

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

Revised: November 19, 2018

**NIH INTRAMURAL RESEARCH PROGRAM POLICIES & PROCEDURES
FOR RESEARCH MISCONDUCT PROCEEDINGS**

Revised: November 19, 2018

I.	INTRODUCTION	1
II.	APPLICABILITY AND SCOPE	1
III.	DEFINITIONS	2
IV.	ROLES AND RESPONSIBILITIES	6
	A. Deciding Official (DO)	6
	B. NIH Agency Research Integrity Liaison Officer (ARILO)	6
	C. NIH Agency Intramural Research Integrity Officer (AIRIO)	7
	D. Complainant	8
	E. Respondent.....	9
	F. Institute/Center Director	11
	G. Institute/Center Scientific Director and Deputy Scientific Director	11
V.	GENERAL POLICIES AND PRINCIPLES	11
	A. Responsibility to Report Misconduct.....	11
	B. Cooperation with NIH Research Misconduct Proceedings	11
	C. Confidentiality	12
	D. Interim Administrative Actions; Notification of Special Circumstances	12
	E. Correction of the Research Record; Communication with Publishers	13
VI.	ASSESSMENT OF ALLEGATIONS OF RESEARCH MISCONDUCT	14
	A. Bringing an Allegation of Research Misconduct.....	14
	B. Assessment of Allegations	15
VII.	CONDUCTING THE INQUIRY	15
	A. Purpose and Initiation of the Inquiry	15
	B. Notice to Respondent.....	16
	C. Sequestration of Research Records.....	16
	D. Appointment of the Inquiry Committee.....	17
	E. First Meeting and Charge to the Committee	18
	F. Inquiry Process.....	19
	G. Timeline for Completion.....	20
VIII.	THE INQUIRY REPORT	20
	A. Elements of the Inquiry Report.....	20
	B. Notice to Respondent and Complainant; Opportunity to Comment	21
	C. NIH Decision and Notification	21
IX.	CONDUCTING THE INVESTIGATION	22
	A. Purpose and Initiation of the Investigation	22
	B. Notice to ORI and Respondent; Sequestration of Research Records	23
	C. Appointment of the Investigation Committee.....	23
	D. First Meeting and Charge to the Committee	24
	E. Investigation Process	26
	F. Timeline for Completion.....	27

X.	THE INVESTIGATION REPORT	27
A.	Elements of the Investigation Report.....	27
B.	Comments on the Draft Report and Access to Evidence	28
C.	Decision by Deciding Official	29
D.	Notification of NIH Findings and Actions; Requests for Comment.....	29
E.	Maintaining Records for Review by ORI	31
XI.	ADMISSIONS AND SETTLEMENTS; REPORTING OBLIGATIONS	31
XII.	NIH ADMINISTRATIVE ACTIONS	31
XIII.	OTHER CONSIDERATIONS	32
A.	Termination or Resignation Prior to Completing Inquiry or Investigation	32
B.	Restoration of the Respondent’s Reputation.....	32
C.	Protection of the Complainant, Witnesses, and Committee Members	33
D.	Allegations Not Made in Good Faith.....	33
E.	ORI Review and HHS Administrative Actions	33

ATTACHMENTS

1. Confidentiality Statement
2. NIH Intramural Research Misconduct Proceeding Federal Employee Participant Statement
3. Outline for an Inquiry Report
4. Outline for an Investigation Report
5. Sample Respondent Admission Statement and Sample Voluntary Settlement Agreement

NIH INTRAMURAL RESEARCH PROGRAM POLICIES & PROCEDURES FOR RESEARCH MISCONDUCT PROCEEDINGS

Revised: November 19, 2018

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) Intramural Research Program (IRP). The process of reviewing allegations must be balanced by equal concern for protecting the integrity of the research as well as the careers and reputations of researchers.

These NIH IRP 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 proceedings to have the opportunity to participate appropriately in addressing the relevant issues and seeks to protect innocent participants from adverse consequences. Confidentiality helps protect innocent people who are incorrectly or unjustly accused and those who bring the allegations. A prompt response to an allegation helps to minimize any harm to the public that could result if research misconduct is found and allows those who are incorrectly accused to clear their names without going through a long process. Allegations of research misconduct that prove to be untrue, even if made in good faith, can damage careers and have a chilling effect on research. Fair, confidential, and prompt treatment of research misconduct allegations is important and also fosters an institutional climate supportive of honest, good-faith reporting of possible research misconduct.

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, available at <https://ori.hhs.gov/statutes-regulations>), this Policy applies to alleged or actual research misconduct involving biomedical or behavioral research, research training, or activities that are related to research or research training, such as the operation of tissue and data banks and the dissemination of research information:

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

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 recommended 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. Intentionally** – Purposefully acts to propose, perform, review research, or report research results that included falsified, fabricated or plagiarized materials.
- K. 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.
- L. Knowingly** – Uses falsified, fabricated, or plagiarized material to propose, perform, review research, or report research results knowing that the material has been falsified, fabricated or plagiarized.
- M. NIH research misconduct proceeding or NIH proceeding** – Any actions taken by or through the NIH intramural research program related to a research misconduct proceeding subject to this Policy including, but not limited to, allegation assessments, Inquiries, Investigations, and administrative actions taken by NIH following completion of an Investigation.
- N. NIH staff** – NIH employees, as well as trainees, fellows, contractors, special government employees (SGEs), volunteers, former employees, and other persons engaged to perform a service in support of NIH.

- O. 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.
- P. 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.
- Q. PHS Regulations** – The Public Health Service (PHS) Policies on Research Misconduct, 42 C.F.R. Part 93.
- R. 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.
- S. Recklessly** – Uses falsified, fabricated or plagiarized material to propose, perform, review research, or report research results without exercising the proper care or caution, and disregarding or showing indifference to the risk that the materials were falsified, fabricated or plagiarized.
- T. 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 the PHS Regulations and 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 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 proceeding, 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 recommended 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; and
2. 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 act promptly and take 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, throughout the NIH Intramural Research Program;
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 recommended 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.

In a given NIH research misconduct proceeding, the AIRIO may delegate, as necessary, one or more of the above-referenced responsibilities to authorized NIH staff.

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, if known, usually is interviewed and, when feasible, an audio recording of the interview is made. Upon the request of an Inquiry Committee, the AIRIO has the discretion to approve preparation of a transcript of the recording. When a transcript is prepared, the Complainant is provided an opportunity to correct errors in transcription. The transcript (or, if no transcript is prepared, the audio recording) is entered into the record of the proceeding. 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. An audio recording of the interview is made and, when feasible, professionally transcribed. When a transcript is prepared, the Complainant is provided an opportunity to correct errors in transcription. The transcript (or, if no transcript is prepared, the audio recording) is entered into the record of the proceeding. 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 NIH proceeding) and, subject to the AIRIO's prior approval, bring the counsel or personal adviser to interviews or meetings during the NIH proceeding. 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 NIH 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 stage if requested by the Inquiry Committee. When feasible, an audio recording of the interview is made. Upon the request of an Inquiry Committee, the AIRIO has the discretion to approve preparation of a transcript of the recording. When a transcript is prepared, the Respondent is provided an opportunity to correct errors in transcription. The transcript (or, if no transcript is prepared, the audio recording) is entered into the record of the proceeding.
- consult with his/her own legal counsel or a non-lawyer personal adviser (who may not be a principal or witness in the NIH proceeding) and bring the counsel or personal adviser to interviews or meetings during the NIH proceeding. 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 NIH 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.
- be interviewed during the Investigation stage. An audio recording of the interview is made and, when feasible, professionally transcribed. When a transcript is prepared, the Respondent is provided an opportunity to correct errors in transcription. The transcript (or, if no transcript is prepared, the audio recording) is entered into the case record.
- 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. An audio recording of the interview is made and, when feasible, professionally transcribed. When a transcript is prepared, the witness is provided an opportunity to correct errors in transcription. The transcript (or, if no transcript is prepared, the audio recording) is entered into the record of the proceeding.
- 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 NIH research misconduct proceeding, the Respondent has the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the AIRIO and/or other NIH officials, the Deciding Official may terminate the NIH's review of an allegation that has been admitted, if the NIH's acceptance of the admission and any proposed settlement is

approved by ORI. The ORI typically will prepare a Voluntary Settlement Agreement (VSA) for review by the Respondent (see Attachment 5 for a sample VSA). Once the VSA is approved and signed by the Respondent and HHS, the NIH proceeding is terminated.

F. Institute/Center Director

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

G. Institute/Center Scientific Director and Deputy Scientific Director

NIH IC Scientific Directors (SDs), Deputy SDs, and other NIH officials as needed, are informed of the NIH research misconduct proceeding and may notify other NIH staff on an as needed basis to manage effectively agency resources and protect agency programs, consistent with the provisions described in section V(C), below. If requested by the AIRIO during an NIH proceeding, the Executive Officer, Chief Information Officer, and/or Administrative Officer, or their agents of a Respondent's IC may assist in the securing of evidence, and in other matters as needed. Typically, the Deputy SD of the Respondent's IC serves as Co-Executive Secretary during the NIH proceeding. The Deputy SD also serves as the AIRIO's point of contact with regard to financial expenditures related to the NIH proceeding, which are the responsibility of the Respondent's IC. For an IC that does not have a SD or Deputy SD, or in a case where a SD or Deputy SD 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 NIH Research Misconduct Proceedings

All NIH staff will cooperate with the AIRIO and other NIH officials in NIH research misconduct proceedings, including the review of allegations and the conduct of Inquiries and Investigations. NIH staff, 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. 42 CFR 93.108.

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 disclosure of the identity of Inquiry or Investigation committee members and Inquiry or Investigation witnesses should be limited, to the extent possible, to those who need to know.

Records related to NIH research misconduct proceedings are part of a Privacy Act system of records, "NIH Records Related to Research Misconduct Proceedings, HHS/NIH," 09-25-0223 (77 Fed. Reg. 52043 (Aug. 28, 2012)). The AIRIO may use written confidentiality statements or other mechanisms to help maintain confidentiality of NIH research misconduct proceedings. (See Confidentiality Statement, Attachment 1).

D. Interim Administrative Actions; Notification of Special Circumstances

Throughout an NIH research misconduct proceeding (*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.

E. Correction of the Research Record; Communication with Publishers

Subject to the Confidentiality provisions in section V(C) above, if an NIH research misconduct proceeding involves published research, the corresponding author has a responsibility to contact the publisher and have the research record corrected as soon as feasible, which may be prior to completion of the NIH proceeding as described below. Where the Respondent is the corresponding author on the publication, this responsibility typically can be handled by the Respondent's supervisor for the research in question (*e.g.*, lab chief or principal investigator). The AIRIO should be consulted for guidance.

If an NIH proceeding is not yet complete or if no finding of research misconduct has been made, communication with a publisher can reference errors in the research without attributing individual responsibility. Unless and until NIH has made a finding at the conclusion of an NIH research misconduct proceeding, a proposed correction or retraction notice should not characterize the errors as research misconduct. Information regarding the existence of a pending NIH research misconduct proceeding, or details of such proceeding, should not be shared with the publisher unless necessary for NIH to obtain information from the publisher to assist review of allegations in an NIH proceeding. The AIRIO shall coordinate any request for assistance or information collection from third parties, including publishers, during an NIH proceeding.

A corresponding author (or supervisor) should work with the AIRIO to avoid the need for multiple corrections of a publication, if feasible. For example, if errors are identified in a single table, the corresponding author should review the remaining figures in the publication to confirm accuracy before contacting the publisher about the errors.

If NIH makes a finding at the conclusion of an NIH research misconduct proceeding and has informed ORI of the finding, NIH may make a disclosure to research collaborators of the Respondent, professional journals, other publications, news media, professional societies, other individuals and entities, and the public. The disclosure may include information concerning the research misconduct finding and the need to correct or retract research results or reports that have been affected by research misconduct, unless NIH determines that release of the specific information in the context of a particular case would constitute a clearly unwarranted invasion of personal privacy. Such disclosure constitutes a “routine use” as described in the applicable Privacy Act system of records notice, “NIH Records Related to Research Misconduct Proceedings, HHS/NIH,” 09-25-0223 (77 Fed. Reg. 52043 (Aug. 28, 2012)).

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 (AIRIO@nih.gov, 301-827-7745).

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). An anonymous complaint may include a situation in which the AIRIO is notified about an anonymous comment or blog posted online regarding alleged research misconduct that has occurred in published research available on the internet.

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. 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. The AIRIO's assessment may include, as needed, confidential consultation with NIH staff who have scientific expertise relevant to the subject matter of an allegation.

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 allegation(s) described in the notification memo should be as specific as feasible given the facts available at the time. Unless further amended during the Inquiry, the allegation(s) as described in the notification memo should provide the basis on which the Inquiry Committee's review is focused. ORI has provided the following example as a recommended format for framing an allegation: *Respondent falsified (Figure X) in (paper X) by (describe what is false and how the figure was falsified).*

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 undistruptive 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. If additional allegations are added during the Inquiry, or if the original allegations described in the notification memo are amended, the Respondent(s) should 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 record of the proceeding), 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. The AIRIO may establish and update as needed one or more Standard Operating Procedures that describe aspects of the intended sequestration process in greater detail.

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. The Inquiry Committee may include members of the CSCE. 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.

If necessary to secure additional 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 NIH 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).

Typically, the Deputy SD of the Respondent's IC serves as Co-Executive Secretary for the Committee. The other Co-Executive Secretary will be designated by the AIRIO. One or more attorneys from the HHS Office of the 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 (which should be consistent with allegations provided to the Respondent in the notification memo per section VII(B) above).
- describes any 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, if desired, to determine whether an allegation or apparent instance of research misconduct warrants an Investigation.
- states that an Investigation is warranted if the Committee determines that the criteria of the PHS Regulations and this Policy, described below in section VII(F), have been met.
- 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 Committee meetings and interviews, Inquiry Committee members are directed not to discuss the NIH 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 needed, as well as examine relevant research records and materials. An audio recording of each interview is made and, when feasible, professionally transcribed. When a transcript is prepared, the interviewee is provided an opportunity to correct errors in transcription. 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 transcript (or, if no transcript is prepared, the audio recording) is entered into the record of the proceeding.

The Inquiry Committee will evaluate the evidence, including testimony obtained during the Inquiry. After consultation with the AIRIO and, if necessary, the Office of the General Counsel, the Committee will decide whether or not to recommend that an Investigation is warranted.

Under the PHS Regulations and this Policy, an Investigation is warranted if the following criteria are met:

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 (see section II above); and
2. The allegation may have substance, based on the preliminary information-gathering and preliminary fact-finding conducted by the Committee during the Inquiry.

The 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, a finding of 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 regarding the sufficiency of the admission statement and

to determine the next steps that should be taken, as described in section XI below and Attachment 5.

Inquiry Committee members are expected to be present for all Committee meetings and interviews. When necessary (*e.g.*, to ensure attendance or to avoid prolonged delay or unreasonable expense), the AIRIO may make arrangements to use video conference, audio conference, or similar technology for an Inquiry Committee meeting or interview. In the event a Committee member is absent from one or more meetings or interviews, the AIRIO may in 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 Inquiry Report must include the following information:

1. The name and position of the Respondent;
2. A description of the allegations of research misconduct (which should be consistent with the allegations provided to Respondent in the original notification memo or, if applicable, an updated version thereof);
3. The PHS support (*e.g.*, if applicable, a statement that the research was funded and carried out within the NIH IRP);
4. The basis for recommending, or not recommending, that the allegations warrant an Investigation, including a summary of the relevant evidence (or lack of evidence) on which the Committee's recommendation is based;
5. If an extension of time was granted for completion of the Inquiry, documentation of the reasons for exceeding the 60-day period;
6. In the final version of the report, any comments submitted by the Respondent or the Complainant on the draft report, per section VIII(B) below.

In addition, the Inquiry Report should include the following information:

7. The names, titles, and affiliations of the Inquiry Committee members;
8. The dates of Committee meetings and interviews;
9. The Inquiry Committee's reply to any comments submitted by the Respondent or the Complainant on the draft report, per section VIII(B) below, including a description of any changes made to the draft Report as a result of the comments;
10. As an attachment, a list of the documentary evidence examined and interviews conducted.

The Inquiry Report may include Committee recommendations as to whether any actions should be taken if an Investigation is not recommended. When the Inquiry Committee's decision is not unanimous, the Report also may include a separate statement summarizing the minority viewpoint.

An outline for an Inquiry Report is provided in Attachment 3.

A draft report will be provided to the HHS Office of the 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 of the Inquiry Committee's recommendation as to whether or not an Investigation is warranted, and will 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 and/or add a written reply to the comments, as appropriate, and prepare the report 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) 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 NIH research misconduct proceeding, as appropriate, to resolve any questions that may exist concerning the status of the NIH 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 (if not previously provided), 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. The AIRIO may establish and update as needed one or more Standard Operating Procedures that describe aspects of the intended sequestration process in greater detail.

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. The Investigation Committee may include members of the CSCE. 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. In addition, if necessary to secure additional 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 NIH 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).

Typically, the Deputy SD of the Respondent's IC serves as Co-Executive Secretary for the Committee. The other Co-Executive Secretary will be designated by the AIRIO. One or more attorneys from the HHS Office of the 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 Committee meetings and interviews, Investigation Committee members are directed not to discuss the NIH 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. An audio recording of each interview is made and, when feasible, professionally transcribed. When a transcript is prepared, the interviewee is provided an opportunity to correct errors in transcription. 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 transcript (or, if no transcript is prepared, the audio recording) is entered into the record of the proceeding.; 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.

A finding of research misconduct made under the PHS Regulations and 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.

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 an NIH research misconduct proceeding or following additional ORI proceedings.

Investigation Committee members are expected to be present for all Committee meetings and interviews. When necessary (*e.g.*, to ensure attendance or to avoid prolonged delay or unreasonable expense), the AIRIO may make arrangements to use video conference, audio conference, or similar technology for an Investigation Committee meeting or interview. In the event a Committee member is absent from one or more meetings or interviews, the AIRIO may in 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 recommended findings, providing the draft Report for comment, review and final decision by the DO, 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. should include the names, titles, and affiliations of the Investigation Committee members;
5. should include the dates of Committee meetings and interviews;
6. includes the NIH policies and procedures under which the Investigation was conducted (*i.e.*, this Policy), unless those policies and procedures were provided to ORI previously;

7. if an extension of time was granted for completion of the Investigation, should document 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 recommended findings; *i.e.*, for each separate allegation of research misconduct identified during the Investigation, includes a recommended 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;
11. when the Committee's decision is not unanimous, may include a separate statement summarizing the minority viewpoint;
12. may document evidence that suggests an allegation may have been made in bad faith; and
13. in the final version of the Investigation Report, includes any comments submitted by the Respondent or the Complainant on the draft report, per section X(B) below, along with the Committee's written reply, which should address any changes made to the draft Report as a result of the comments.

An outline for an Investigation Report is provided in Attachment 4.

A draft report will be provided to the HHS Office of the General Counsel for legal review. Modifications may be made as appropriate, in consultation with the AIRIO and the Investigation Committee.

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 considered and included 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 considered and included 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 considered and included, and transmit the final Investigation Report to the DO, who will determine in writing: (1) whether the NIH accepts the Investigation Report, its recommended findings, and any recommended NIH actions; and (2) the appropriate NIH actions to be taken, if any, in response to accepted findings of research misconduct. If this determination varies from the recommended 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 recommended 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.

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. Notification of NIH Findings and Actions; Requests for Comment

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.

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.

After NIH makes a finding of research misconduct and has informed ORI of the finding, NIH will determine whether notice to other parties is necessary. To the extent consistent with the “routine uses” described in the applicable Privacy Act system of records notice, “NIH Records Related to Research Misconduct Proceedings, HHS/NIH,” 09-25-0223 (77 Fed. Reg. 52043 (Aug. 28, 2012)), such parties may include the following depending on the circumstances:

- Other Federal, State, local, or Tribal governmental agencies and offices;
- Law enforcement;
- Institutional Review Boards, research-sponsoring institutions, individual research subjects;
- Responsible officials of NIH- or PHS-supported institutions or organizations;
- Research collaborators of the Respondent, professional journals, other publications, news media, professional societies, other individuals and entities, and the public.

The AIRIO is responsible for ensuring compliance with all notification requirements of other funding or sponsoring agencies, if applicable.

If NIH IRP receives a request for comment regarding an NIH research misconduct proceeding, *e.g.*, a press inquiry following NIH’s disclosure of a finding, a response should be coordinated through the AIRIO’s office. The following statement has been approved for use in response to a request for comment:

NIH takes allegations of research misconduct seriously. NIH does not discuss whether or not a research misconduct proceeding is taking place, and does not comment on ongoing or completed NIH proceedings. The HHS Office of Research Integrity (ORI) oversees and directs Public Health Service (PHS) research integrity activities on behalf of HHS. After NIH makes a finding of research misconduct, it informs ORI of the finding. Once it has reported to ORI, NIH may, if necessary, make disclosures under certain conditions to professional journals, research collaborators, and others concerning the NIH finding and the need to correct or retract research results or reports that have been affected by research misconduct. All ORI findings of research misconduct are posted on the HHS Office of Research Integrity website: <https://ori.hhs.gov/>.

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 (42 CFR 93.317). 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, whichever is later. 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. At any time during the NIH research misconduct proceeding, the Respondent has the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the AIRIO and/or other NIH officials, the Deciding Official may terminate the NIH’s review of an allegation that has been admitted, if the NIH’s acceptance of the admission and any proposed settlement (typically known as a Voluntary Settlement Agreement) is approved by ORI. A sample Respondent Admission Statement and Voluntary Settlement Agreement are included in Attachment 5.

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 NIH proceeding 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 recommended 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:

- retraction or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found (though earlier corrective action may be appropriate for publications, per section V(E) above);
- 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 NIH 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 NIH proceeding 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 also may 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 Inquiry Report or 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 [<https://ori.hhs.gov/>](https://ori.hhs.gov/).

CONFIDENTIALITY STATEMENT

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

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

The NIH Intramural Research Program is conducting an NIH 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. sec. 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 NIH 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 that 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 proceeding), or with others who may assist Respondent in his or her defense.

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)

**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) Intramural Research Program by sharing my scientific expertise and participating in an NIH 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 NIH 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 NIH 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

Outline for an Inquiry Report

The PHS Regulations and this NIH Policy require an Inquiry Report to be prepared during the course of an NIH research misconduct proceeding (see section VIII of this Policy). The following outline is based, in part, on guidance received from ORI. This outline may be used to prepare an Inquiry Report, though special factors in a given NIH proceeding may necessitate a different approach. Section VIII(A) of this Policy describes mandatory, recommended, and discretionary elements of the Inquiry Report.

1. Background

Provide sufficient background information to ensure a full understanding of the issues that concern NIH and the Public Health Service under the definition of research misconduct, including:

- a. The name and position of the Respondent;
- b. Role of the Complainant and his or her name and position (unless the allegation was made anonymously or upon request that identity be withheld);
- c. The facts leading to the Inquiry, including a description of the research at issue, relevant dates, identification of relevant persons involved, and any associated public health issues.

2. Allegations

Describe the allegations of research misconduct against the Respondent, including any additional allegations that arose during the Inquiry. The allegations listed in this section should be consistent with those identified in the original notification memo to the Respondent or, if applicable, an updated version thereof. These allegations will form the structure or context in which the subsequent analysis and findings are presented in the report.

3. PHS Support

For each allegation, identify the PHS support (*e.g.*, if applicable, a statement that the research was funded and carried out within the NIH IRP).

4. Inquiry Committee Members and Activities

Summarize the Inquiry process, including the following information:

- a. The names, titles, and affiliations of the Inquiry Committee members;
- b. The dates of Committee meetings and interviews and identification of persons interviewed;

- c. Reference to the policies and procedures used by the Committee for the Inquiry, *i.e.*, this Policy (The NIH IRP Policies and Procedures for Research Misconduct Proceedings);
- d. If an extension of time was granted for completion of the Inquiry, documentation of the reasons for exceeding the 60-day period;
- e. Any other factors that may have influenced the proceedings.

5. Evidence Examined

Summarize the evidence secured and reviewed. Describe the sequestration process, including how and when records were sequestered and the measures taken to ensure security of the records. Include as an attachment a list of the documentary evidence examined and interviews conducted.

6. Analysis

As a reminder, under the PHS Regulations and this Policy, an Investigation is warranted if the following criteria are met:

- a. 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 (see section II of this Policy); and
- b. The allegation may have substance, based on the preliminary information-gathering and preliminary fact-finding conducted by the Committee during the Inquiry.

For each allegation, the analysis should describe the basis for recommending, or not recommending, that the allegation warrants an Investigation, including a summary of the relevant evidence (or lack of evidence) on which the Committee's recommendation is based.

The analysis for each allegation should take into account all of the relevant statements, claims (*e.g.*, a claim of a significant positive result in an experiment), rebuttals, documents, and other evidence, including circumstantial evidence, related to the issue. The source of each statement, claim, or other evidence should be cited (*e.g.*, laboratory notebook with page and date, medical chart documents and dates, relevant manuscripts, transcripts of interviews, etc.).

Summarize or quote relevant statements, including rebuttals, made by the Complainant, Respondent, and other pertinent witnesses and reference/cite the appropriate sources. The analysis should describe the relative weight given to the various witnesses and pieces of evidence, noting inconsistencies, credibility, and persuasiveness.

Include discussion of each argument that the Respondent raised in his or her defense against the research misconduct allegation and cite the source of each argument. Any inconsistencies among the Respondent's various arguments should be noted.

If the allegations involve images, indicate whether the Committee reviewed them visually or by forensic image analysis in order to reach its decisions.

If applicable, any use of additional expert analysis should be discussed. The forensic, statistical, or special analysis of the physical evidence, such as similarity of features or background in contested figures, should be noted and included with attachments.

7. Conclusion

Based on the analysis in section 6 above, concisely state whether, for each allegation, the Inquiry Committee recommends or does not recommend that the allegation warrants an Investigation.

The Inquiry Committee may choose to include recommendations as to whether any actions should be taken if an Investigation is not recommended (*e.g.*, correction or retraction of a publication for errors, even if such errors were determined by the Committee not to result from research misconduct).

When the Inquiry Committee's decision is not unanimous, the Report also may include a separate statement summarizing the minority viewpoint.

8. Reply to Comments (for final version of Report)

If the Respondent or Complainant submits comments on the draft Inquiry Report, it is recommended that the Inquiry Committee include a written reply to such comments in the final version of the Inquiry Report. The reply should include a description of any changes made to the draft Report as a result of the comments.

9. Report Attachments

At a minimum, the Inquiry Report should include a list of the documentary evidence examined and interviews conducted. If feasible, the attachments also should include copies of significant documentary evidence that is referenced in the report (*e.g.*, relevant notebook pages or other research records, relevant committee or expert analyses of data, transcripts or summary of each interview, manuscripts, publications or other documents).

The final version of the Inquiry Report must include any comments submitted by the Respondent or the Complainant on the draft report.

If documentary evidence is attached, it is useful to identify the allegedly false statements, misrepresentations in figures or parts of figures, areas of plagiarism, etc. on a copy of the page or section of the questioned document (*e.g.*, a page from a research notebook). For alleged plagiarism, a side-by-side comparison with the original data or text that is alleged to have been plagiarized is helpful.

Where multiple attachments are included with the Report, add a “List of Attachments” as the first attachment.

Outline for an Investigation Report

The PHS Regulations and this NIH Policy require an Investigation Report to be prepared during the course of an NIH research misconduct proceeding (see section X of this Policy). The following outline is based, in part, on guidance received from ORI. This outline may be used to prepare an Investigation Report, though special factors in a given NIH proceeding may necessitate a different approach. The Investigation Report must incorporate, at a minimum, the required elements described in section X(A) of this Policy.

1. Background

Provide sufficient background information to ensure a full understanding of the issues that concern NIH and the Public Health Service under the definition of research misconduct, including:

- a. The name and position of the Respondent;
- b. Role of the Complainant and his or her name and position (unless the allegation was made anonymously or upon request that identity be withheld);
- c. The facts leading to the NIH research misconduct proceeding, including a description of the research at issue, relevant dates, identification of relevant persons involved, and any associated public health issues;
- d. A list of any current support or known applications or proposals for support that the Respondent has pending with non-PHS federal agencies.

2. Allegations

Describe the allegations of research misconduct against the Respondent, including any additional allegations that arose during the Investigation. The allegations listed in this section should be consistent with those identified in the Investigation notification memo to the Respondent or, if applicable, an updated version thereof. These allegations will form the structure or context in which the subsequent analysis and findings are presented.

3. PHS Support

For each allegation, identify the PHS support (*e.g.*, if applicable, a statement that the research was funded and carried out within the NIH IRP).

4. Inquiry Summary

Summarize the Inquiry process, including reference to the Inquiry Report. Discuss any factors of particular relevance to the Investigation Committee's subsequent review.

5. Investigation Committee Members and Activities

Summarize the Investigation process, including the following information:

- a. The names, titles, and affiliations of the Investigation Committee members;
- b. The dates of Committee meetings and interviews and identification of persons interviewed;
- c. Reference to the policies and procedures used by the Committee for the Investigation, *i.e.*, this Policy (The NIH IRP Policies and Procedures for Research Misconduct Proceedings);
- d. If an extension of time was granted for completion of the Investigation, documentation of the reasons for exceeding the 120-day period;
- e. Any other factors that may have influenced the proceedings.

6. Evidence Examined

Summarize the research records and evidence secured and reviewed, including any new evidence sequestered after the Inquiry. Describe the sequestration process, including how and when records were sequestered and the measures taken to ensure security of the records. Include as an attachment a list that identifies the interviews conducted and the research records and evidence reviewed, as well as any evidence taken into custody but not reviewed.

7. Analysis

As a reminder, a finding of research misconduct made under the PHS Regulations and 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.

Points to be Addressed

For each allegation, the analysis should summarize the relevant facts and identify and analyze the relevant evidence supporting the Investigation Committee's statement of recommended findings as set forth in section 8 (below). If not already included as background in section 1, describe the particular matter (*e.g.*, experiment or component of a clinical protocol) in which the alleged misconduct occurred and why and how the issue came to be under investigation.

The analysis should indicate the extent and seriousness of the alleged fabrication, falsification, or plagiarism, including its effect on research findings, publications, research subjects, and the laboratory or project in which the research misconduct occurred. The Report should include the significance of each incident of alleged

misconduct to the overall research results that were reported. For example, in a case involving allegedly falsified or fabricated images, the Investigation Committee should describe the significance of each image alteration to the overall results that are reported in the figure.

Similarly, the analysis should describe the basis for a determination that the alleged misconduct was (or was not) a significant departure from accepted practices in the relevant research community. Specifically, the Report should identify the relevant research community, articulate its accepted practices, and state how the alleged misconduct was (or was not) a significant departure from these accepted practices at the time the alleged misconduct occurred. For purposes of identifying accepted practices, the Committee may choose to reference publications, standards of the institution or relevant professional societies, applicable regulations, or expert opinion.

The analysis also should describe any evidence that shows that the Respondent acted with intent, that is, any evidence that the Respondent knowingly, intentionally, or recklessly engaged in the alleged falsification, fabrication, or plagiarism. Similarly, if applicable, describe the evidence supporting the possibility that honest error or differences of scientific opinion occurred with respect to the allegation in question.

Methodology and Content

The analysis for each allegation should take into account all of the relevant statements, claims (*e.g.*, a claim of a significant positive result in an experiment), rebuttals, documents, and other evidence, including circumstantial evidence, related to the issue. The source of each statement, claim, or other evidence should be cited (*e.g.*, laboratory notebook with page and date, medical chart documents and dates, relevant manuscripts, transcripts of interviews, etc.).

Summarize or quote relevant statements, including rebuttals, made by the Complainant, Respondent, and other pertinent witnesses and reference/cite the appropriate sources. The analysis should describe the relative weight given to the various witnesses and pieces of evidence, noting inconsistencies, credibility, and persuasiveness.

Include discussion as to consideration of 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. Cite the source of each argument. Any inconsistencies among the Respondent's various arguments should be noted.

If the allegations involve images, indicate whether the Committee reviewed them visually or by forensic image analysis in order to reach its decisions.

If applicable, any use of additional expert analysis should be discussed. The forensic, statistical, or special analysis of the physical evidence, such as similarity of features or background in contested figures, should be noted and included with attachments.

8. Statement of Recommended Findings

Based on the analysis in section 7 above, for each allegation, include a concise statement of recommended findings. Specifically, for each separate allegation of research misconduct identified during the Investigation:

- a. include a recommended finding as to whether research misconduct did or did not occur, and if so;
- b. identify whether the research misconduct was falsification, fabrication, or plagiarism;
- c. identify whether it was intentional, knowing, or in reckless disregard;
- d. identify the person(s) responsible for the research misconduct; and
- e. identify whether any publications need correction or retraction.

Where no finding is recommended for a particular allegation, the Investigation Committee may, if applicable, document evidence that suggests the allegation may have been made in bad faith.

9. Reply to Comments (for final version of Report)

If the Respondent or Complainant submits comments on the draft Investigation Report, the Investigation Committee is obligated to consider such comments prior to finalizing the Report. It is recommended that the Committee incorporate a written reply to such comments in the final version of the Investigation Report. The reply should include a description of any changes made to the draft Report as a result of the comments.

10. Recommendations for Administrative Action (Optional)

Based on its recommended findings, the Investigation Committee may recommend administrative actions that it believes should be taken. If the Committee has recommended correction or retraction of a publication, the Committee may include suggested text for a notice of correction or notice of retraction to be published. The Report also should identify any other sources of scientific information (such as data bases) that should be retracted or corrected so that NIH can take steps to ensure that appropriate officials who can effect these corrections or retractions are notified.

11. Minority Opinion (Optional)

When the Investigation Committee's decision is not unanimous, the Report may include a separate statement summarizing the minority viewpoint.

12. Report Attachments

At a minimum, the Investigation Report should include a list of the documentary evidence examined and interviews conducted. If feasible, the attachments also should include copies of significant documentary evidence that is referenced in the report (*e.g.*, relevant notebook pages or other research records, relevant committee or expert analyses of data, transcripts or summary of each interview, manuscripts, publications or other documents). These attachments should be cited in the Report and pages numbered, if possible, when the attachment consists of more than one page.

The final version of the Investigation Report must include any comments submitted by the Respondent or the Complainant on the draft report.

If documentary evidence is attached, it is useful to identify the allegedly false statements, misrepresentations in figures or parts of figures, areas of plagiarism, etc. on a copy of the page or section of the questioned document (*e.g.*, a page from a research notebook). For alleged plagiarism, a side-by-side comparison with the original data or text that is alleged to have been plagiarized is helpful.

Where multiple attachments are included with the Report, add a “List of Attachments” as the first attachment.

Sample Respondent Admission Statement

CONFIDENTIAL
DRAFT

DATE: <Date>

TO: <NIH Agency Intramural Research Integrity Officer (AIRIO)>

FROM: <Respondent>
<Position, IC>

SUBJECT: Admission of Research Misconduct NIH-XX-YY

Dear Dr. Colbert,

I was a <position> with Dr. <Supervisor> in <Branch or division> of the <IC>I from <start date>to <end date>. During that time, I was an author on several publications.

On <Date>, I received a Notification of Inquiry regarding allegations of research misconduct for falsifying and fabrication data, <which was expanded from the original allegations presented on date>, to now include figures in <n> of my publications.

It is with regret and much sorrow that I admit to knowingly and intentionally falsifying and fabricating the results you identified.

1. I admit to falsifying Figure X by <duplication, alterations, etc.> <e.g., *The gel images in fibroblasts and melanocytes are identical in*>
< citation: Title, Authors, Journal, reference, year>
2. I admit to falsifying Figure Y by <duplication, alterations, etc.> <e.g. *Bands have been erased from the final image in*>
< citation: Title, Authors, Journal, reference, year>
3. I admit to falsifying the image in Figure Z by manipulating the image shown there. Specifically, bands have been manipulated by <How manipulated>... in
< citation: Title, Authors, Journal, reference, year>

I was solely responsible for my actions and sincerely apologize to my mentor and my co-workers in Dr. <Supervisor's> laboratory for the embarrassment this has caused. I recognize that it is imperative to correct the research record as required. Please notify the HHS Office of Research Integrity that I will work with them to do what is necessary and appropriate for my case.

Signature and Date

Sample Voluntary Settlement Agreement (based on text provided by ORI)

This Voluntary Settlement Agreement (Agreement) is entered into by and between the United States Department of Health and Human Services (HHS), through the U.S. Public Health Service (PHS), the Office of Intramural Research (OIR) at the National Institutes of Health (NIH), and <Respondent>.

The purpose of this Agreement is to settle the Office of Research Integrity's (ORI's) research misconduct findings against Respondent, who was a <Position (e.g., postdoctoral fellow, staff scientist, research fellow)> in the <Branch>, <IC>, NIH.

Based on Respondent's admission, an assessment conducted by NIH and analysis conducted by ORI in its oversight review, this settlement resolves ORI's research misconduct finding that Respondent engaged in research misconduct supported by <IC>, NIH.

ORI finds that Respondent engaged in research misconduct by reporting falsified and/or fabricated data in the following (*n*) publications <and submitted manuscripts, grant applications, abstracts, etc.>:

- Paper 1
- Paper 2, etc.

ORI finds that Respondent knowingly falsified and/or fabricated data and related images by alteration and/or reuse and /or relabeling of experimental data. Specifically:

- In Paper 1, Respondent falsified and or fabricated results in Figure X by...
- In Paper 2, Respondent falsified and or fabricated results in Figure Y by...

The terms of this agreement are as follows... (to be completed by ORI)