

GUIDELINES AND PROCEDURES FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

I. Introduction

A. Scope

This statement of policy and procedures is intended to describe TTUHSC El Paso's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93 (Code of Federal Regulations, Title 42, Part 93) and the National Science Foundation (NSF) Policy on Research Misconduct, 45 CFR 689. This document applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) involving any individual who, at the time of the alleged research misconduct was employed by, was an agent of, or was affiliated with TTUHSC El Paso to include scientists, trainees, technicians and other staff members, students, fellows, residents, faculty researchers or collaborators at TTUHSC El Paso. This policy applies to all individuals engaged in research at TTUHSC El Paso regardless of the funding source for the research activities.

This statement of policy and procedures does not apply to authorship or collaboration disputes, and applies only to allegations of research misconduct that occurred within six years of the date TTUHSC El Paso or the Department of Health and Human Services received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

This statement of policy and procedures does not apply to allegations of research noncompliance which do not meet the level of research misconduct as defined later in this document. Allegations of research non-compliance which are not covered by this policy will be reviewed by the TTUHSC El Paso Office of Research (OR) in accordance with policies and procedures in effect for the relevant funding agency, the relevant TTUHSC El Paso Review Board (Institutional Review Board [IRB], Institutional Animal Care and Use Committee [IACUC], Institutional Biosafety Committee [IBC], Conflict of Interest in Research Committee [COIRC]), HSC OP 73.14 (Research Compliance) and/or the relevant department.

II. Definitions

Allegation: a disclosure of possible research misconduct through any means of communication (either oral or written) to an institutional official.

Assessment: an initial review in which the Research Integrity Officer assesses the (1) allegations of research misconduct to determine, if true, whether they would fall within the definition of research misconduct and warrant an inquiry and (2) assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be

identified.

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

Conflict of Interest: real or apparent interference of one person's interests with the interests of another person or organization, where potential bias may occur due to prior or existing personal or professional relationships.

Deciding Official (DO): the institutional responsible party who makes final determinations on allegations of research misconduct and who implements any institutional administrative actions. The DO should have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment. The DO's role, as described throughout this policy, particularly in working with the RIO in the early stages of the process, is not considered to be direct prior involvement.

The vice president for research (VPR) or designee shall serve as the TTUHSC El Paso DO.

Evidence: includes any documents, whether in hard copy or electronic form, tangible item, or testimony offered or obtained during a proceeding addressing research misconduct that tends to prove or disprove the existence of an alleged fact.

Fabrication: making up data or results and recording or reporting them.

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.

Good faith: as applied to a complainant or a witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness' position could have, based on the information known to the complainant or witness at the time.

Inquiry: preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures outlined in this document and in 42 CFR 93.307-309.

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

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

Office of Research Integrity (or ORI): office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to Public Health Service (PHS) supported activities.

Plagiarism: the theft or misappropriation of intellectual property and substantial unattributed textual copying of another's work.

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

Public Health Service or PHS: the unit within HHS that includes the Office of Public Health and Science and its component operating divisions.

Research: systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general or specific knowledge by establishing, discovering, developing, elucidating, or confirming information about the matters to be studied.

Research Integrity Officer (RIO): the person responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing inquires and investigations; and (3) performing the other responsibilities described in this policy. The TTUHSC El Paso RIO shall be appointed by the managing director of the OR in consultation with the VPR.

Research Misconduct: 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.

Research record: the record of data or results that embody the facts resulting from the 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 an institutional official by a respondent in the course of the research misconduct proceeding.

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

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

Sponsor: For purposes of these guidelines and procedures, the sponsor is the external agency or company which is providing funding for a research project.

III. Rights and Responsibilities

A. Research Integrity Officer

The RIO or designee will have primary responsibility for implementation of the institution'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 in accordance with Section V.A. of this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;
- As necessary, take interim action and notify ORI or the sponsor, if applicable, of special circumstances, in accordance with Section IV.F. of this policy;
- Sequester research data and evidence, pertinent to the allegation of research misconduct in accordance with Section V.C. of this policy and maintain it securely in accordance with this policy and applicable law and regulation;
- Provide confidentiality to those involved in the research misconduct proceeding as required by this policy and other applicable laws.
- Notify the respondent and provide opportunities for him/her to review/comment/respond to allegations, evidence, and committee reports in accordance with Section III.C. of this policy;
- Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- With advice from the VPR or designee as necessary, appoint the chair and members of the inquiry and investigation committees; and ensure that those committees are properly staffed, and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;
- Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict 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 DO, and others who need to know, apprised of the progress of the review of the allegation of research misconduct;
- In cooperation with other institutional officials, notify and make reports to ORI or any other sponsoring agency as required.
- Ensure that administrative actions taken by the institution, ORI and/or the sponsor 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 make them available to ORI or the sponsor in accordance with Section VIII.F. of this policy.

B. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. As a matter of good practice, the complainant should be interviewed at the inquiry stage, provided with a draft of the relevant portions of the inquiry report and given the opportunity to respond to it. The complainant must be interviewed during an investigation, and be given the draft of relevant portions of the investigation report and given an opportunity to respond. Comments on the draft investigation report must be submitted within 30 days of the date on which the complainant received the draft report. TTUHSC El Paso will include the complainant's comments in the final investigation report. Note that there is not a requirement to provide a copy of a draft inquiry or draft investigation report to the complainant.

C. 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 be notified in writing at the time of or before beginning an inquiry;
- An opportunity to comment on the inquiry report and have his/her comments attached to the report;
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to 42 CFR Part 93 as well as TTUHSC El Paso's policies and procedures on research misconduct;
- Be notified in writing of the allegations to be investigated after the determination that an investigation is warranted, but before the investigation begins (within 30 days after the institution decides to begin an investigation), and be notified in writing of any new allegations, not addressed in the inquiry or in the initial notice of investigation, after the determination to pursue those allegations;
- 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;
- Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of 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; and
- Concurrently receive a copy of the draft investigation report and 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 receiving the copy, and that the comments will be considered by the institution and addressed in the final report.

The respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO and/or other institutional officials, the DO may terminate the institution's review of an allegation that has been admitted, if the institution's acceptance of the admission and any proposed settlement is approved by ORI or the study sponsor.

D. Deciding Official

The DO will receive the inquiry report and after consulting with the RIO and/or other institutional officials, decide whether an investigation is warranted. Any finding that an investigation is warranted must be made in writing by the DO and must be provided to ORI or the sponsor, together with a copy of the inquiry report, 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, so that ORI or the sponsoring organization, if applicable, may assess the reasons why the institution decided not to conduct an investigation.

The DO will receive the investigation report and, after consulting with the RIO and/or other institutional officials, decide the extent to which this institution accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate. The DO shall ensure that the final investigation report, the findings of the DO and a description of any pending or completed administrative actions are provided to ORI or the study sponsor.

IV. General Policies and Principles

A. Responsibility to Report

All institutional members will report observed, suspected, or apparent research misconduct to the RIO or to the Compliance Hotline at 1-866-294-9352 (toll free). If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the RIO or designee, 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 resolving the problem.

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

B. Cooperation with Research Misconduct Proceedings

Institutional members will cooperate with the RIO and other institutional 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 or other institutional officials.

C. Confidentiality

The RIO shall: (1) limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding. The RIO should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

D. Protecting Complainants, Witnesses, and Committee Members

Institutional members may not retaliate in any way against complainants, witnesses, or committee members. Institutional members and any individuals who have been subject to any retaliatory actions should immediately report any alleged or apparent retaliation against complainants, witnesses or committee members to the RIO, who shall review the matter. If necessary, institutional members will make all reasonable and practical efforts to counter any potential or actual retaliation, and protect and restore the position and reputation of the person against whom the retaliation is directed.

E. Protecting the Respondent

As appropriate, the RIO and other institutional officials shall 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.

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and in relevant policies and procedures of TTUHSC El Paso.

F. Interim Administrative Actions and Notification of Special Circumstances

Throughout the research misconduct proceeding, the RIO 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 research process. In the event of such a threat, the RIO will, in consultation with other institutional officials, ORI and/or the sponsoring agency, 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, suspension of research activities, or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI or the sponsor immediately if he/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;
- Federal or other research 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.

V. Conducting the Assessment and Inquiry

A. Assessment of Allegations

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 and whether the allegation falls within the definition of research misconduct as defined. An inquiry must be conducted if these criteria are met.

The assessment period should be brief, preferably concluded within two weeks. 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. The RIO shall, on or before the date on which the respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence, needed to conduct the research misconduct proceeding, as provided in paragraph C of this section.

B. Initiation and Purpose of the Inquiry

If the RIO determines that the criteria for an inquiry are met, the inquiry process will be initiated. The process will be initiated when inquiry committee members are appointed, following the procedure outlined in Section D, below. 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.

C. Notice to Respondent; Sequestration of Research Records

When the decision has been made to initiate 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. On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the 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. The RIO must then inventory the records and evidence and sequester them in a secure manner, except when the research records or evidence encompass scientific instruments shared by a number of users. Custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

D. Appointment of the Inquiry Committee

The RIO, in consultation with the VPR or designee, 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. The committee should 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. If feasible, the respondent will be notified of the proposed committee membership. The respondent will have 10 calendar days to object, in writing to any of the proposed members based upon a personal, professional, or financial conflict of interest. If the respondent provides a written objection, the RIO, in consultation with the VPR or designee, will make a final determination regarding whether a conflict exists.

E. Charge to the Committee and First Meeting

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

- Sets forth the time for completion of the inquiry;
- 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, (2) the allegation may have substance, based on the committee's review during the inquiry.
- Informs the inquiry committee that they are responsible for preparing or directing the

preparation of a written report of the inquiry that meets the requirements of this policy.

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.

F. Inquiry Process

The inquiry committee will normally interview the complainant, the respondent, and key witnesses and examine relevant research records and materials. Then 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 based on the criteria in this policy. 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 the respondent makes a legally sufficient admission of research misconduct, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the institution shall promptly consult with ORI or the sponsoring agency to determine the next steps that should be taken. See Section IX.

G. 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 90 calendar days of the appointment of the inquiry committee members, 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 90-day period.

VI. The Inquiry Report

A. Elements of the Inquiry Report

The chairperson of the inquiry committee must prepare a written inquiry report. The report will include the following information: (1) the names and titles of the committee members; (2) the name and position of the respondent; (3) a description of the allegations of research misconduct; (4) the funding agency, if applicable, which may include grant numbers, grant applications, contracts and publications; (5) a list of the research records reviewed and individuals interviewed; (6) the basis for recommending or not recommending that the allegations warrant an investigation; (7) alternate recommended actions if an investigation is not recommended; and (8) any comments on the draft report by the respondent or complainant.

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

B. Notification to the Respondent and Opportunity to Comment

The RIO shall notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within 10 days, and include a copy of the institution's policies and procedures on research misconduct.

Any comments that are submitted by the respondent 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.

C. Institutional Decision and Notification

1. Decision by Deciding Official

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

2. Notification to ORI or sponsoring agency

Within 30 calendar days of the DO's decision that an investigation is warranted, the RIO will provide ORI or the study sponsor 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: (1) the institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, recordings of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the investigation.

3. Documentation of Decision Not to Investigate

If the DO decides that an investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted. These documents must be provided to ORI, other authorized HHS personnel, or any other sponsoring agency upon request.

VII. Conducting the Investigation

A. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted. The purpose of the investigation is to develop a factual record by exploring the 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.

B. Notifying ORI or other Sponsoring Agency and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the RIO must: (1) notify the ORI or sponsoring agency of the decision to begin the investigation and provide a copy of the inquiry report; and (2) 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.

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 proceedings 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.

C. Appointment of the Investigation Committee

The RIO, in consultation with the VPR or designee, 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 should 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. In order to secure the necessary expertise or to avoid conflicts of interest, committee members from outside the institution may be selected. The respondent will be notified of the proposed committee membership. The respondent will have 10 calendar days to object, in writing, to any of the proposed members based upon a personal, professional, or financial conflict of interest. If the respondent provides a written objection, the RIO, in consultation with the VPR or designee, will make a final determination regarding whether a conflict exists.

D. Charge to the Committee and the First Meeting

1. Charge to the 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 paragraph E of this section;
- 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 investigation report that meets the requirements of this policy.

2. First Meeting

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.

E. 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;
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
- 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; 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.

F. Time for Completion

The investigation is to be completed within 180 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to ORI or the sponsor. However, if the RIO determines that the investigation will not be completed within this 180-day period, he/she will submit to ORI or the sponsoring agency a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress reports are filed with ORI or the sponsor if the request for an extension has been granted and the agency directs the filing of such reports.

VIII. The Investigation Report

A. Elements of the 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 research funding, which may include the grant numbers, grant applications, contracts, and publications;
- Describes the specific allegations of research misconduct considered in the

investigation;

- Includes the institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI or sponsoring agency previously;
- Identifies and summarizes the research records, evidence reviewed, and interviews conducted, and identifies any evidence taken into custody but not reviewed; and
- Includes a statement of findings for each allegation of research misconduct identified during the investigation. Each statement of findings must: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any arguments raised 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; (3) identify the specific research support received; (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 with any funding agency.

B. Comments on the Draft Report and Access to Evidence

1. Respondent

The RIO must concurrently give the respondent a copy of the draft investigation report for comment and 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 he/she received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.

2. Complainant

The complainant may be provided 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 he/she received the draft report and the comments must be included and considered in the final report.

3. Confidentiality

In distributing the draft report, or portions thereof, to the respondent (and complainant, when relevant) the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may require that the recipient sign a confidentiality agreement.

C. Decision by Deciding Official

The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's (and complainant's, when relevant) comments are included and considered, and transmit the final investigation report to the DO, who will determine in writing: (1) whether the institution accepts the investigation report, its findings, and the recommended institutional actions; and (2) 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/her 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. After informing ORI or the sponsoring agency, the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Appeals

The respondent has the right to appeal the findings of the investigation report that finds research misconduct. The written appeal must be completed and submitted to the DO within 20 business days of the filing of the investigational report. The DO will review the appeal and make a decision within 30 days.

E. Notice to ORI or Sponsoring Agency of Institutional Findings and Actions

Unless an appeal is pending, the RIO, in cooperation with the DO must, within the 180-day period after completing the investigation, submit the following to ORI or sponsoring agency: (1) a copy of the final investigation report with all attachments and any appeal; (2) a statement of whether the institution accepts the findings of the investigation report or the outcome of the appeal; (3) a statement of whether the institution found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent.

F. Maintaining Records for Review by ORI or Sponsor

The RIO must maintain and provide to ORI or sponsoring agency, upon request, all records of research misconduct proceedings. Unless custody has been transferred to a funding agency 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 7 years after completion of the proceeding or the completion of any sponsoring agency's proceeding involving the research misconduct allegation. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI or the sponsor to carry out the entity's review of an allegation of research misconduct or of the institution's handling of such an allegation.

IX. Completion of Cases; Reporting Premature Closures

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify ORI if the case is closed 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, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI or the sponsor.

X. Institutional Administrative Actions

If the DO determines that research misconduct is substantiated by the findings, he or she 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.

XI. Other Considerations

A. 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 this policy.

If the respondent, without admitting to the misconduct, elects to resign his or her 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.

B. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI or sponsor concurrence where required, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation. Depending on the particular circumstances and after consultation with respondent, among the actions the RIO may take include the following: 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; expunging all reference to the research misconduct allegation from the respondent's personnel file; and any other actions that the RIO deems appropriate given the particular facts and circumstances of the specific investigation and proceeding. Any institutional actions to restore the respondent's reputation should first be approved by the DO.

C. Protection of the Complainant, Witnesses and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the institution, ORI or the sponsor 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 any witnesses and committee members who participated in good faith with the research misconduct proceeding. 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.

D. Allegations Not Made in Good Faith

When a formal complaint is received alleging the absence of good faith, 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/she will determine whether any administrative action should be taken against the person who failed to act in good faith.