



ORIC OFFICE OF RESEARCH INTEGRITY
AND COMPLIANCE

Research Misconduct Policy and Procedures

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I. Introduction

The mission of the Pacific Institute for Research and Evaluation (PIRE) is to promote, undertake, and evaluate activities, studies, and programs that improve individual and public health, welfare, and safety. In support of this mission, we create and support an environment within which skilled, innovative, and dedicated researchers and practitioners work to extend the leading edges of their respective fields.

Central to this mission is PIRE's overarching commitment to the ethical conduct of research. For more than four decades, PIRE scientists have been conducting important work on a wide variety of public health and safety issues. PIRE supports the responsibility of each of its researchers by fostering an environment of research ethics and providing institutional oversight.

II. Scope of This Policy

This statement of policy and procedures is intended to carry out PIRE's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. While the PHS policy applies to all individuals with a project supported by, or who have submitted a grant application to, PHS, PIRE's policy applies to all work undertaken at PIRE. For research that involves PHS support, the Office of Research Integrity (ORI) at the U.S. Department of Health and Human Services must be involved. For research that does not involve PHS funding, other entities may be involved as this policy is implemented.

With respect to matters applicable to the PHS, it is intended that the policy meet the requirements set forth in 42 CFR Part 93. To the extent any provisions set forth in this policy are inconsistent with said regulations, the regulations shall control. Similarly, to the extent a matter is not addressed in this policy, reference should be made to 42 CFR Part 93 regarding the applicable provisions.

In applying this policy to research that does not involve PHS support, references to PHS or interaction with ORI should be replaced by sponsoring entity requirements and, to the extent practical, dealt with in a manner similar to PHS matters. PIRE may supplement or modify the policy as it deems appropriate where non-PHS support is involved.

This document applies to allegations of research misconduct that involve a person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with PIRE;¹ and

- has PHS or other support of biomedical or behavioral research, research training or activities related to that research or research training, including, but not limited to the operation of data banks and the collection, analysis, and/or dissemination of research information, or
- has developed applications or proposals for PHS or other support for research, research training or activities related to that research or research training, or

- uses research records produced in the course of PHS- or other-supported research, research training or activities related to that research or research training.

This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS or other sponsor resulted in a grant, contract, cooperative agreement, subaward, or other form of PHS or other support.²

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- *Fabrication* is making up data or results and recording or reporting them.
- *Falsification* is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- *Plagiarism* is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest error or differences of opinion.³

This statement of policy and procedures does not apply to authorship or collaboration disputes.

A finding of research misconduct made under this policy requires:

- there be a significant departure from accepted practices of the relevant research community; and
- the misconduct be committed intentionally, knowingly, or recklessly; and
- the allegation be proven by a preponderance of the evidence.⁴

III. Definitions

Allegation means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to the RIO or other institutional official.

Complainant means a person who in good faith makes an allegation of research misconduct.

Deciding Official (DO) means the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. PIRE's DO is William Wiczorek, President and Chief Executive Officer.

Evidence means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

Good faith as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have 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 knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties

assigned impartially for the purpose of helping an institution meet its responsibilities. A committee member does not act in good faith if their acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

Inquiry means preliminary information-gathering and preliminary fact-finding to determine whether an investigation is warranted.

Institutional member means a person who is employed by, is an agent of, or is affiliated by contract or agreement with PIRE. Institutional members may include, but are not limited to, board members, officials, researchers, research coordinators, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.

Investigation means the formal development of a factual record and the examination of that record leading to a finding of no research misconduct or to a finding of research misconduct and may include a recommendation for other actions.

Office of Research Integrity or ORI means the office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities.

Notice means a written communication served in person, sent by mail, or its equivalent, facsimile number, or email address of addressee.

Preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Public Health Service or PHS means a division of the Department of Health and Human Services concerned with public health that includes Centers for Disease Control and Prevention, Food and Drug Administration, Indian Health Service, National Institutes of Health, the Substance Abuse and Mental Health Services Administration, and other operating divisions.

PHS support means PHS funding, or applications or proposals therefor, for biomedical or behavioral research, research training, or activities related to that research or training, that may be provided through: Funding for PHS intramural research; PHS grants, cooperative agreements, or contracts or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.

Research Integrity Officer or RIO means the institutional official responsible for: (1) receiving and assessing allegations of research misconduct; (2) overseeing inquires and investigations; and (3) performing other responsibilities related to this policy. PIRE's current RIO is Ryan Treffers, Director of Research Integrity and Compliance.

Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to the RIO by a respondent in the course of the research misconduct proceeding.

Respondent means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

Retaliation means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to either a good faith allegation of research misconduct, or good faith cooperation with a research misconduct proceeding.

Other terms used in the policy have the same meaning as given them in 42 CFR Part 93.

IV. General Principles

Responsibility to Report Misconduct

All institutional members have the responsibility to report observed, suspected, or apparent research misconduct to the Research Integrity Officer (RIO); if reported to another institutional official, that official will forward the allegation to the RIO.

If an individual is unsure whether a suspected incident falls within the definition of research misconduct, they may meet with or contact the RIO to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically.

If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for solving the problem.

At any time, an institutional member may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

Confidentiality

PIRE recognizes the importance of confidentiality in circumstances involving research misconduct allegations. Disclosure of the identity of respondents and complainants in research misconduct proceedings, as well as research subjects identifiable from research records or evidence, will be limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective, and fair research misconduct proceeding. Complainants, respondents, witnesses, and other individuals as appropriate will be required to sign confidentiality agreements.

Cooperation with Research Misconduct Proceedings

Institutional members will cooperate with the RIO and other PIRE officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO.

Protection of Complainants, Witnesses, and Committee Members

Institutional members may not retaliate in any way against complainants, witnesses, or committee members. Institutional members should immediately report any alleged or apparent retaliation to the RIO. PIRE will take all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses and committee members and protect them from retaliation by respondents and other institutional members.

Protection of the Respondent

As requested and as appropriate, PIRE will make all reasonable and practical efforts 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.⁵

Consequences of a Finding of Research Misconduct

After the conclusion of the case and, when required, notification to ORI, PIRE will determine whether notification of the outcome of the case to other entities is warranted; possible entities include but are not limited to professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, law enforcement agencies, collaborators of the respondent in the work, or other relevant parties.

V. Rights and Responsibilities

Research Integrity Officer (RIO)

PIRE's Chief Executive Officer (CEO) will appoint the Research Integrity Officer (RIO) who will have primary responsibility for implementation of PIRE's policies and procedures on research misconduct. These responsibilities include the following duties related to research misconduct proceedings:

- Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;
- Receive allegations of research misconduct;
- Assess each allegation of research misconduct to determine whether it falls within the definition of research misconduct and warrants an inquiry;
- As necessary, take interim action and, when required, notify ORI of special circumstances;
- Sequester research data and evidence pertinent to the allegation of research misconduct and maintain it securely in accordance with this policy and applicable law and regulation;
- Provide confidentiality, as required by 42 CFR 93.108, other applicable law, and institutional policy, of those involved in the research misconduct proceeding;
- Notify the respondent and provide opportunities for the respondent to review, comment, and respond to allegations, evidence, and committee reports;

- Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- Appoint, in consultation with the CEO, the chair and members of the inquiry and investigation committees, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;
- Ensure that no person with an unresolved personal, professional, or financial conflict of interest is involved in the research misconduct proceeding;
- In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and counter potential or actual retaliation against them by respondents or other institutional members;
- Keep the Deciding Official (DO) and others who need to know apprised of the progress of the review of the allegation of research misconduct;
- Notify and make reports to ORI and/or other entities as required;
- Ensure that administrative actions taken by PIRE (and ORI, if applicable) are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and
- Maintain records of the research misconduct proceeding and, if appropriate, make them available to ORI as required.

Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the research misconduct proceedings.

If the complainant is interviewed at the inquiry stage, they will be given the transcript or recording of the interview for correction. The complainant must be interviewed during an investigation and be given the transcript or recording of the interview for correction.⁶

If the complainant is provided a copy of the draft investigation report or relevant portions of it, PIRE must consider any comments made by the complainant on the draft investigation report and include those comments in the final investigation report.

Respondent

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation.

The respondent is entitled to:

- A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry;⁷
- An opportunity to comment on the inquiry report and have their comments attached to the report;⁸
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to, 42 CFR Part 93 and the institution's policies and procedures on research misconduct;⁹

- 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, and be notified in writing of any new allegations, not addressed in the inquiry or in the initial notice of investigation, within a reasonable time after the determination to pursue those allegations;¹⁰
- Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;¹¹
- Identify any witness having information on relevant aspects of the investigation, have the witness interviewed during the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation;¹²
- Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the evidence on which the report is based, and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by the institution and addressed in the final report;¹³
- Be given the opportunity to admit that research misconduct occurred and that they committed the research misconduct; and
- Be given the opportunity to request an appeal if there is a finding of research misconduct.

Deciding Official (DO)

The DO will receive the inquiry report and, after consulting with the RIO and/or other institutional officials, decide whether an investigation is warranted. If the investigation involves PHS-supported research, the DO will notify ORI of any finding that an investigation is warranted within 30 days of the finding. If it is found that an investigation is not warranted, the DO and the RIO will ensure that detailed documentation of the inquiry is retained for at least 7 years after termination of the inquiry.

The DO will receive the investigation report and, after consulting with the RIO and/or other institutional officials, decide the extent to which PIRE accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate. If the investigation involves PHS-supported research, the DO will ensure that the final investigation report, the findings of the DO, and a description of any pending or completed administrative actions are provided to ORI as appropriate.

VI. Research Misconduct Proceedings

Allegations

Any institutional member may make an allegation of research misconduct in writing to the RIO.

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine:

- whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified,

- whether it is within the jurisdictional criteria of 42 CFR § 93.102(b), and
- whether the allegation falls within the definition of research misconduct.

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

If the above criteria are met, an inquiry will be conducted.

If the criteria are not met, the decision will be communicated in writing to the complainant (with a copy to the CEO and DO), along with a copy of the confidentiality obligations, and the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

Inquiry

If the RIO determines that the criteria for an inquiry are met, she will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.¹⁴

Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted, must be completed within 60 calendar days of initiation of the inquiry, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period.¹⁵ The respondent will be notified of the extension.

Sequestration of Research Records

On or before the date on which the respondent is notified or the inquiry begins, whichever is earlier, the institution/RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.¹⁶ For PHS-supported research the RIO may consult with ORI for advice and assistance in this regard.

Notice to Respondent

At the time of or before beginning an inquiry, the RIO must make a good faith effort to notify the respondent in writing, if the respondent is known. If the inquiry subsequently identifies additional respondents, they must be notified in writing.

Appointment of the Inquiry Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical. The inquiry committee must:

- consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry; and
- include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry.¹⁷

Charge to the Inquiry Committee

The RIO will prepare a charge for the inquiry committee that:

- Sets forth the time for completion of the inquiry (within 60 calendar days of initiation of inquiry, including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted);
- Describes the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
- States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b) and (2) the allegation may have substance, based on the committee's review during the inquiry; and
- Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry.

First Meeting of Inquiry Committee

At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The RIO will be present or available throughout the inquiry to advise the committee as needed.

Work of the Inquiry Committee

The inquiry committee will normally interview the complainant, the respondent, and key witnesses as well as examine relevant research records and materials. The inquiry committee will evaluate the evidence, including the testimony obtained during the inquiry. After consultation with the RIO, the committee members will decide whether an investigation is warranted.

The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct, or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, for research involving PHS funding, the institution will promptly consult with ORI to determine the next steps that should be taken. In cases not involving PHS funding, the DO and RIO will determine the next steps that should be taken.

Inquiry Report

A written inquiry report will be prepared that includes the following information:

- the name and position of the respondent;
- a description of the allegations of research misconduct;
- the PHS or other support, including, for example, grant numbers, grant applications, contracts and publications listing the support;
- the basis for recommending or not recommending that the allegations warrant an investigation; and
- any comments on the draft report by the respondent or complainant.¹⁸

Institutional counsel should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the inquiry committee.

Notification to the Respondent and Opportunity to Comment

The RIO will notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within ten (10) days, and include a copy of, or refer to, 42 CFR Part 93 and the institution's policies and procedures on research misconduct.¹⁹ The RIO may notify the complainant whether the inquiry found an investigation to be warranted and provide relevant portions of the inquiry report to the complainant for comment within ten (10) days. A confidentiality agreement should be a condition for access to the report.

Any comments that are submitted by the respondent or complainant will be attached to the final inquiry report. Based on the comments, the inquiry committee may revise the draft report as appropriate and prepare it in final form. The committee will deliver the final report to the RIO.

Institutional Decision

The RIO will transmit the final inquiry report and any comments to the DO, who will determine in writing whether an investigation is warranted. The inquiry is completed when the DO makes this determination.

Documentation of Decision Not to Investigate

If the DO decides that an investigation is not warranted, the RIO will secure and maintain for seven (7) years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by PIRE, or ORI in the case of PHS research, of the reasons why an investigation was not conducted. In the case of PHS research, these documents must be provided to ORI or other authorized HHS personnel upon request.

Notification to ORI for PHS-Funded Research

Within 30 calendar days of the DO's decision that an investigation is warranted, the RIO will provide ORI with the DO's written decision and a copy of the inquiry report. The RIO will also notify those institutional officials who need to know of the DO's decision. The RIO must provide the following information to ORI upon request:

- the institutional policies and procedures under which the inquiry was conducted,
- the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents, and
- the charges to be considered in the investigation.²⁰

Investigation

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted.²¹ The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent.

The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice.

The findings of the investigation must be set forth in an investigation report.

Time for Completion

The investigation is to be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and, in the case of PHS-funded research, sending the final report to ORI.

In the case of PHS-funded research, if the RIO determines that the investigation will not be completed within this 120-day period, she will submit to ORI a written request for an extension, setting forth the reasons for the delay. If ORI grants the request for an extension and directs the filing of such reports, the RIO will ensure that periodic progress reports are filed with ORI.²²

Sequestration of Research Records

The RIO will, prior to notifying respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry.

The need for additional sequestration of records for the investigation may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured.

The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.²³

Notifying the Respondent

On or before the date on which the investigation begins, the RIO must notify the respondent in writing of the allegations to be investigated. The RIO must also give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.²⁴

Notifying ORI

If the research involves PHS funding, on or before the date on which the investigation begins, the RIO must notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report.

Appointment of the Investigation Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair as soon after the beginning of the investigation as is practical. The investigation committee must:

- consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation, and
- include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant, and conduct the investigation.

Individuals appointed to the investigation committee may also have served on the inquiry committee. To secure the necessary expertise or to avoid conflicts of interest, the RIO may select committee members from outside the institution.

Charge to the Investigation Committee

The RIO will define the subject matter of the investigation in a written charge to the committee that:

- Describes the allegations and related issues identified during the inquiry;
- Identifies the respondent;
- Informs the committee that it must conduct the investigation as prescribed in the Investigation Process section of this document;
- Defines research misconduct;
- Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
- Informs the committee that in order to determine that the respondent committed research misconduct it must find that a preponderance of the evidence establishes that: (1) research misconduct, as defined in this policy, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (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; and
- Informs the committee that it must prepare or direct the preparation of a written report of the investigation.

First Meeting of Investigation Committee

The RIO will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan.

The investigation committee will be provided with a copy of this statement of policy and procedures and 42 CFR Part 93. The RIO will be present or available throughout the investigation to advise the committee as needed.

Investigation Process

The investigation committee and the RIO must:

- Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;²⁵
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;²⁶
- Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation;²⁷ and
- Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.²⁸

Requirements for Findings of Research Misconduct

A finding of research misconduct made under this policy requires:

- there be a significant departure from accepted practices of the relevant research community;
- the misconduct be committed intentionally, knowingly, or recklessly; and
- the allegation be proven by a preponderance of the evidence.

Investigation Report

The investigation committee and the RIO are responsible for preparing a written draft report of the investigation that:

- Describes the nature of the allegation of research misconduct, including identification of the respondent;
- Describes and documents the funding support including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing the funding support;
- Describes the specific allegations of research misconduct considered in the investigation;
- Includes the institutional policies and procedures under which the investigation was conducted;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed;
- Includes, for each allegation of research misconduct identified during the investigation, a statement of findings as to whether research misconduct did or did not occur.²⁹ For each finding of research misconduct, the statement of findings must:
 - 1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;
 - 2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent;

- 3) identify the specific funding support;
 - 4) identify whether any publications need correction or retraction;
 - 5) identify the person(s) responsible for the misconduct; and
 - 6) list any current support or known applications or proposals for support that the respondent has pending.³⁰
- Includes and considers any comments made by the respondent and complainant on the draft investigation report.

All relevant research records and records of the institution's research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews should be maintained and, for research involving PHS support, provided to ORI upon request.

Comments on the Draft Report and Access to Evidence

The RIO will give the respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed 30 days from the date they received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.³¹

The RIO may provide the complainant a copy of the draft investigation report, or relevant portions of it, for comment. The complainant's comments must be submitted within 30 days of the date on which they received the draft report, and the comments must be included and considered in the final report.

Confidentiality

In distributing the draft report, or portions thereof, to the respondent and/or complainant, the RIO will inform the recipient of the confidentiality under which the draft report is made available and will verify that the recipient has signed a confidentiality agreement.

Institutional Decision

The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the comments of the respondent and, if applicable, the complainant, are included and considered, and transmit the final investigation report to the DO.

The DO will determine in writing:

- whether the institution accepts the investigation report, its findings, and the recommended institutional actions, and
- the appropriate institutional actions in response to the accepted findings of research misconduct.

If this determination varies from the findings of the investigation committee, the DO will, as part of his written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the DO may return the report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, the RIO will normally notify both the respondent and the complainant in writing.

Appeals

If the respondent requests an appeal in writing, it must be completed within 120 days of its filing, unless, regarding PHS support, ORI finds good cause for an extension, based on the institution's written request for an extension that explains the need for the extension. If ORI grants an extension, it may direct the filing of periodic progress reports.³²

Completion of Cases

Generally, all inquiries and investigations will be carried through to completion, and all significant issues will be pursued diligently.

The RIO must notify ORI in the case of PHS-supported research, or funders in the case of research not supported by PHS, in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason.³³ Advance notice is not required in the closing of a case at the inquiry stage on the basis that an investigation is not warranted, or a finding of no misconduct at the investigation stage.

Institutional Administrative Actions

If the DO determines that research misconduct is substantiated by the findings, he will decide on the appropriate actions to be taken, after consultation with the RIO. The administrative actions may include:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
- Restitution of funds to the grantor agency as appropriate; and
- Other action appropriate to the research misconduct.

Notice of Institutional Findings and Actions

Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation, or the 120-day period for completion of any appeal, submit the following to ORI or appropriate entity:

- a copy of the final investigation report with all attachments, including any appeal;
- a statement of whether the institution accepts the findings of the investigation report or the outcome of the appeal, if any;
- a statement of whether the institution found misconduct and, if so, who committed the misconduct; and
- a description of any pending or completed administrative actions against the respondent.³⁴

After the conclusion of the case and notification to ORI or to the appropriate funder, PIRE will determine whether notification of the outcome of the case to other entities is warranted; possible entities include but are not limited to professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, law enforcement agencies, collaborators of the respondent in the work, or other relevant parties.

The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

Maintaining Records for Review

The RIO must maintain and provide to ORI or appropriate sponsor upon request “records of research misconduct proceedings” as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for seven (7) years after completion of the proceeding or the completion of any applicable PHS proceeding involving the research misconduct allegation.³⁵

The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI or appropriate sponsor to carry out its review of an allegation of research misconduct or of the institution’s handling of such an allegation.³⁶

VII. Other Considerations

Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the institution’s responsibilities under 42 CFR Part 93.

If the respondent, without admitting to the misconduct, elects to resign their position after the institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps.

If the respondent refuses to participate in the process after resignation, the RIO and any inquiry 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.

Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI concurrence (in the case of PHS-supported research) where required by 42 CFR Part 93, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation.³⁷

Depending on the particular circumstances and the views of the respondent, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation should first be approved by the DO.

Protection of the Complainant, Witnesses, and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the institution or ORI determines that research misconduct occurred, the RIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding.³⁸

The DO will determine, after consulting with the RIO, and with the complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The RIO is responsible for implementing any steps the DO approves.

Institutional members should immediately report any alleged or apparent retaliation against the complainant, witnesses, or committee members to the RIO.

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 that there was an absence of good faith, he will determine whether any administrative action should be taken against the person who failed to act in good faith.

Interim Administrative Actions

Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal or other funds and equipment, or the integrity of the research process. In the event of such a threat, the RIO will, in consultation with other institutional officials, ORI, or applicable sponsor, take appropriate interim action to protect against any such threat.³⁹ Interim action might include:

- additional monitoring of the research process and the handling of federal funds and equipment,
- reassignment of personnel or of the responsibility for the handling of federal funds and equipment,
- additional review of research data and results, or
- delaying publication.

The RIO will, at any time during a research misconduct proceeding, notify ORI or relevant sponsor, as appropriate, immediately if she has reason to believe that any of the following conditions exist:

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

- The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.⁴⁰

¹ 42 CFR § 93.214

² 42 CFR § 93.102

³ 42 CFR § 93.103

⁴ 42 CFR § 93.104

⁵ 42 CFR § 93.304(k)

⁶ 42 CFR § 93.310(g)

⁷ 42 CFR §§ 93.304(c), 93.307(b)

⁸ 42 CFR §§ 93.304(e), 93.307(f)

⁹ 42 CFR § 308(a)

¹⁰ 42 CFR § 310(c)

¹¹ 42 CFR § 310(g)

¹² 42 CFR § 310(g)

¹³ 42 CFR §§ 93.304(f), 93.312(a)

¹⁴ 42 CFR § 93.307(c)

¹⁵ 42 CFR § 93.307(g)

¹⁶ 42 CFR §§ 93.305, 93.307(b)

¹⁷ 42 CFR § 93.304(b)

¹⁸ 42 CFR § 93.309(a)

¹⁹ 42 CFR § 93.308(a)

²⁰ 42 CFR § 93.309(a) and (b)

²¹ 42 CFR § 93.310(a)

²² 42 CFR § 93.311

²³ 42 CFR § 93.310(d)

²⁴ 42 CFR § 93.310(b) and (c)

²⁵ 42 CFR § 93.310(e)

²⁶ 42 CFR § 93.310(f)

²⁷ 42 CFR § 93.310(g)

²⁸ 42 CFR § 93.310(h)

²⁹ 42 CFR § 93.313

³⁰ 42 CFR § 93.313(f)

³¹ 42 CFR §§ 93.312(a), 93.313(g)

³² 42 CFR § 93.314

³³ 42 CFR § 93.316(a)

³⁴ 42 CFR § 93.315

³⁵ 42 CFR § 93.317(b)

³⁶ 42 CFR §§ 93.300(g), 93.403(b) and (d)

³⁷ 42 CFR § 93.304(k)

³⁸ 42 CFR § 93.304(l)

³⁹ 42 CFR § 93.304(h)

⁴⁰ 42 CFR § 93.318