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

Effective January 1, 2026

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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 NIH to address allegations in accordance with 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 satisfies NIH's obligation under the PHS Regulations to have written policies and procedures for addressing research misconduct. The Policy is intended to address and be consistent with all applicable requirements pertaining to institutional responsibilities included in the PHS Regulations. The Policy also includes and is intended to be consistent with applicable definitions in the PHS Regulations. Most importantly, the Policy is intended to enable allegations of research misconduct to be processed fairly, confidentially, and promptly. This includes providing for all reasonable and practical efforts, if requested and appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made.

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.

I. APPLICABILITY AND SCOPE

Consistent with the NIH's responsibilities under the PHS Regulations, this Policy applies to allegations of research misconduct involving any of the following activities if carries out in NIH facilities by any person; funded by the NIH Intramural Research Program (IRP) in any location; or undertaken by NIH staff as part of official NIH duties or NIH training activities, regardless of location:

1. Applications or proposals for PHS support for biomedical or behavioral intramural or extramural research, biomedical or behavioral research training, or activities related to

that research or research training;

2. PHS-supported biomedical or behavioral intramural or extramural research;

3. PHS-supported biomedical or behavioral intramural or extramural research training programs;

4. PHS-supported intramural or extramural activities that are related to biomedical or behavioral research or research training, or activities related to that research or research training, such as, but not limited to, the operation of tissue and data banks or the dissemination of research information;

5. Research records produced during PHS-supported research, research training, or activities related to that research or research training;

6. Research proposed, performed, reviewed, or reported, as well as any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a form of PHS support.

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, including the subsequent use exception.

II. 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 who serves as the Research Integrity Officer or RIO for the NIH Intramural Research Program (IRP) and who is responsible for administering the IRP's written policies and procedures for addressing allegations of research misconduct in compliance with 42 C.F.R. Part 93.

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) and brought directly to the attention of an NIH or HHS official. In accordance with this Policy, allegations should be communicated to the AIRIO.

D. Assessment – A consideration of whether an allegation of research misconduct appears to fall within the definition of research misconduct; appears to involve PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training; and is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The Assessment only involves the review of readily accessible information relevant to the allegation. The AIRIO is responsible for assessing allegations of research misconduct subject to this Policy.

E. Certifying Official – The institutional official responsible for assuring on behalf of the NIH that the NIH IRP has written policies and procedures for addressing allegations of research misconduct, in compliance with the PHS Regulations; and complies with this Policy and the requirements of the PHS Regulations. The Deputy Director for Intramural Research (DDIR) is the Certifying Official for NIH.

F. Complainant – An individual who in good faith makes an allegation of research misconduct.

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

H. DO – Deciding Official – The Deputy Director for Intramural Research (DDIR) is the Institutional Deciding Official for Inquiries. The NIH ARILO is the Institutional Deciding Official who makes final determinations on allegations of research misconduct and any institutional measures. The Deciding Official will not be the same individual as the AIRIO.

I. Evidence – Evidence means anything offered or obtained during a research misconduct proceeding that tends to provide or disprove the existence of an alleged fact. Evidence includes documents, whether in hard copy or electronic form, information, tangible items, and testimony.

J. Fabrication – Making up data or results and recording or reporting them.

K. Falsification – 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.

L. Good faith – As applied to a complainant or witness, good faith means having a reasonable belief in the truth of one's allegation or testimony, based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowledge of or reckless disregard for information that would negate the allegation or testimony. As applied to NIH staff or a committee member, good faith means cooperating with the research misconduct proceeding by impartially carrying out

the duties assigned for the purpose of helping NIH meet its responsibilities under the PHS Regulations and this Policy. An NIH staff member or committee member does not act in good faith if their acts or omissions during the research misconduct proceedings are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

M. Inquiry – The process of preliminary information-gathering information and preliminary 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.

N. Institutional Record - The institutional record comprises:

(a) The records that NIH compiled or generated during the NIH research misconduct proceeding, except records NIH did not consider or rely on. These records include, but are not limited to:

(1) Documentation of the Assessment as required by 42 C.F.R. § 93.306(c).

(2) If an Inquiry is conducted, the Inquiry Report and all records (other than drafts of the report) considered or relied on during the Inquiry, including, but not limited to, research records and the transcripts of any transcribed interviews conducted during the Inquiry, information the Respondent provided to NIH, and the documentation of any decision not to investigate as required by 42 C.F.R. § 93.309(c).

(3) If an Investigation is conducted, the Investigation Report and all records (other than drafts of the report) considered or relied on during the Investigation, including, but not limited to, research records, the transcripts of each interview conducted pursuant to 42 C.F.R. § 93.310(g), and information the Respondent provided to NIH.

(4) Decision(s) by the Deciding Official, such as the written decision from the Deciding Official under 42 C.F.R. § 93.314.

(b) A single index listing all the research records and evidence that NIH compiled during the NIH research misconduct proceeding, except records NIH did not consider or rely on.

(c) A general description of the records that were sequestered but not considered or relied on.

O. Intentionally – To act intentionally means to act with the aim of carrying out the act.

P. Investigation – The formal development of a factual record and the examination of that record. An Investigation must meet the criteria and follow the procedures of the PHS Regulations.

Q. Knowingly – To act knowingly means to act with awareness of the act.

R. NIH research misconduct proceeding or **NIH proceeding** – Any activities by or through the NIH Intramural Research Program related to a research misconduct proceeding subject to this Policy and the PHS Regulations including, but not limited to, allegation Assessments, Inquiries, Investigations, and administrative measures taken by NIH following completion of an Investigation.

S. NIH staff – Individuals who are employed by, are agents of, or are affiliated by contract or agreement with NIH, including NIH employees, as well as NIH trainees, contractors, special government employees (SGEs), volunteers, former employees, and other individuals engaged to perform a service in support of NIH.

T. NIH trainee – Trainees, scholars, fellows, research fellows, and clinical fellows employed by NIH nationwide, including post baccalaureate Cancer Research Training Award (CRTA) and Intramural Research Training Award (IRTA) fellows; predoctoral CRTA, IRTA, and visiting fellows; postdoctoral CRTA, IRTA, and visiting fellows; research fellows; senior research fellows; clinical fellows; communications fellows; data science fellows; genetic counseling training program fellows; medical research scholars; national biosafety and biocontainment fellows; otolaryngology surgery fellows; Postbaccalaureate Research Education Program (PREP) scholars; and technology transfer fellows.

U. Notice – A written or electronic 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.

V. ORI – The Office of Research Integrity – The office established by Public Health Service Act section 493 (42 U.S.C. § 289b) and to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS-supported activities.

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

X. Plagiarism – The appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Plagiarism (a) includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contributions of the author. It does not include the limited

use of identical or nearly identical phrases that describe a commonly used methodology; (b) does not include self-plagiarism or authorship or credit disputes, including disputes among former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct.

Y. Preponderance of the evidence – Proof by evidence that, compared with evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not.

Z. Recklessly – To act recklessly means to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism.

AA. Research – A systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) by establishing, discovering, developing, elucidating, or confirming information or underlying mechanisms related to biological causes, functions or effects; diseases; treatments; or related matters to be studied.

BB. Research misconduct – Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

CC. Research misconduct proceeding – Any actions related to alleged research misconduct taken under the PHS Regulations including, allegation Assessments, Inquiries, Investigations, ORI oversight reviews, and appeals under subpart E of 42 C.F.R. Part 93. See also definition of NIH research misconduct proceeding (section II.R).

DD. Research record – The record of data or results that embody the facts resulting from scientific inquiry. Data or results may be in physical or electronic form. Examples of items, materials, or information that may be considered part of the research record include, but are not limited to, research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meeting reports, and journal articles.

EE. Respondent – The individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

FF. **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 (a) a good faith allegation of research misconduct; or (b) good faith cooperation with a research misconduct proceeding.

GG. **Subsequent use exception** – The Respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the use of, republication of, or citation to the portion(s) of the research record (*e.g.*, processed data, journal articles, funding proposals, data repositories) alleged to have been fabricated, falsified, or plagiarized, for the potential benefit of the Respondent. The subsequent use exception applies to the six-year limitation established under 42 C.F.R. § 93.104 when the Respondent uses, republishes, or cites to the portion(s) of the research record that is alleged to have been fabricated, falsified, or plagiarized, in submitted or published manuscripts, submitted PHS grant applications, progress reports submitted to PHS funding components including NIH, posters, presentations, or other research records within six years of when the allegations were received by HHS or NIH.

III. 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 (if applicable), and/or other NIH officials, decide whether an Investigation is warranted under the criteria in the PHS Regulations. Any determination 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 determination. 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 seven years after termination of the Inquiry, so that ORI may assess the reasons why the NIH decided not to investigate. Where the DO is involved in the proceeding, the NIH Director or their designee will assume the DO's responsibilities as described above.

For Investigations

The ARILO is the DO for Investigations and final determinations of research misconduct findings (Institutional DO). 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 a final determination of research misconduct is made, the DO will determine, or will refer to other appropriate NIH officials to determine, what, if any, NIH administrative measures are appropriate. After the DO has made a final determination of research misconduct findings, NIH will transmit the institutional record 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

3. serves as the DO for Investigations and final determinations of research misconduct findings (Institutional Deciding Official).

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. administers NIH's written policies and procedures for addressing allegations of research misconduct in compliance with the PHS Regulations.

3. conducts institutional Assessments to determine whether a research misconduct allegation warrants an Inquiry;

4. conducts Inquiries, as needed (if, as determined by NIH, the AIRIO has unresolved personal, professional, or financial conflicts of interest with the Respondent(s), Complainant(s), or witnesses or is otherwise unavailable, the DDIR will designate another NIH official to conduct an Inquiry);

5. oversees Inquiries and Investigations;

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

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

8. 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 determination of the Deciding Official that an Investigation is warranted and a copy of the Inquiry Report; and (b) for an Investigation, the institutional record;

9. has lead responsibility for ensuring that NIH takes all reasonable and practical steps to foster research integrity consistent with the PHS Regulations, including informing NIH staff about this Policy and NIH's commitment to compliance with this Policy, and making this Policy publicly available; and

10. may delegate duties to the Deputy AIRIO or other authorized NIH staff to the extent permitted by the PHS Regulations.

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 an Inquiry, the Complainant, if known, may be interviewed and, when feasible, the interview is recorded and transcribed. During an Investigation, the Complainant is interviewed, and the interview is recorded and transcribed. When a transcript is prepared, the Complainant is provided an opportunity to correct errors in transcription. The transcript, with any corrections and numbered exhibits, is entered into the institutional record of the Investigation. The NIH may choose to provide the Complainant the portions of the draft Inquiry Report or Investigation Report that address the Complainant's role and statements in the Inquiry or Investigation and give the Complainant an opportunity to submit comments.

The Complainant:

- May consult with their 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 interview or meeting, their activities will be limited to advising the Complainant, as opposed to representing the Complainant during the interview. The adviser or counsel should not direct questions to the individual(s) conducting the interview.

- May 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's destruction of research records documenting the questioned research is evidence of research misconduct where NIH or HHS establishes by a preponderance of the evidence that the Respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations. The Respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the Respondent claims to possess records but refuses to provide them upon request.

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. If additional allegations are raised, the Respondent will be notified in writing of the additional allegations raised against them.

- Will have an opportunity, at the Inquiry stage (if applicable) and the Investigation stage, 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.

- May raise affirmative defenses, which must be proven by a preponderance of the evidence.

- May be interviewed during the Inquiry stage if requested. When feasible, an audio recording of the interview and a transcript of the recording is made. When a transcript is prepared, the Respondent is provided an opportunity to correct errors in transcription. The transcript is entered into the record of the proceeding.

- May consult with their 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 during an interview or meeting, their activities will be limited to advising the Respondent, as opposed to representing the Respondent. The adviser or counsel should not direct questions to the individual(s) conducting the interview.

- May consult with others who may assist Respondent in their defense, consistent with the responsibility to maintain confidentiality within the bounds established under the PHS Regulations (see section IV(C) below). Individuals who are consulted will be asked to sign a Confidentiality Statement provided by the AIRIO.
- May request that an interpreter for him/her be present during an interview or meeting in the course of the NIH research misconduct proceeding.
- May consult with their union representative if authorized by law and agency policy.
- Will have an opportunity to comment on the draft Inquiry Report and have his/her comments attached to the Report.
- Will be notified of the outcome of the Inquiry, and receive a copy of the final Inquiry Report.
- If there is to be an Investigation, the Respondent will 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 allegations of research misconduct not addressed in the Inquiry or in the initial notice of Investigation, within a reasonable time after the determination to pursue those allegations.
- Will be interviewed during the Investigation stage. The Investigation interview will be recorded and transcribed. Any exhibits shown during the interview are to be numbered and referred to by that number in the interview. The Respondent will be provided an opportunity to correct errors in transcription. The transcript with any corrections and numbered exhibits will be included in the institutional record of the Investigation.
- May 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. The respondent is not permitted to be present during witnesses' interviews but will be provided a transcript of the interview.
- Will receive a copy of the draft Investigation Report and, concurrently, a copy of, or supervised access to the research records and other evidence that the Investigation Committee considered or relied on, and be notified that any comments must be submitted within 30 days of receiving the draft report and that the comments will be considered by the NIH and addressed in the final report.
- Where no finding of research misconduct is made, the Respondent may 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 to committing research misconduct. The admission must be made in writing and signed by the Respondent. The admission must specify the falsification, fabrication, and/or plagiarism that occurred and which research results were affected. The admission statement must meet all elements required for a research misconduct finding under the PHS Regulations. NIH, through the AIRIO and/or other NIH official, will provide the admission to ORI before NIH closes its research misconduct proceeding. NIH also will provide a statement to ORI describing how it determined that the scope of the misconduct was fully addressed by the admission and confirmed the Respondent's culpability.

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 measures, 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 IV(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 research records or other 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.

IV. 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 V(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 conduct of Assessments, 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, Complainants, and witnesses while conducting research misconduct proceedings is limited, to the extent possible, to those who need to know, as determined by NIH, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law. Those who "need to know" may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions, to the extent the disclosure is consistent with Privacy Act system of records, "NIH Records Related to Research Misconduct Proceedings, HHS/NIH," 09-25-0223 (77 Fed. Reg. 52043 (Aug. 28, 2012)) (Privacy Act SORN). The limitation on disclosure of the identity of Respondents, Complainants, and witnesses no longer applies once NIH has made a final determination of research misconduct findings, to the extent consistent with the Privacy Act SORN. However, the NIH must disclose the identity of Respondents, Complainants, or other relevant persons to ORI pursuant to an ORI review of research misconduct proceedings under the PHS Regulations.

Confidentiality must be maintained for any records or evidence from which research subjects might be identified, except as may otherwise be prescribed by applicable law. Disclosure is limited to those who need to know to carry out a research misconduct proceeding, or to implement research misconduct 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. To the extent consistent with the Privacy Act SORN, NIH may manage published data or acknowledge that data may be unreliable.

Records related to NIH research misconduct proceedings are part of the Privacy Act SORN. The AIRIO may use written confidentiality statements or other mechanisms to help maintain confidentiality of NIH research misconduct proceedings.

The confidentiality provisions described in this Policy are consistent with and do not supersede, conflict with, or otherwise alter an NIH staff member's obligations, rights, or liabilities created by existing statute or Executive order relating to (1) classified information, (2) communications to Congress, (3) the reporting to an Inspector General of a violation of any law, rule, or regulation, or mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, or (4) any other whistleblower protection. The definitions, requirements, obligations, rights,

sanctions, and liabilities created by controlling Executive orders and statutory provisions are incorporated into this Policy and are controlling.

D. Notification to ORI of Special Circumstances; Interim Administrative Actions

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;
- HHS may need to take appropriate action to safeguard evidence and protect the rights of those involved.

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.

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 IV(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 final determination of research misconduct findings 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.

F. Record Sequestration, Access, and Maintenance

On behalf of NIH, the AIRIO will promptly take all reasonable and practical steps to obtain all research records and other evidence, which may include copies of the data or other evidence so long as those copies are substantially equivalent in evidentiary value and needed to conduct the research misconduct proceeding. The AIRIO will inventory the records and other evidence, and sequester them in a secure manner. Where the research records or other evidence are located on or encompass scientific instruments shared by multiple users, NIH may obtain copies of the data or other evidence from such instruments, so long as those copies are substantially equivalent in evidentiary value to the instruments. Whenever possible, NIH must obtain the research records or other evidence (1) before or at the time NIH notifies the Respondent of the allegation(s); and

(2) whenever additional items become known or relevant to the Inquiry or Investigation. When the Respondent is a student trainee, the AIRIO will coordinate with the Respondent's affiliated academic institution to ensure all Family Educational Rights and Privacy Act (FERPA) requirements are met before sequestration of any covered documents.

Where appropriate, NIH must give the Respondent copies of, or reasonable supervised access to, the research records that are sequestered in accordance with the above steps. The AIRIO may consult with ORI for advice and assistance in this regard.

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, in order to preserve the integrity of the original research records and evidence received by the AIRIO. NIH must maintain the sequestered records and other evidence as required by 42 C.F.R. § 93.318, as described in section IV(G) below.

Disclosures about the research misconduct proceedings may be made in furtherance of sequestration, to any person able to obtain information or provide information or assistance in a research misconduct proceeding or related proceeding, including extramural institutes for a case when allegation involve research records both in intramural and extramural institutes. 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.

G. Record Retention

NIH is required to maintain the institutional record and all sequestered evidence including physical objects (regardless of whether the evidence is part of the institutional record) in a secure manner for seven years after completion of the NIH research misconduct proceeding or the completion of any HHS proceeding involving the research misconduct allegation under subparts D and E of 42 C.F.R. Part 93, whichever is later, unless custody has been transferred to HHS (as described immediately below) or ORI advises otherwise in writing.

On request, NIH must transfer custody, or provide copies, to HHS of the institutional record or any component of the institutional record and any sequestered evidence (regardless of whether the evidence is included in the institutional record) for ORI to conduct its oversight review, develop the administrative record, or present the administrative record in any proceeding under subparts D and E of 42 C.F.R. Part 93.

For research misconduct that appears subject to the subsequent use exception (see definition at section II.GG above), NIH must document its determination that the subsequent use exception does not apply and retain such documentation pursuant to this section.

H. Role of Certifying Official; Providing Information to ORI

The NIH DDIR serves as the Certifying Official responsible for NIH IRP compliance with the requirements of 42 C.F.R. § 93.301, assuring that NIH: (1) has written policies and procedures for addressing allegations of research misconduct, in compliance with the PHS Regulations; (2) complies with its policies and procedures for addressing allegations of research misconduct; (3) complies with all provisions of the PHS Regulations.

NIH maintains its active research assurance and compliance with the PHS Regulations by (1) having policies and procedures for addressing allegations of research misconduct according to the PHS Regulations, keeping those policies in compliance with the PHS Regulations, and upon request, providing them to ORI and other HHS components; (2) complying with its policies and procedures for addressing allegations of research misconduct; (3) complying with the PHS Regulations; (4) taking all reasonable and practical specific steps to foster research integrity consistent with 42 C.F.R. § 93.300, including but not limited to: (a) informing NIH staff about its policies and procedures for addressing allegations of research misconduct, and NIH's commitment to compliance with the policies and procedures; and (b) making its policies and procedures for addressing allegations of research misconduct publicly available.

V. ASSESSMENT OF ALLEGATIONS OF RESEARCH MISCONDUCT

A. Bringing an Allegation of Research Misconduct

An allegation is a disclosure of possible research misconduct through any means (*e.g.*, by written or oral statement) and brought directly to the attention of 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, 301-917-7233). Allegations may also be communicated using the Anonymous Reporting of Research Misconduct Concerns web form (https://oir.nih.gov/sourcebook/ethical-conduct/research-misconduct/anonymous-reporting-research-misconduct-concerns). The AIRIO's office is notified when a web form is submitted and will assess the information as it would for any allegation of research misconduct received.

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.

In some cases where an allegation of research misconduct is communicated anonymously, or where an individual asks their name to be withheld, an Inquiry or

Investigation may not be able to proceed without identifying and/or obtaining further information from the individual who made the allegation (*i.e.*, the Complainant). An anonymous complaint may include a situation in which an anonymous comment or blog posted online regarding alleged research misconduct in published research is brought directly to the attention of the AIRIO.

If an individual is unsure whether a suspected incident falls within the definition of research misconduct, they 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, the AIRIO will proceed with an Assessment. The AIRIO need not inform the Respondent of the allegation(s) at this stage but may do so in the furtherance of the Assessment.

B. Assessment of Allegations

Upon receiving an allegation of research misconduct, or at the AIRIO's discretion upon becoming aware of evidence of possible research misconduct, the AIRIO or another designated institutional official will promptly assess the allegation to determine whether the allegation:

(1) Falls within the definition of research misconduct in the PHS Regulations and this Policy;

(2) Is within the applicable jurisdictional criteria of the PHS Regulations and this Policy;

(3) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

If these criteria are met, an Inquiry is warranted. If the AIRIO or another designated institutional official determines that requirements for an Inquiry are met, they must document the Assessment and promptly sequester all research records and other evidence, consistent with the PHS Regulations and this Policy (see section IV(F)), and promptly initiate the Inquiry.

If the AIRIO or another designated institutional official determines that requirements for an Inquiry are not met, they must keep sufficiently detailed documentation of the Assessment to permit a later review by ORI of the reasons why the institution did not conduct an Inquiry, and retain such documentation in accordance with the PHS Regulations and this Policy (see section IV(G)).

In conducting the Assessment, the AIRIO need not interview the Complainant, Respondent, or other witnesses, or gather research records or other evidence beyond any that may have been submitted with the allegation, except as necessary to determine whether the criteria for an Inquiry have been met. The 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 Assessment.

VI. CONDUCTING THE INQUIRY

A. Criteria Warranting an Inquiry; Purpose

An Inquiry is warranted if the allegation meets the following three criteria: (1) falls within the definition of research misconduct in the PHS Regulations and this Policy; (2) is within the applicable jurisdictional criteria of the PHS Regulations and this Policy; and (3) is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

The purpose of an Inquiry is to conduct an initial review of the evidence to determine whether an allegation warrants 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 the evidence related to the allegation, although interviewing of key witnesses, including the Complainant(s) and Respondent(s) is permitted.

B. Notice to Respondent

At the time of, or before beginning, an Inquiry, the AIRIO or other designated official 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. Proceedings involving multiple Respondents or multiple institutions are addressed in section XII(B) below.

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 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 undisruptive manner in order to minimize disturbance to the laboratory and embarrassment to the Respondent. When feasible, the Respondent's supervisor (as long as they are not the Complainant), or another IC official, will be present. If the Respondent is an NIH trainee, they may request the presence of a union representative at the time of the notification meeting to the extent authorized by law and agency policy. If a union representative is present at a notification meeting, their activities will be limited to advising the Respondent.

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 they may acquire their own legal counsel. 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. Whenever possible, NIH must obtain the research records or other evidence (1) before or at the time NIH notifies the Respondent of the allegation(s); and (2) whenever additional items become known or relevant to the Inquiry (see section IV(F) above).

C. Options for Conducting the Inquiry

Pursuant to the PHS Regulations, NIH has several options for conducting an Inquiry: (1) review by the AIRIO; (2) review by another designated NIH official; or (3) review by a committee of experts, to be known as the Inquiry Committee. If the review is conducted by the AIRIO or other designated NIH official, they may consult one more subject matter experts to assist them in the Inquiry.

When feasible, an Inquiry will be conducted by the NIH AIRIO. The SD of the Respondent's IC will delegate an IC liaison (typically the Deputy SD) to assist with Inquiry proceedings and to review the draft Inquiry report. If, as determined by NIH, the AIRIO has unresolved personal, professional, or financial conflicts of interest with the Respondent(s), Complainant(s), or witnesses or is otherwise unavailable, the Inquiry will be conducted by another NIH official designated by the DDIR. The designated NIH official must not have unresolved personal, professional, or financial conflicts of interest with the Respondent(s), Complainant(s), or witnesses. If neither of these options is viable for a particular proceeding as determined by NIH, an Inquiry Committee will be appointed to conduct the Inquiry.

D. For Proceedings Using an Inquiry Committee: Appointment

For a research misconduct proceeding in which NIH has determined to use an Inquiry Committee, the AIRIO, in consultation with other NIH officials as appropriate, will appoint the 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 relevant to the Inquiry, including with the Respondent(s), Complainant(s), and witness(es), as determined by NIH, 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.

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

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. For Proceedings Using an Inquiry Committee: First Meeting and Charge

1. Charge to the Committee

For a research misconduct proceeding in which NIH has determined to use an Inquiry 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 VI(B) above).
- describes any related issues identified during the Assessment.
- identifies the Respondent(s).
- defines research misconduct.
- states that an Inquiry is the process of gathering information and initial fact-

finding, which may include 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. This expectation of confidentiality is consistent with and does not supersede, conflict with, or otherwise alter an NIH staff member's obligations, rights, or liabilities created by existing law relating to classified information, communications to Congress, reporting to an Inspector General, or any other whistleblower protection (see Section IV.C above).

2. First Meeting

For a research misconduct proceeding in which NIH has determined to use an Inquiry Committee, at the 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

During the Inquiry, the Respondent, the Complainant, if known, and key witnesses may be interviewed as needed. Relevant research records and other evidence are examined. When feasible, an audio recording of each interview and a transcript of the recording is made. 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 their transcript as an addendum. The transcript (or, if no transcript is prepared, the audio recording) is entered into the record of the proceeding. In the event that an interviewee reveals sensitive personal information, which is not relied upon in conducting a research misconduct proceeding, the AIRIO may redact that information from the transcript, in consultation with the Office of the General Counsel.

During the Inquiry, relevant research records and other evidence will be evaluated, including any testimony obtained. After consultation, if necessary, with the Office of the General Counsel, a decision will be made 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; and

2. The allegation may have substance, based on the preliminary information-gathering and preliminary fact-finding conducted during the Inquiry. Findings of research misconduct, including the determination of whether the alleged misconduct is intentional, knowing, or reckless, cannot be made at the Inquiry stage.

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 X below.

For a research misconduct proceeding in which NIH has determined to use an Inquiry Committee, the Committee's decision need not be unanimous. 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.

At any time during Inquiry process or if it is determined that an Investigation is warranted, the initial allegations may be reviewed and changes made to the wording of the allegations for accuracy and completeness.

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 ninety (90) calendar days of its initiation, 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 90-day period. In addition, the AIRIO should notify the Respondent of the extension.

VII. THE INQUIRY REPORT

A. Elements of the Inquiry Report

The AIRIO, working if applicable with the Inquiry Committee, is responsible for preparing a written draft report for the Inquiry. The Inquiry Report must include the following information:

1. The names, professional aliases, and position of the Respondent and Complainant;
2. A description of the allegation(s) of research misconduct. The description should be substantively consistent with the allegations provided to Respondent in the original notification memo or, if applicable, any modified or additional allegations provided to Respondent in one or more subsequent notification memos;
3. The PHS support (*e.g.*, if applicable, a statement that the research was funded and carried out within the NIH IRP);
4. The composition of the Inquiry Committee, if used, including name(s), position(s), and subject matter expertise;
5. Inventory of sequestered research records and other evidence and description of how sequestration was conducted;
6. Transcripts of any transcribed interviews;
7. Timeline and procedural history;
8. Any scientific or forensic analyses conducted;
9. The basis for recommending that the allegation(s) warrant an Investigation;
10. The basis on which any allegation(s) do not merit an Investigation.
11. In the final version of the report, any comments submitted by the Respondent on the draft report, per section VII(B) below.
12. Any measures taken by NIH, including communications with journals or other funding agencies;
13. A note regarding potential evidence of honest error or difference of opinion;
14. If an extension of time was granted for completion of the Inquiry, documentation of the reasons for exceeding the 90-day period.

In addition, the Inquiry Report may include:

1. The dates of interviews and, if relevant, Inquiry Committee meetings;
2. In the final version of the report, if applicable, any comments submitted by the Complainant on the draft report, per section VII(B) below;
3. A reply to any comments submitted by the Respondent or the Complainant on the draft report, per section VII(B) below, including a description of any changes made to the draft Report as a result of the comments;
4. Written decision from the DO that an Investigation is warranted;
5. If the Inquiry determines that the allegation(s) do not merit an Investigation, recommendations for additional administrative measures that have not yet been taken;
6. If applicable for a proceeding utilizing an Inquiry Committee, a separate statement summarizing the minority viewpoint if the Committee's decision was not unanimous;
7. As an attachment, a list of the research records and other evidence examined, including any interviews conducted, during the Inquiry.

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, if applicable, the Inquiry Committee.

B. Notice to Respondent and Complainant; Opportunity to Comment

The AIRIO shall notify the Respondent whether the Inquiry found that an Investigation is warranted. The notice will include a copy of the draft Inquiry Report and a copy of, or reference to, this Policy and the PHS Regulations.

The NIH is not required to notify the Complainant whether the Inquiry found that an Investigation is warranted. If there are multiple Complainants in a proceeding and NIH decides to provide notice to one Complainant, it will also provide notice, to the extent possible, to the other Complainants in the proceeding. The NIH may, but is not required, to provide the Complainant, if known, relevant portions of the draft Inquiry Report addressing the Complainant's role and statements in the Inquiry and offer the Complainant an opportunity to comment.

The Respondent and, if applicable, the Complainant will provide their comments, if any, to the AIRIO within the time period requested by the AIRIO. Any comments that are submitted by the Respondent will be attached to the final Inquiry Report. Any comments submitted by the Complainant may be attached to the final Inquiry Report. Based on the comments, the draft Inquiry Report may be revised and/or a written reply to the comments may be added, as appropriate, before the report is finalized. The Respondent and, if applicable, the Complainant will not have an additional opportunity to review and comment on the Inquiry Report once comments are submitted. The AIRIO will prepare

the final version of the Inquiry Report for review by the DO.

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 NIH's decision that an Investigation is warranted, the AIRIO will provide ORI with the NIH's written decision and a copy of the Inquiry Report. The AIRIO will also notify those NIH officials who need to know of the NIH'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 other evidence reviewed, and copies of all relevant documents. The AIRIO will also notify ORI of any special circumstances that may exist in accordance with section IV(D) above and the PHS Regulations.

3. Documentation of Decision Not to Investigate

If NIH decides that an Investigation is not warranted, the AIRIO does not need to notify ORI. However, the AIRIO must keep detailed documentation of the Inquiry to permit later assessment by ORI of the reasons why NIH decided not to investigate. Such documentation must be retained in accordance with section IV(G) above and the PHS Regulations. 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 protect or restore the Respondent's reputation, as further described in section XII(C) below.

4. Return of Sequestered Materials

If the DO decides that an Investigation is not warranted, the AIRIO will arrange for all sequestered materials, or copies of them, to be returned to the Respondent

or other parties as appropriate, with consultation and approval by ORI.

VIII. CONDUCTING THE INVESTIGATION

A. Purpose and Initiation of the Investigation; Notice to ORI and Respondent

An Investigation is the formal development of a factual record and the examination of that record in a manner that meets the criteria, and follows the procedures, described in this Policy and in the PHS Regulations. The Investigation ultimately will lead to a recommendation(s) to the Deciding Official as to whether or not there should be a finding of research misconduct. The recommendation(s) will be included in an Investigation Report, which will also include the additional information described in section IX below.

The NIH must begin an Investigation within thirty (30) calendar days after deciding an Investigation is warranted. On or before the date on which the Investigation begins, the AIRIO must (1) notify ORI 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 allegation(s) within a reasonable amount of time of deciding to pursue such allegation(s)

The AIRIO must also give the Respondent written notice of any allegation(s) of research misconduct not addressed during the Inquiry (or in the initial notice of Investigation) within a reasonable amount of time of deciding to pursue such allegation(s). Proceedings involving multiple Respondents or multiple institutions are addressed in section XII(B) below.

B. Appointment of the Investigation Committee

The AIRIO, in consultation with other NIH officials as appropriate, will appoint an Investigation Committee, usually consisting of five voting members, as soon after the initiation of the Investigation as is practical. The Investigation Committee should include individuals who are federal employees and who have the appropriate scientific expertise to evaluate the evidence and issues related to the allegation(s), interview the principals and key witnesses as appropriate, and conduct the Investigation. Individuals who have unresolved personal, professional, or financial conflicts of interest relevant to the Investigation, including with the Respondent(s), Complainant(s), or witnesses, as determined by NIH, may not serve on the Investigation Committee.

When feasible, one member of the Investigation Committee should be an individual 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. The Investigation Committee may include members of the CSCE. In research misconduct proceedings where an Inquiry Committee has been used, the Investigation Committee may consist of the same members who served on the

Inquiry Committee.

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

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.

C. 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 in a manner that meets the criteria, and follows the procedures, described in this Policy and in the PHS Regulations, ultimately leading to a recommendation(s) to the Deciding Official as to whether or not there should be a finding of research misconduct.
- describes the Investigation process (see section VIII(D) below).
- informs the Committee that it must evaluate the research records and other evidence, including testimony, to determine whether to recommend, based on a preponderance of the evidence, a finding(s) of research misconduct and, if so, the individual(s) responsible, the type of misconduct, and the state of mind of the individual(s) responsible.

- informs the Committee that in order to recommend a finding(s) of research misconduct against the Respondent, 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. This expectation of confidentiality is consistent with and does not supersede, conflict with, or otherwise alter an NIH staff member's obligations, rights, or liabilities created by existing law relating to classified information, communications to Congress, reporting to an Inspector General, or any other whistleblower protection (see Section IV.C above).

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.

D. Investigation Process

The Investigation Committee and the AIRIO must:

- obtain all research records and other evidence needed to conduct the Investigation, consistent with the PHS Regulations and section IV(F) of this Policy (Record Sequestration, Access, and Maintenance).

- use diligent efforts to ensure that the Investigation is thorough and sufficiently documented and includes examination of all research records and other evidence relevant to reaching a decision on the merits of the allegation(s);

- 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, subject to the following requirements:

    - Interviews during the Investigation must be recorded and transcribed;

    - Any exhibits shown to the interviewee during the interview must be numbered and referred to by that number in the interview;

    - The transcript of the interview must be made available to the relevant interviewee for correction;

    - The transcript(s) with any corrections and numbered exhibits must be included in the institutional record of the Investigation;

    - The Respondent must not be present during the witnesses' interviews but must be provided a transcript of the interview; 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. If additional allegations are raised, the Respondent(s) must be notified in writing of the additional allegations raised against them.

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, which must be proved by a preponderance of the evidence. A Respondent's destruction of research records documenting the questioned research is evidence of research misconduct where NIH establishes by a preponderance of the evidence that the Respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations, A Respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the Respondent claims

to possess the records but refuses to provide them upon request.

The Respondent has the burden of going forward with and proving, by a preponderance of the evidence, all affirmative defenses raised, including honest error or a difference of opinion. The Respondent also has the burden of going forward with and proving, by a preponderance of the evidence, any mitigating factors relevant to a decision to impose administrative actions after 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.

E. Timeline for Completion

The Investigation is to be completed within 180 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 and the institutional record to ORI. However, if the AIRIO determines that the Investigation cannot be completed within this 180-day period, the AIRIO 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.

IX. THE INVESTIGATION REPORT

A. Elements of the Investigation Report

The Investigation Committee and the AIRIO are responsible for preparing a written draft Investigation Report for each Respondent that includes the following:

1. Description of the nature of the allegation(s) of research misconduct, including any additional allegation(s) addressed during the research misconduct proceeding, as well as the identification of the Respondent;
2. Description of the specific allegation(s) of research misconduct considered in the Investigation of the Respondent;

3. Description and documentation of the PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support;
4. Composition of the Investigation Committee, including names, positions, and subject matter expertise and, if feasible, the dates of Committee meetings and interviews;
5. If an extension of time was granted for completion of the Investigation, the Report may document the reasons for exceeding the 180-day period;
6. Inventory of sequestered research records and other evidence, except records NIH did not consider or rely on; and a description of how any sequestration was conducted during the Investigation. This inventory must include manuscripts and funding proposals, if any, that were considered or relied on during the Investigation;
7. Transcripts of all interviews conducted;
8. Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS funding applications if any, progress reports, annual reports, presentations, posters, or other research records that allegedly contained the falsified, fabricated, or plagiarized material;
9. Any scientific or forensic analyses conducted:
10. 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;
11. A statement for each separate allegation whether the Investigation Committee recommends a finding of research misconduct.
    (a) If the Investigation Committee recommends a finding of research misconduct, the Investigation Report must, for that allegation:
        i. identify the individual(s) who committed the research misconduct;
        ii. indicate whether the research misconduct was falsification, fabrication, and/or plagiarism;
        iii. indicate whether the research misconduct was committed intentionally, knowingly, or recklessly;
        iv. indicate whether there was a significant departure from accepted practices of the relevant research community;
        v. summarize 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;
        vi. identify the specific PHS support; and
        vii. identify whether any publications need correction or retraction.
    (b) If the Investigation Committee does not recommend a finding of research misconduct for an allegation, the Investigation Report must provide a detailed rationale.
    (c) List any current support or known applications or proposals for support

that the Respondent has pending with other PHS agencies or non-PHS federal agencies, if any.

12. The Investigation Report may describe any recommended administrative measures the Investigation Committee believes the NIH should take;
13. When the Committee's decision is not unanimous, the Investigation Report may include a separate statement summarizing the minority viewpoint;
14. The Investigation Report may document evidence that suggests an allegation may not have been made in good faith;
15. The final version of the Investigation Report must include any comments made by the Respondent or the Complainant on the draft report, per section IX(B) below, along with a description of the Committee's consideration of those comments. The final report should address any changes made to the draft Report as a result of the comments.

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 and Complainant(s)

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 research records and other evidence that the Investigation Committee relied on. The Respondent must submit any comments on the draft report to the AIRIO within thirty (30) days of receiving the draft Investigation Report. The Respondent's comments, if any, will be considered and included in the final report.

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

The Respondent and, if applicable, the Complainant(s) will not have an additional opportunity to review and comment on the Investigation Report once comments are submitted.

2. Confidentiality

In distributing the draft report, or portions thereof, to the Respondent and

Complainant, the AIRIO should remind the recipient of their obligation to maintain the confidentiality of the research misconduct proceeding (see section IV(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 NIH found research misconduct and, if so, who committed the misconduct; and (2) a description of relevant NIH administrative measures taken or to be taken. If the DO's decision varies from the recommendations of the Investigation Committee, the DO will, as part of their written decision, explain the DO's consideration of the Investigation Committee's recommendations. 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 not have been made in good faith, the DO will review the evidence and may recommend further measures (section XII(E)).

D. Notification of NIH Findings and Administrative Measures; 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 180-day period for completing the Investigation, submit the following to ORI a copy of the institutional record (see section II(M) above), which includes, but is not limited to: (1) a copy of the final Investigation Report and all records (other than drafts of the report) considered or relied on during the Investigation, including, but not limited to, research records, the transcripts of each interview conducted, and information the Respondent provided to NIH; and (2) a copy of the written decision of the Deciding Official.

ORI findings are not required for institutional decisions regarding research misconduct to be considered final and to warrant "remediation under the institution's policy." (42 C.F.R. § 93.404(b)).

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, "NIH Records Related to Research Misconduct Proceedings, HHS/NIH," 09-25-0223, 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.

After NIH makes its determination, if additional allegations of research misconduct against the Respondent are brought directly to NIH's attention, NIH will consult with ORI. ORI may require that a new Investigation be initiated. Absent ORI objection, NIH will use an Investigation Committee to review the additional allegations consisting of the same members who served on the Investigation Committee for the original allegations.

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. No Institutional Appeal

The NIH Deciding Official's determination of research misconduct findings is the final decision for NIH. There is no internal institutional appeal in the NIH IRP procedures for NIH research misconduct proceedings.

X. ADMISSIONS AND SETTLEMENTS; REPORTING OBLIGATIONS

The NIH is expected to carry Inquiries and Investigations through to completion and to pursue diligently all significant issues and credible allegations of research misconduct. The NIH must notify ORI in advance if it plans to close a case at the Assessment, Inquiry or Investigation stage on the basis that the Respondent has admitted to committing research misconduct or a settlement with the Respondent has been reached.

At any time during the NIH research misconduct proceeding, the Respondent has the opportunity to admit that research misconduct occurred and that they committed the research misconduct. A Respondent's admission of research misconduct must be made in writing and signed by the Respondent. An admission must specify the falsification, fabrication, and/or plagiarism that occurred and which research records were affected. The admission statement must meet all elements required for a research misconduct finding under 42 C.F.R. § 93.103 of the PHS Regulations and must be provided to ORI before the institution closes its research misconduct proceeding. NIH must also provide a statement to ORI describing how it determined that the scope of the misconduct was fully addressed by the admission and confirmed the respondent's culpability.

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.

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) directing the NIH to address deficiencies in the institutional record; (4) referring the matter for further investigation by HHS; or (5) taking a compliance action. The AIRIO is responsible for providing any information requested by ORI to carry out its review of an allegation of research misconduct or of NIH's handling of such an allegation.

XI. NIH ADMINISTRATIVE MEASURES

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

If the DO determines that research misconduct is substantiated by the Investigation findings, the DO 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 measures should be taken. The administrative measures 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 IV(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 measures appropriate in light of the research misconduct.

XII. 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. Proceedings Involving Multiple Respondents or Multiple Institutions

If NIH identifies additional Respondents during an Inquiry or Investigation, NIH is not required to conduct a separate Inquiry for each new Respondent. However, each additional Respondent must be provided notice of and an opportunity to respond to the allegations, consistent with the PHS Regulations and this Policy. The AIRIO or other designated official will seek to notify each Respondent separately, if feasible. Only allegations specific to a particular Respondent are to be included in the notification to that Respondent. While an Investigation into multiple Respondents can convene with the same Investigation Committee members, separate Investigation Reports and research misconduct determinations are required for each Respondent.

When allegations involve research conducted at multiple institutions, one institution must be designated as the lead institution if a joint research misconduct proceeding is conducted. In a joint research misconduct proceeding, the lead institution should obtain research records and other evidence pertinent to the proceeding, including witness

testimony, from the other relevant institutions. Any information disclosures by NIH must be consistent with the requirements in the applicable Privacy Act system of records notice, "NIH Records Related to Research Misconduct Proceedings, HHS/NIH," 09-25-0223.

Under the PHS Regulations, a determination of (a) whether further inquiry and/or investigation is warranted, (b) whether research misconduct occurred, or (c) the institutional actions to be taken, may be made by the participating institutions jointly or tasked to the lead institution. The PHS Regulations also permit, by mutual agreement, a joint research misconduct proceeding to include committee members from the institutions involved. Any arrangements made by NIH with one or more other institutions to conduct a joint research misconduct proceeding, or to make or implement determinations made in the course of such proceeding, must be consistent with NIH's obligations under federal law, including requirements pertaining to government decision making and the Federal Advisory Committee Act, 5 U.S.C. § 1001 *et seq*.

C. Restoration of the Respondent's Reputation

Under the PHS Regulations, NIH is obligated to provide for all reasonable and practical efforts, if requested and as appropriate, to restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding or research misconduct is made. Depending on the particular circumstances and the views of the Respondent, the AIRIO should consider notifying those individuals 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 their 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 their original laboratory.

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

D. Protection of Good Faith Complainants, 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 NIH must take all reasonable and practical steps to protect the positions and reputations of good

faith Complainants, witnesses, and committee members and to protect these individuals from retaliation by Respondents and/or other NIH staff. The DO will determine, after consulting with the AIRIO, and if necessary with the Complainant, witnesses, or committee members, respectively, what steps, if any, are needed to protect these individuals from retaliation. 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.

E. 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, the DO will determine or, as necessary, will refer to other appropriate NIH officials (*e.g.*, Director of Human Resources) to determine, whether any administrative measures should be taken against the individual who failed to act in good faith.

F. 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/>.