research[a] – Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- ***Fabrication*** is making up data or results and recording or reporting them.
- ***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.
- ***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 difference of opinion.

Complainant – a person who makes an allegation of scientific misconduct.

Respondent – the person against whom an allegation of scientific misconduct is directed or the person whose actions are the focus of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

Allegation – any written and signed statement describing possible scientific misconduct and given to the NIH AIRIO.

- ***Good Faith Allegation*** – an allegation made with the honest belief that scientific misconduct may have occurred.
- ***Bad Faith Allegation*** – an allegation by a complainant who should have known, or through reasonable inquiry could have known, that the allegation is untrue or frivolous.

Research Record – any data or results that embody the facts resulting from scientific inquiry; it includes, for example, laboratory records, both physical and electronic, research proposals, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.

- ***Evidence*** – includes, but is not limited to, research records, transcripts or recordings of interviews, committee correspondence, administrative records, grant applications and awards, manuscripts, publications, and expert analyses.
- ***E-mail*** – NIH e-mail messages (including attachments that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities at NIH or have informational value are considered Federal records/Government property.

CSCE – NIH Committee on Scientific Conduct and Ethics.

AIRIO-NIH Agency Intramural Research Integrity Officer – the primary official in the NIH Intramural Research Program designated by the NIH Director to be responsible for all matters related to the NIH's intramural research integrity program[b].

ARILO-NIH Agency Research Integrity Liaison Officer – the primary official designated by the NIH Director to be responsible for all matters related to the NIH's research integrity programs[c].

Deciding Official – the NIH ARILO, the official who makes a final determination on findings of scientific misconduct and any responsive NIH actions for all Institutes and Centers. 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.

[a] The Federal Policy on Research Misconduct - <http://www.ostp.gov/html/001207_3.html>

[b] The current AIRIO is Dr. Joan P. Schwartz, Bldg. 1/Room 135, 496-1248, email:jps@helix.nih.gov

[c] The acting ARILO is Dr. Ron Geller, Rockledge 2/Room 6182, 435-2686, email:rg33k@nih.gov

Allegation Assessment

a determination as to whether the allegations, if true, would constitute research misconduct and whether the information is sufficiently specific to warrant and enable an Inquiry

If individuals believe that they have evidence of or have observed research misconduct, they may share their concerns or seek advice from individuals they trust. NIH employees are required to report suspected or apparent misconduct in science to the AIRIO orDeputy Director for Intramural Research (DDIR). Reports of observed or suspected misconduct may also be made to a supervisor, an IC Scientific or Institute Director, ORI, or the DHHS Office of the Inspector General. False allegations of misconduct may do irreversible damage to the reputation of an accused scientist even when he or she is later exonerated. Therefore, an employee who intentionally makes a false misconduct allegation will be subject to disciplinary action[d].

In order to bring a formal complaint, allegations of research misconduct must be made in writing and contain sufficient details to make clear the nature of the activity and a description of the facts, events and circumstances that led to the allegation. The signed allegation document is sent to the Agency Intramural Research Integrity Official (AIRIO). The AIRIO may consider and act upon any information that reasonably suggests the occurrence of research misconduct. The identity of the complainant may remain confidential unless the allegations lead to an Inquiry.

Within a week of receipt, the AIRIO will assess whether the report of the alleged research misconduct, if true, meets the definition of research misconduct and whether the allegations are sufficiently specific as to warrant and enable an Inquiry.

The AIRIO may decide:

1) the allegation warrants an Inquiry which will initiate the Inquiry phase of the process;
2) the allegation does not warrant an Inquiry, in which case the complainant will be notified in writing, the matter will be closed, and the records held for 5 years; or
3) the allegation describes events or conduct that may pose a threat to human or animal research subjects, a violation of safety regulations, financial irregularities, discrimination, sexual harassment or criminal activity, in which case the appropriate NIH official will be notified.

[d] Manual Chapter 3006 - Policies and Procedures Relating to Possible Scientific Misconduct in the IRP at NIH <http://www3.od.nih.gov/oma/manualchapters/intramural/3006/>

Inquiry

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

The purpose of an Inquiry is to gather preliminary information and to determine whether there is sufficient credible evidence of possible scientific misconduct to warrant a full-scale Investigation. At all times the respondent will be considered innocent of scientific misconduct unless later proven otherwise by a preponderance of the evidence; complete confidentiality will be maintained; and the process will be carried out as rapidly as possible.

1. The AIRIO, in consultation with the Committee on Scientific Conduct and Ethics, will appoint an Inquiry Committee and notify the respondent. This Committee will consist of at least 3 members, one of whom serves as the Committee chair, and none of whom have personal or professional conflicts of interest in the case. A member of the CSCE, preferably with appropriate scientific expertise, will serve as Executive Secretary (non-voting) for the Committee, advising the Committee on procedural issues. In general, it is desirable to include among the members of the Inquiry Committee a person of similar professional designation as the respondent (e.g., another postdoctoral fellow if the respondent is a postdoctoral fellow). The respondent will be given the opportunity (7 calendar days) to submit a written objection to any appointed member of the Inquiry Committee. Inquiries shall be completed within 60 calendar days after the first meeting of the Inquiry Committee.

2. Notification of the respondent will occur in a way that will cause minimum disturbance to the laboratory and embarrassment to the respondent. In the meeting convened to notify the respondent of the allegations, the AIRIO will explain the mechanism of the Inquiry into misconduct in research and the process of sequestration of research materials. The nature of the allegations will be outlined, and a copy of the allegations will be given to the respondent. All relevant materials are removed from the laboratory/office and sequestered to ensure that all materials relevant to the allegations are available for the Inquiry, and to protect all parties from concerns about subsequent modification of records.

3. The Inquiry Committee will interview the complainant, the respondent, and other relevant individuals, gather information, conduct the preliminary fact finding, and determine whether there are sufficient grounds to warrant a formal Investigation of misconduct. The respondent has the right to bring counsel or an advisor to interviews. The Committee will then prepare a written report recommending either that the case be closed or that an Investigation be conducted. The respondent will be given the opportunity to make a written reply to the report. The Deputy Director for Intramural Research will act as the Deciding Official in determining whether an Investigation is required.

Investigation

the formal examination and evaluation of all relevant facts to determine if scientific misconduct has occurred, and, if so, to determine the person(s) who committed it and the seriousness of the misconduct

The purpose of the Investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The Investigation will also determine whether there are circumstances that would justify adding additional charges of misconduct and identify these circumstances.

1. The AIRIO, in consultation with the Committee on Scientific Conduct and Ethics, will appoint an Investigation Committee and notify the respondent. This Committee shall consist of at least five members, one of whom serves as the Committee chair, and none of whom have personal or professional conflicts of interest in the case. One member will be a person of similar professional designation as the respondent (e.g., another postdoctoral fellow if the respondent is a postdoctoral fellow). A member of the CSCE, preferably with appropriate scientific expertise, will serve as Executive Secretary (non-voting), advising the Committee on procedural issues. The respondent will be given the opportunity (7 calendar days) to submit a written objection to any appointed member of the Investigation Committee. Investigations shall be completed within 120 calendar days after the first meeting of the Committee.

2. The AIRIO will notify the respondent within 24 hours, if possible, after the determination is made to open an Investigation. The notification includes: a copy of the Inquiry Report; the specific charges of scientific misconduct; the definition of scientific misconduct; the procedures to be followed in the Investigation, including the appointment of the Investigation Committee and experts; the opportunity for the respondent to be interviewed, to provide information, to be assisted by counsel, to challenge the membership of the Committee and experts based on bias or conflict of interest, and to comment on the draft Report; the fact that ORI will perform an oversight review of the report; and an explanation of the respondent's right to request a hearing before the DHHS Departmental Appeals Board if a finding of scientific misconduct is made.

3. The Investigation Committee will interview the complainant, the respondent, and other relevant individuals, and gather information. The respondent has the right to bring counsel or an advisor to interviews. In reaching a conclusion on whether there was scientific misconduct and who committed it, the burden of proof is on the NIH to support its conclusions and findings by a preponderance of the evidence. The Committee will consider whether there is sufficient evidence such that the NIH can meet this burden of proof; whether the misconduct was committed intentionally, or knowingly, or recklessly; and whether it represents significant departure from accepted practices of the relevant research community. The Committee will also consider whether there is evidence of honest error or honest differences in interpretations or judgments of data, such that scientific misconduct cannot be proven by a preponderance of the evidence. The Committee will then prepare a written draft Investigation Report, including recommendations for NIH sanctions, which will be provided to the

respondent for comment and rebuttal. The respondent will be given 30 calendar days to respond in writing.

4. The ARILO will make the final determination whether to accept the Investigation Report, its findings and the recommended NIH sanctions. When a final decision on the case has been reached by the ARILO, the AIRIO will notify both the respondent and the complainant, if any, in writing. In addition, the ARILO will determine whether law enforcement agencies, appropriate regulatory agencies, professional societies, professional licensing boards, editors of journals in which falsified reports were published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case.

The ARILO will submit a report on the Investigation to ORI for review. ORI will have 240 calendar days to review the report to determine whether the investigation was fair, objective, and competent. If a finding of misconduct was made, ORI will also review the finding of misconduct and supporting evidence, as well as recommend PHS sanctions. ORI will then forward its recommendations for sanctions to the HHS Assistant Secretary of Health (ASH), who will issue a final decision regarding the proposed sanctions.

If the ASH makes a finding of scientific misconduct, the respondent may request, within 30 calendar days of receipt of the notification of findings, a hearing before the HHS Departmental Appeals Board.

Sanctions

the NIH administrative actions to be taken if a finding of research misconduct is made

Determining appropriate NIH sanctions will likely be very difficult and may vary in every case. It should be noted that sanctions imposed on a particular individual may have consequences that are much broader; i.e., members of the laboratory may be indirectly or directly affected as well. There should be a logical correspondence between the nature and severity of the proven allegations and the sanctions imposed.

The sanctions may include, but are not limited to, the following:

- removal from a particular project
- letter of reprimand to be included in the individual's NIH personnel file
- special monitoring of work
- decrease in laboratory support (e.g., loss of a Fellow position or technical support position)
- probation
- suspension with or without pay
- denial of a raise in salary or a salary/rank reduction
- termination of employment

The Investigation Committee makes recommendations to the ARILO and appropriate IC Director on possible sanctions; the IC Director will be responsible for implementing the sanctions.

Any individual who is subject to a sanction will be afforded any government appeal processes that would ordinarily apply before that sanction goes into effect.