NATIONAL INSTITUTES OF HEALTH
INTRAMURAL RESEARCH PROGRAM
POLICIES & PROCEDURES FOR
RESEARCH MISCONDUCT PROCEEDINGS

Revised: August 3, 2010

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ATTACHMENTS

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I. INTRODUCTION

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 National Institutes of Health (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.

These NIH Intramural Research Program Policies & Procedures for Research Misconduct Proceedings (hereinafter referred to as the "Policy") are 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 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.

II. APPLICABILITY AND SCOPE

Consistent with the NIH's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 C.F.R. Part 93 (*i.e.*, the PHS Regulations) <http://www.ori.dhhs.gov/documents/FR_Doc_05-9643.shtml>, this 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 Intramural Research Program (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 this Policy if, for example, he or she is involved in:

1. NIH- or 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).

This 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.

III. DEFINITIONS

Unless otherwise indicated below, terms used in this Policy have the same meaning as defined in the PHS Regulations. For convenience, several of the definitions from the PHS Regulations have been reproduced without change below.

A. AIRIO – NIH Agency Intramural Research Integrity Officer – 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 this Policy.

B. ARILO – NIH Agency Research Integrity Liaison Officer – the NIH official responsible for overseeing the NIH's research integrity programs, both intramural and extramural.

C. 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.

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.

Bad Faith Allegation – An allegation made by an individual with knowing or reckless disregard for information that would negate the allegation.

D. Assessment – The review of an allegation of research misconduct to determine whether an Inquiry is warranted 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 this Policy.

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

F. CSCE – NIH Committee on Scientific Conduct and Ethics.

G. DO – Deciding Official – The Deputy Director for Intramural Research (DDIR) is the Deciding Official 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.

H. 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.

I. 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.

J. 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.

K. 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.

L. Notice – A written communication served in person, or sent by mail or its equivalent to the last known street address, facsimile number, or e-mail address of the addressee.

M. 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.

N. PHS Regulations – The Public Health Service (PHS) Policies on Research Misconduct, 42 C.F.R. Part 93.

O. 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.

P. 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.

Q. Research misconduct – 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;

(4) 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.

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

S. 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.

T. 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.

U. Retaliation – An adverse action, such as a demotion or firing, taken against a Complainant, witness, or committee member by NIH or one of its institutional members (as defined in the PHS Regulations) in response to:

(1) a good faith allegation of research misconduct; or

(2) good faith cooperation with a research misconduct proceeding.

IV. ROLES AND RESPONSIBILITIES

A. Deciding Official (DO)

For Inquiries

The Deputy Director for Intramural Research (DDIR) is the DO for Inquiries. The DO will receive the Inquiry Report and, after consulting as needed with the AIRIO, the Inquiry Committee, and/or other NIH officials, decide whether an Investigation is warranted under the criteria in the PHS Regulations. Any finding that an Investigation is warranted must be made in writing by the DO and must be provided to ORI, together with a copy of the Inquiry Report meeting the requirements of the PHS Regulations, within 30 days of the finding. If it is found that an Investigation is not warranted, the DO and the AIRIO will ensure that detailed documentation of the Inquiry is retained for at least 7 years after termination of the Inquiry, so that ORI may assess the reasons why the NIH decided not to conduct an Investigation. Where the DO is involved in the case, the NIH Director or his/her designee will assume the DO's responsibilities as described above.

For Investigations

The ARILO is the DO for Investigations and findings of research misconduct (see below). The DO will receive the Investigation Report and, after consulting as needed with the AIRIO, the Investigation Committee, and/or other NIH officials, decide whether and to what extent the NIH accepts the findings of the Investigation. If research misconduct is found, the DO will decide, or will refer to other appropriate NIH officials to decide, what, if any, NIH administrative actions are appropriate. The DO shall ensure that the final Investigation Report, the findings of the DO, and a description of any pending or completed administrative actions are provided to ORI as required by the PHS Regulations.

B. NIH Agency Research Integrity Liaison Officer (ARILO)

The ARILO:

1. oversees and coordinates the NIH's activities and policies related to research integrity in both intramural and extramural research supported by the NIH;

2. represents the NIH on matters of research integrity policy through membership on the PHS Agency Research Integrity Liaison Group; and

3. serves as the Deciding Official for Investigations and findings of research misconduct.

C. NIH Agency Intramural Research Integrity Officer (AIRIO)

The AIRIO:

1. oversees and coordinates the NIH's activities and policies related to research integrity in the NIH Intramural Research Program;

2. assesses allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by this Policy and the PHS Regulations, and warrant an Inquiry on the basis that the allegations are sufficiently credible and specific so that potential evidence of research misconduct may be identified;

3. oversees Inquiries and Investigations;

4. is authorized to take promptly, throughout the NIH Intramural Research Program, all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct a research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner;

5. provides Inquiry Reports to the DDIR and Investigation Reports to the ARILO (Deciding Officials for Inquiry and Investigation respectively); and

6. is responsible for ensuring that the NIH complies with all ORI notice and reporting requirements contained in the PHS Regulations including, but not limited to, providing to ORI in a timely manner the following: (a) for an Inquiry, the written finding by the Deciding Official that an Investigation is warranted and a copy of the Inquiry Report; and (b) for an Investigation, a copy of the Investigation Report, a statement of whether NIH accepts the Investigation's findings, a statement of whether NIH found research misconduct and, if so, who committed it, and a description of any pending or completed administrative actions against the Respondent.

The AIRIO 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 activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.

- has written policies and procedures for responding to allegations of research misconduct and reporting information about that response to ORI (*i.e.*, this Policy), as required by the PHS Regulations.

- complies with this Policy and the requirements of the PHS Regulations.

- informs NIH staff who are subject to the PHS Regulations about this Policy and the NIH's commitment to compliance with this Policy.

- takes appropriate interim action during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the NIH- and PHS-supported research process.

D. Complainant

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.

E. Respondent

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, this 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 (see section V(C) below). Individuals who are consulted will be asked to sign a Confidentiality Statement provided by the AIRIO (see Attachment 1).

- 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.

F. Institute/Center Director

The NIH Institute and Center (IC) Directors assist the AIRIO and others, as needed, in the research misconduct proceeding. At the close of research misconduct proceeding, they assist with the implementation of administrative actions, if any, as directed by the Deciding Official or other appropriate NIH official.

G. Institute/Center Scientific Director

NIH IC Scientific Directors, and other NIH officials as needed, are informed of the decision to open an Inquiry and may notify other NIH staff on a confidential basis as appropriate to manage effectively agency resources and protect agency programs, consistent with the provisions described in section V(C), below. If requested by the AIRIO, the Scientific Director may assist in the notification of Respondents of allegations of possible research misconduct, in securing evidence, and in other matters as needed during the research misconduct proceeding. For an IC that does not have a Scientific Director, or in a case where a Scientific Director has unresolved personal, professional, or financial conflicts of interest, the IC Director will designate another individual to carry out these responsibilities.

V. GENERAL POLICIES AND PRINCIPLES

A. Responsibility to Report Misconduct

All NIH staff are expected to report observed, apparent, or suspected research misconduct. Reporting procedures are described in section VI(A) below.

B. Cooperation with Research Misconduct Proceedings

All NIH staff will cooperate with the AIRIO and other NIH officials in research misconduct proceedings, including the review of allegations and the conduct of Inquiries and Investigations. NIH staff, including Respondents, have an obligation to provide evidence relevant to research misconduct allegations to the AIRIO or other NIH officials.

C. Confidentiality

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 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.

The AIRIO may use written confidentiality statements or other mechanisms to maintain confidentiality of research misconduct proceedings. (See Confidentiality Statement, Attachment 1).

D. Interim Administrative Actions; Notification of Special Circumstances

Throughout a research misconduct proceeding at NIH (*i.e.*, the assessment, Inquiry, and Investigation stages), the AIRIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the NIH- or PHS-supported research process. In the event of such a threat, the AIRIO will, in consultation with other NIH officials and ORI, take appropriate interim action to protect against any such threat. Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results, or delaying publication.

The AIRIO shall, at any time during a research misconduct proceeding, notify ORI and appropriate NIH officials immediately if the AIRIO has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- HHS resources or interests are threatened;
- Research activities should be suspended;
- There is a reasonable indication of possible violations of civil or criminal law;
- Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

If the AIRIO has reason to believe that there has been a violation of applicable safety regulations, financial irregularities related to federal funds, discrimination, or sexual harassment, not covered by the criteria set forth above, the AIRIO shall inform appropriate NIH officials.

VI. ASSESSMENT OF ALLEGATIONS OF RESEARCH MISCONDUCT

A. Bringing an Allegation of 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 NIH encourages allegations to be communicated directly to the Agency Intramural Research Integrity Officer (AIRIO), Office of Intramural Research, Office of the Director, NIH (301-496-1921).

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 (or persons) 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.

B. Assessment of Allegations

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 this Policy;

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

If these criteria are met, an Inquiry is warranted (see section VII below). If no Inquiry is initiated, the matter shall be closed and the AIRIO's records related to the allegation will be retained for seven (7) years (or longer, if other record retention requirements apply to the records).

The assessment period should be brief, preferably concluded within a week of the AIRIO's receipt of the allegation. In conducting the assessment, the AIRIO need not interview the Complainant, Respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

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.

VII. CONDUCTING THE INQUIRY

A. Purpose and Initiation of the Inquiry

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.

An Inquiry does not require a full review of all the evidence related to the allegation, although the process usually involves interviewing of key witnesses, including the Complainant(s) and Respondent(s).

B. Notice to Respondent

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 this Policy and/or related materials explaining NIH and PHS policies and procedures regarding research misconduct.

The AIRIO will lead the notification process. The AIRIO will make a good faith effort to arrange that this process be performed, where feasible, in a private place in an undisruptive manner in order to minimize disturbance to the laboratory and embarrassment to the Respondent. When feasible, the Respondent's supervisor (as long as he/she is not the Complainant), or another IC official, will be present.

In addition to providing the notification memo and policy information, when feasible, the AIRIO will seek to explain verbally the Inquiry process to the Respondent and to inform the Respondent that he/she may acquire his/her own legal counsel. If there is more than one Respondent, the AIRIO will seek to notify each Respondent separately when feasible. If the Inquiry subsequently identifies additional Respondents, they will be notified in writing.

C. Sequestration of Research Records

On or before the date on which the Respondent is notified, or the Inquiry begins, whichever is earlier, 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 case record), and sequester them in a secure manner. Starting at the time of sequestration, the AIRIO or designee will seek to maintain a chain of custody for all sequestered materials, as well as any additional research records or evidence gathered during the Inquiry, in order to preserve the integrity of the original research records and evidence received by the AIRIO.

When the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. When appropriate, the Respondent may be provided copies or supervised access to the materials to facilitate continuation of research. The AIRIO may consult with ORI for advice and assistance in this regard.

D. Appointment of the Inquiry Committee

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 should include individuals who are federal employees and who have the appropriate scientific expertise to evaluate the evidence and issues related to the allegation(s), interview the principals and key witnesses, as appropriate, and conduct the Inquiry. Individuals who have unresolved personal, professional, or financial conflicts of interest with those involved with the Inquiry, including the Respondent(s) and Complainant(s), may not serve on the Inquiry Committee.

Members of the CSCE are eligible to serve on the Inquiry Committee. In addition, when required to secure the necessary scientific expertise or to avoid conflicts of interest, the AIRIO may appoint employees of other federal agencies. Except under extraordinary circumstances, the Inquiry Committee should not include as a member an individual who was consulted or was otherwise involved in the assessment of allegation(s). When appointment of an individual with previous involvement in the research misconduct proceeding is determined to be useful, the AIRIO will document the basis for the NIH's conclusion that the appointment satisfies the PHS Regulations' requirement to ensure a fair investigation, and include such documentation in the record of the Inquiry.

At the time of appointment, a proposed Inquiry Committee member will be asked to sign a Federal Employee Participant Statement. (See Attachment 2).

A member of the CSCE or another NIH staff member will serve as Executive Secretary for the Committee. The AIRIO may appoint the Executive Secretary as one of the voting members if the Executive Secretary has the appropriate scientific expertise and is a federal employee. One or more attorneys from the HHS Office of General Counsel may be present at committee meetings and/or interviews.

The AIRIO will notify the Respondent of the names of the proposed Inquiry Committee members and provide an opportunity for the Respondent to object to a proposed 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.

E. First Meeting and Charge to the Committee

1. Charge to the Committee

The AIRIO may prepare a written charge for the Inquiry Committee that:

- describes the allegations and related issues identified during the allegation assessment.
- identifies the Respondent(s).
- defines research misconduct.

- states that an Inquiry is the process of gathering information and initial fact-finding, which usually includes interviews with the Respondent, Complainant, and key witnesses, to determine whether an allegation or apparent instance of research misconduct warrants an Investigation.

- states that 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 this Policy; and (2) the allegation may have substance, based on the Committee's review during the Inquiry.

- informs the Committee that it must prepare, or direct the preparation of, a written Inquiry Report that meets the requirements of this Policy and the PHS Regulations.

- describes the timeline for completion of the Inquiry.

- describes NIH's expectation that confidentiality will be maintained consistent with this Policy and to the extent required by law. Outside of the official proceedings of the Committee, Inquiry Committee members are directed not to discuss the proceedings with the Respondent, Complainant, witnesses, or anyone not otherwise authorized to discuss the Inquiry.

2. First Meeting

At the Inquiry Committee's first meeting, the AIRIO may review the charge with the Committee; discuss the allegations, any related issues, and the process for conducting the Inquiry; assist the Committee with organizing plans for the Inquiry; and answer any questions raised by the Committee. The Inquiry Committee should be provided a copy of this Policy and the PHS Regulations. One member of the Committee will serve as Chair. The AIRIO will be present or available throughout the Inquiry to advise the Committee as needed.

F. Inquiry Process

The Inquiry Committee usually interviews the Respondent, the Complainant, if known, and key witnesses as well as examine relevant research records and materials. When feasible, interviews should be recorded and transcribed. In such instances, each interviewee will be provided with his/her transcript and given the opportunity to request corrections. Changes to a transcript will only be made to correct errors in transcription, but an interviewee may add comments or additional information that will be included with his/her transcript as an addendum.

The Inquiry Committee will evaluate the evidence, including testimony obtained during the Inquiry. After consultation with the AIRIO, the Committee will decide whether an Investigation is warranted based on the criteria in this Policy and the PHS Regulations. The Committee's decision need not be unanimous. The scope of the Inquiry is not required to, and does not normally include, deciding whether research misconduct definitely occurred, determining definitively who committed the research misconduct, or conducting exhaustive interviews and analyses. If a legally sufficient admission of research misconduct is made by the Respondent, research misconduct may be determined at the Inquiry stage if all relevant issues are resolved. In that case, the NIH will promptly consult with ORI to determine the next steps that should be taken, as described in section XI below.

Inquiry Committee members are expected to be present for all Committee meetings and interviews. In the event a Committee member is absent from one or more meetings or interviews, the AIRIO may at his or her discretion determine whether the Inquiry process should be modified, *e.g.*, by having the member continue to serve on the Committee in a non-voting capacity only, or by removing the member from further participation on the Committee.

G. Timeline for Completion

The Inquiry, including preparation of the final Inquiry Report and the decision of the DO on whether an Investigation is warranted, is to be completed within sixty (60) calendar days of its initiation (defined as the date of the first meeting of the Inquiry Committee), unless the AIRIO determines that circumstances clearly warrant a longer period. If the AIRIO approves an extension, the Inquiry record must include documentation of the reasons for exceeding the 60-day period. In addition, the AIRIO should notify the Respondent of the extension.

VIII. THE INQUIRY REPORT

A. Elements of the Inquiry Report

The Inquiry Committee and the AIRIO are responsible for preparing a written draft report for the Inquiry. The report should include the following information:

1. The name and position of the Respondent;
2. A description of the allegations of research misconduct;
3. The PHS support;
4. The names, titles, and affiliations of the Inquiry Committee members;
5. The dates of Committee meetings and interviews;

6. A list of the documentary evidence examined and interviews conducted;
7. Summaries of relevant evidence upon which the Committee's conclusions are based;
8. If an extension of time was granted for completion of the Inquiry, documentation of the reasons for exceeding the 60-day period;
9. The basis for recommending, or not recommending, that the allegations warrant an Investigation;
10. Whether any actions should be taken if an Investigation is not recommended.

When the Committee's decision is not unanimous, the Report may include a separate statement summarizing the minority viewpoint. A draft report will be provided to the HHS Office of General Counsel for legal review. Modifications may be made as appropriate and in consultation with the AIRIO and the Inquiry Committee.

B. Notice to Respondent and Complainant; Opportunity to Comment

The AIRIO shall notify the Respondent whether the Inquiry Committee found an Investigation to be warranted, and include a copy of the draft Inquiry Report and a copy of, or reference to, this Policy and the PHS Regulations. The NIH may choose to provide the Complainant, if known, that portion of the draft Report that addresses the Complainant's role and statements in the Inquiry. The Respondent and Complainant will provide their comments, if any, to the Inquiry Committee within fourteen (14) calendar days of receipt. Any comments that are submitted by the Respondent or Complainant will be attached to the final Inquiry Report. Based on the comments, the Inquiry Committee may revise the draft report as appropriate and prepare it in final form. The Committee will deliver the final report to the AIRIO.

C. NIH Decision and Notification

1. Decision by Deciding Official (DO)

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.

2. Notification to ORI

Within thirty (30) calendar days of the DO's decision that an Investigation is warranted, the AIRIO will provide ORI with the DO's written decision and a copy of the Inquiry Report. The AIRIO will also notify those NIH officials who need to know of the DO's decision as part of their official duties. Upon ORI's request, the AIRIO must also provide to ORI the following information: (1) the NIH policies and procedures under which the Inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the Investigation.

3. Documentation of Decision Not to Investigate

If the DO decides that an Investigation is not warranted, the AIRIO does not need to notify ORI. However, the AIRIO must secure and maintain for seven (7) years (or longer, if other record retention requirements apply to the records) after the termination of the Inquiry sufficiently detailed documentation of the Inquiry to permit a later assessment by ORI of the reasons why an Investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request.

If no Investigation is initiated, the AIRIO will notify the Respondent. The AIRIO may also notify the Complainant, if known, and anyone else of whom the AIRIO is aware who has knowledge of the research misconduct proceeding, as appropriate, to resolve any questions that may exist concerning the status of the proceeding. At the request of the Respondent, the AIRIO will undertake, as appropriate, all reasonable and practical efforts to restore the Respondent's reputation, as further described in section XIII(B) below.

4. Return of Sequestered Materials

If the DO decides that an Investigation is not warranted, the AIRIO will arrange for all sequestered materials to be returned to the Respondent or other parties, as appropriate, as soon as practicable following closure of the case.

IX. CONDUCTING THE INVESTIGATION

A. Purpose and Initiation of the Investigation

The Investigation must begin within thirty (30) calendar days after the determination by the DO that an Investigation is warranted. 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. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. In accordance with the PHS Regulations, the findings of the Investigation must be set forth in an Investigation Report.

B. Notice to ORI and Respondent; Sequestration of Research Records

On or before the date on which the Investigation begins, the AIRIO must (1) notify the ORI Director of the decision to begin the Investigation and provide ORI a copy of the Inquiry Report; and (2) 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, this 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 will, prior to notifying the Respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the Inquiry. The need for additional sequestration of records for the Investigation may occur for any number of reasons, including the NIH's decision to investigate additional allegations not considered during the Inquiry stage or the identification of records during the Inquiry process that had not been previously secured. The procedures to be followed for sequestration during the Investigation are the same procedures that apply during the Inquiry.

C. Appointment of the Investigation Committee

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 should include individuals who are federal employees and who have the appropriate scientific expertise to evaluate the evidence and issues related to the allegation(s), interview the principals and key witnesses as appropriate, and conduct the Investigation. Individuals who have unresolved personal, professional, or financial conflicts of interest with those involved with the Investigation or Inquiry, including the Respondent(s) and Complainant(s), may not serve on the Investigation Committee.

When feasible, one member of the Investigation Committee should be a person of similar professional designation as the Respondent. Members of the CSCE are eligible to serve on the Investigation Committee. In addition, when required to secure the necessary scientific expertise or to avoid conflicts of interest, the AIRIO may appoint employees of other federal agencies.

Except under extraordinary circumstances, the Investigation Committee should not include as a member an individual who served on the Inquiry Committee or who was consulted or was otherwise involved in the assessment of allegation(s). When appointment of an individual with previous involvement in the research misconduct proceeding is determined to be useful, the AIRIO will document the basis for the NIH's conclusion that the appointment satisfies the PHS Regulations' requirement to ensure a fair investigation, and include such documentation in the record of the Investigation.

At the time of appointment, a proposed Investigation Committee member will be asked to sign a Federal Employee Participant Statement. (See Attachment 2).

A member of the CSCE or another NIH staff member will serve as Executive Secretary for the Committee. The AIRIO may appoint the Executive Secretary as one of the voting members if the Executive Secretary has the appropriate scientific expertise and is a federal employee. One or more attorneys from the HHS Office of General Counsel may be present at committee meetings and/or interviews.

The AIRIO will notify the Respondent of the names of the proposed Investigation Committee members and provide an opportunity for the Respondent to object to a proposed 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.

D. First Meeting and Charge to the Committee

1. Charge to the Committee

The AIRIO may prepare a written charge to the Committee that:

- describes the allegations and related issues identified during the Inquiry.
- identifies the Respondent(s).
- defines research misconduct.
- states that 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.
- describes the Investigation process (see section IX(E) below).
- informs the Committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent and who was responsible.
- informs the Committee that in order to determine that the Respondent committed research misconduct, it must find that a preponderance of the evidence establishes that: (1) research misconduct, as defined in this Policy, occurred; (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the Respondent committed the research misconduct intentionally, knowingly, or recklessly. The Committee's decision need not be unanimous.
- informs the Committee that it must prepare, or direct the preparation of, a written Investigation Report that meets the requirements of this Policy and the PHS Regulations.
- describes the timeline for completion of the Investigation.

- describes NIH's expectation that confidentiality will be maintained consistent with this Policy and to the extent required by law. Outside of the official proceedings of the Committee, Investigation Committee members are directed not to discuss the proceedings with the Respondent, Complainant, witnesses, or anyone not otherwise authorized to discuss the Investigation.

2. First Meeting

At the Investigation Committee's first meeting, the AIRIO may review the charge; discuss the allegations, the Inquiry Report, any related issues, and the process for conducting the Investigation; assist the Committee with organizing plans for the Investigation; and answer any questions raised by the Committee. The Investigation Committee should be provided a copy of this Policy and the PHS Regulations. One member of the Committee will serve as Chair. The AIRIO will be present or available throughout the Investigation to advise the Committee as needed.

E. Investigation Process

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. Each interview will be recorded and transcribed, the transcript provided to the interviewee for correction of errors in transcription, and the transcript included in the record of the Investigation. Changes to a transcript will only be made to correct errors in transcription, but an interviewee may add comments or additional information that will be included with his/her transcript as an addendum; 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 NIH has the burden of proof for making a finding of research misconduct, based on a preponderance of the evidence. The destruction, absence of, or Respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the NIH establishes by a preponderance of the evidence that the Respondent intentionally, knowingly, or recklessly had research records and destroyed them; had the opportunity to maintain the records but did not do so; or maintained the records and failed to produce them in a timely manner; and that the Respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

The Respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion. The Respondent also has the burden of proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose administrative actions following a research misconduct proceeding.

Investigation Committee members are expected to be present for all Committee meetings and interviews. In the event a Committee member is absent from one or more meetings or interviews, the AIRIO may at his or her discretion determine whether the Investigation process should be modified, *e.g.*, by having the member continue to serve on the Committee in a non-voting capacity only, or by removing the member from further participation on the Committee.

F. Timeline for Completion

The Investigation is to be completed within 120 days of its initiation (defined as the date of the first meeting of the Investigation Committee), including conducting the Investigation, preparing the report of findings, providing the draft Report for comment and sending the final Report to ORI. However, if the AIRIO determines that the Investigation cannot be completed within this 120-day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay. The AIRIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports. In addition, the AIRIO will notify the Respondent of the extension.

X. THE INVESTIGATION REPORT

A. Elements of the Investigation Report

The Investigation Committee and the AIRIO are responsible for preparing a written draft report for the Investigation that:

1. describes the nature of the allegation(s) of research misconduct, including identification of the Respondent;
2. describes the specific allegations of research misconduct considered in the Investigation;
3. describes and documents the PHS support;
4. includes the names, titles, and affiliations of the Investigation Committee members;
5. includes the dates of Committee meetings and interviews;
6. includes the NIH policies and procedures under which the Investigation was conducted, unless those policies and procedures were provided to ORI previously;
7. if an extension of time was granted for completion of the Investigation, documents the reasons for exceeding the 120-day period;
8. identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed;
9. 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, and if so:
   (a) identifies whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;
   (b) summarizes the facts and the analysis which support the conclusion and considers the merits of any reasonable explanation by the Respondent, including any effort by Respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion;
   (c) identifies the person(s) responsible for the research misconduct;
   (d) identifies the specific PHS support;
   (e) identifies whether any publications need correction or retraction; and
   (f) lists any current support or known applications or proposals for support that the Respondent has pending with non-PHS federal agencies.
10. may describe any recommended administrative actions that the Investigation Committee believes the NIH should take, including appropriate actions against the Respondent; and
11. may document evidence that suggests an allegation may have been made in bad faith.

When the Committee's decision is not unanimous, the Report also will include a separate statement summarizing the minority viewpoint. A draft report will be provided to the HHS Office of General Counsel for legal review. Modifications may be made as appropriate, in consultation with the AIRIO and the Investigation Committee.

A suggested standard format for the Investigation Report is provided in Attachment 3.

B. Comments on the Draft Report and Access to Evidence

1. Respondent

The AIRIO must give the Respondent a copy of the draft Investigation Report for comment and, concurrently, a copy of, or supervised access to, the evidence on which the report is based. The Respondent will be allowed thirty (30) days from the date he/she receives the draft report to submit comments to the AIRIO. The Respondent's comments, if any, will be included and considered in the final report.

2. Complainant

The NIH may choose to provide the Complainant, if known, the portions of the draft Investigation Report that address the Complainant's role and statements in the Investigation. Any comments from the Complainant must be submitted within thirty (30) days of the date on which he/she receives the draft report, and the comments will be included and considered in the final report.

3. Confidentiality

In distributing the draft report, or portions thereof, to the Respondent and Complainant, the AIRIO should remind the recipient of his/her obligation to maintain the confidentiality of the research misconduct proceeding (see section V(C) above).

C. Decision by Deciding Official

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, who 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. If this determination varies from the findings of the Investigation Committee, the DO will, as part of his/her written determination, explain the basis for rendering a decision different from the findings of the Investigation Committee. Alternatively, the DO may return the report to the Investigation Committee with a request for further fact-finding, analysis or clarification of the Report.

When a final decision has been reached, the AIRIO will notify both the Respondent and the Complainant, if known, in writing. The AIRIO will also notify those NIH officials who need to know of the decision as part of their official duties. After informing ORI, the DO will determine whether law enforcement agencies, other government agencies, NIH- or PHS-supported institutions or organizations, research collaborators of the Respondent, editors or publishers of professional journals or other publications, professional societies, professional licensing boards, or other relevant parties should be notified of the outcome of the case to the extent permitted under applicable law. The AIRIO is responsible for ensuring compliance with all notification requirements of other funding or sponsoring agencies, if applicable.

If, in the Investigation Report, the Investigation Committee documents evidence that suggests an allegation may have been made in bad faith, the DO will review the evidence and may recommend further action (Section XIII(D)).

D. Notice to ORI of NIH Findings and Actions

Unless an extension has been granted, the AIRIO must, within the 120-day period for completing the Investigation, submit the following to ORI: (1) a copy of the final Investigation Report with all attachments; (2) a statement of whether the NIH accepts the findings of the Investigation Report; (3) a statement of whether the NIH found research misconduct and, if so, who committed the research misconduct; and (4) a description of any pending or completed administrative actions against the Respondent.

E. Maintaining Records for Review by ORI

The AIRIO must maintain and provide to ORI upon request "records of research misconduct proceedings" as that term is defined in the PHS Regulations. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for seven (7) years (or longer, if other record retention requirements apply to the records) after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation. The AIRIO also is responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or of NIH's handling of such an allegation.

XI. ADMISSIONS AND SETTLEMENTS; REPORTING OBLIGATIONS

The NIH is expected to carry Inquiries and Investigations through to completion and to pursue diligently all significant issues. The NIH must notify ORI in advance if it plans to close a case at the Inquiry or Investigation stage on the basis that the Respondent has admitted guilt, a settlement with the Respondent has been reached, or for any other reason, except: (1) the closing of a case at the Inquiry stage on the basis that an Investigation is not warranted; or (2) a finding of no research misconduct at the Investigation stage, which is to be reported in any event under the PHS Regulations, as described in section X(D) above.

ORI will consult with the NIH on its basis for closing the case and may conduct an oversight review of the handling of the case and take appropriate actions including: (1) approving or conditionally approving closure of the case; (2) directing the NIH to complete its process; (3) referring the matter for further investigation by HHS; or (4) taking a compliance action.

XII. NIH ADMINISTRATIVE ACTIONS

If, in the Investigation Report, the Investigation Committee includes a finding of research misconduct, the Investigation Committee may describe any recommended administrative actions that the Investigation Committee believes the NIH should take, including appropriate actions against the Respondent.

If the DO determines that research misconduct is substantiated by the Investigation findings, he/she will decide after consultation with the AIRIO or, as necessary, will refer to other appropriate NIH officials (*e.g.*, Director of Human Resources) to 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:

- withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;

- 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

- other action appropriate to the research misconduct.

XIII. OTHER CONSIDERATIONS

A. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of a Respondent's employment at NIH, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not necessarily preclude or terminate a research misconduct proceeding or otherwise limit any of the NIH's responsibilities under the PHS Regulations.

If a Respondent, without admitting to the research misconduct, elects to resign his or her position after the NIH receives an allegation of research misconduct, the assessment of the allegation, as well as the Inquiry and Investigation, may proceed as appropriate based on the outcome of the preceding steps. If the Respondent refuses to participate in the process after resignation, the AIRIO and any Inquiry Committee or Investigation Committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the Respondent's failure to cooperate and its effect on the evidence available for analysis.

B. Restoration of the Respondent's Reputation

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. Depending on the particular circumstances and the views of the Respondent, the AIRIO should consider notifying those individuals that are known to the AIRIO to be aware of or involved in the research misconduct proceeding or the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and requesting that all reference to the research misconduct allegation be expunged from the Respondent's personnel file, if appropriate.

An IC for which the Respondent works should seek to mitigate the impact that the Investigation may have had on the Respondent's position, reputation, and responsibilities. In the case of Fellows, NIH has the discretion to permit the Fellow to move his/her fellowship to another NIH laboratory, if available. To the extent permitted by law and NIH policy, the NIH may also consider whether to extend an existing fellowship award or grant a new award in recognition of the time that the Fellow may have lost in his/her original laboratory.

Any NIH actions intended to restore the Respondent's reputation should first be approved by the DO.

C. Protection of the Complainant, Witnesses, and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the NIH or ORI determines that research misconduct occurred, the AIRIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any Complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding. The DO will determine, after consulting with the AIRIO, and with the Complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The DO may consult with, or refer matters to, other appropriate NIH officials, *e.g.*, the Director of Human Resources for matters that may involve employee standards of conduct and related personnel regulations. The AIRIO may assist the DO by implementing measures that the DO has approved.

D. Allegations Not Made in Good Faith

If relevant, the DO will determine whether the Complainant's allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the DO determines, based on the Investigation Report, that there was an absence of good faith, he/she will determine or, as necessary, will refer to other appropriate NIH officials (*e.g.*, Director of Human Resources) to determine, whether any administrative action should be taken against the person who failed to act in good faith.

E. ORI Review and HHS Administrative Actions

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 are beyond the scope of this Policy. These descriptions and related matters are contained in the PHS Regulations. Additional information is also available on the ORI web site <http://ori.dhhs.gov/>.

Attachment 1

CONFIDENTIALITY STATEMENT

Note: To be provided to complainants, respondents, witnesses or others, as needed, related to a research misconduct proceeding

From: Deputy Director for Intramural Research, National Institutes of Health (NIH)

The NIH Intramural Research Program is conducting a research misconduct proceeding to examine allegations of research misconduct about which you may have, or may acquire, some knowledge. The NIH maintains confidentiality of research misconduct proceedings as required under federal law, 42 C.F.R. Part 93. An unlawful breach of confidentiality may disrupt the NIH's ability to carry out this proceeding fairly, may cause undue damage to the scientific reputations of the individuals involved, or may constitute a breach of the Privacy Act, 5 U.S.C. § 552a.

It is your obligation to maintain the confidentiality of this research misconduct proceeding to the extent required by law. You agree not to disclose the identity of respondents, complainants or witnesses, except to those who need to know in order for this research misconduct proceeding to be carried out in a thorough, competent, objective and fair manner, or unless otherwise allowed by law. In addition, you agree not to disclose any records or evidence from which research subjects might be identified except to those who need to know in order to carry out this research misconduct proceeding or as otherwise prescribed by applicable law.

Unless you are a Respondent in this proceeding or have received prior permission from the NIH Agency Intramural Research Integrity Officer (AIRIO), you should not make copies of any information provided to you and should return all materials you received to the AIRIO at the conclusion of your involvement in this proceeding. For more information, you may refer to the NIH Intramural Research Program Policies & Procedures for Research Misconduct Proceedings.

Note to Respondents: To the extent consistent with the obligations described above and applicable law, a Respondent 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), or with others who may assist Respondent in his or her defense.

Michael M. Gottesman, M.D.

Please sign below to indicate that you have received and read this statement and understand your obligation to maintain confidentiality.

Name (please print): _____

_____ _____

(signature) (date)

Attachment 2

NIH INTRAMURAL RESEARCH MISCONDUCT PROCEEDING
FEDERAL EMPLOYEE PARTICIPANT STATEMENT

I, _____ *(name),* am an employee of the Federal Government and offer to assist the National Institutes of Health (NIH) by sharing my scientific expertise and participating in an NIH intramural research misconduct proceeding. In making this offer, I understand and agree with the following statements:

1. To the best of my knowledge, I do not have unresolved personal, professional, or financial conflicts of interest with those involved with the research misconduct proceeding, and I have appropriate scientific expertise to participate in it.
2. This assignment is within the scope of my federal employment position description, and my supervisor is aware of, and has approved, my participation in the NIH research misconduct proceeding during official business hours.
3. For purposes of this assignment, I will be under the direct supervision of the NIH Agency Intramural Research Integrity Officer (AIRIO), or designee.
4. For purposes of this assignment, I agree to be bound by the provisions of the NIH Intramural Research Program Policies & Procedures for Research Misconduct Proceedings and the Public Health Service (PHS) Policies on Research Misconduct, 42 C.F.R. Part 93 (PHS Regulations).
5. I will maintain the confidentiality of the research misconduct proceeding to the extent required by law. I will not disclose the identity of respondents, complainants, or witnesses except to those who need to know in order for the research misconduct proceeding to be carried out in a thorough, competent, objective and fair manner, or unless otherwise allowed by law. In addition, I will not disclose any records or evidence from which research subjects might be identified except to those who need to know in order to carry out the research misconduct proceeding or as otherwise prescribed by law.
6. While on the premises of NIH, and while performing services for this assignment off the premises of NIH, I will conform to all applicable administrative instructions and requirements of the Department of Health and Human Services and NIH.

I understand that my assignment becomes effective upon the date of my signature below and ends upon the completion of my services with regard to the intramural research misconduct proceeding, or as otherwise instructed by the AIRIO or designee. I also understand that my assignment may be terminated at any time by the NIH, and that a request by me to terminate my assignment may be considered by the AIRIO in his or her discretion.

_____

Signature of Federal Employee Participant Date

Attachment 3

Standard Format for the Investigation Report

The following format should be used in preparing the Investigation Report, except when an Investigation's unique circumstances suggest a different approach. In any Investigation, the report must incorporate the elements described in section X.A of the Research Misconduct Policy.

Background

- Allegation(s) (including identification of the Respondent)
- Chronology of relevant events
- Identification of PHS support

Inquiry: Summary of Process and Recommendations

Investigation: Summary of Process

- Composition of Investigation Committee
- Identification of research misconduct policies and procedures on which Committee relied
- Committee meeting dates (including discussion of any time extension granted)
- Individuals interviewed and dates of interviews
- Research records and evidence sequestered and reviewed

Investigation: Analysis of Each Allegation

- Summary of the relevant facts for each allegation
- Identification and analysis of the relevant evidence supporting the Committee's statement of findings for each allegation (below)

Statement of Findings for Each Allegation

- Identify whether research misconduct did or did not occur, and if so:
- Identify whether the misconduct was falsification, fabrication, or plagiarism
- Identify whether it was intentional, knowing, or in reckless disregard
- Identify the person(s) responsible for the research misconduct

Recommendations for Administrative Action

- Identify whether any publications need correction or retraction
- List any current support or known applications or proposals for support that the Respondent has pending with non-PHS federal agencies
- Describe any recommended administrative actions that the Investigation Committee believes the NIH should take, including appropriate actions against the Respondent (optional)
- Document evidence that suggests an allegation may have been made in bad faith (optional)

Attachments