



2.7.1 *Policy For Responding to Allegations of Research Misconduct Involving Externally-Funded Research*

I. Introduction

A. General Policy

The University of San Diego fosters an environment of ethical conduct within which its faculty, staff and students carry out research. The university believes that the same ethical standards apply regardless of the researcher's field. Allegations of research misconduct are a grave matter. In the event that allegations of research misconduct by an institutional member of the university concerning externally-funded research projects at the university arise, the provisions of this policy will be followed to ascertain the veracity of the allegations and, if misconduct is found, determine the appropriate course of action.

B. Scope

This policy is intended to carry out this institution's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. The university adopts the standards articulated in 42 CFR Part 93 for all externally-funded research, whether the funding source is PHS or another entity. Where reference is made in this policy to 42 CFR Part 93, or any subpart thereof, and the matter at issue involves non-PHS funded research, any reference to the Office of Research Integrity (ORI) or PHS should be substituted with the name of the external funding source. This policy applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) involving:

- 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 this institution; and
- One or more of the following: (1) externally-funded research, research training or activities related to that research or research training, including the dissemination of research information, (2) applications or proposals for external funding for research, research training or activities related to that research or research training, or (3) plagiarism of research records produced in the course of externally-funded 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 external funds resulted in a grant, contract, cooperative agreement, or other form of external support.

This policy and the associated procedures do not apply to authorship or collaboration disputes and apply only to allegations of research misconduct that occurred within six years of the date USD or the external funding source received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

II. Definitions

A. “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 an institutional or external funding source official.

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

C. “Deciding Official” or “DO” means the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. The Vice President for Academic Affairs and Provost is the DO at USD.

D. “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.

E. “Externally-funded research” means funding, or applications or proposals therefore, for research, research training, or activities related to that research or training, that may be provided through: external grants, cooperative agreements, or contracts or subgrants or subcontracts under those external funding instruments; or salary or other payments under external grants, cooperative agreements or contracts. Research funded by the HHS, or any agency of HHS, is considered externally-funded research.

F. “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 it is 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 purpose of helping an institution meet its responsibilities under 42 CFR Part 93. A committee member does not act in good faith if his/her 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.

G. “HHS” means the United States Department of Health and Human Services.

H. “Inquiry” means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of this policy and 42 CFR §§ 93.307-93.309.

I. “Institutional member” means a person who is employed by, is an agent of, or is affiliated by contract or agreement with USD. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.

J. “Investigation” means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.

K. “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.

L. “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.

M. “Public Health Service” or “PHS” means the unit within HHS that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.

N. “Records of research misconduct proceedings” means: (1) the research records and evidence secured for the research misconduct proceeding pursuant to this policy and 42 CFR §§ 93.305, 93.307(b), and 93.310(d), except to the extent the Research Integrity Officer determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that have been retained; (2) the documentation of the determination of irrelevant or duplicate records; (3) the inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate, as required by 42 CFR § 93.309(c); (4) the investigation report and all records (other than drafts of the report) in support of the report, including the recordings or transcripts of each interview conducted; and (5) the complete record of any appeal within the institution from the finding of research misconduct.

O. “Research Integrity Officer” or “RIO” means the institutional official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93 or this policy, 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; and (2) overseeing inquiries and investigations; and (3) the other responsibilities described in this policy.

P. “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.

Q. “Research misconduct proceeding” means any actions related to alleged research misconduct that is within 42 CFR Part 93 or the scope of this policy, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings and administrative appeals.

R. “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 an external or an institutional official by a respondent in the course of the research misconduct proceeding.

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

T. “Retaliation” means an adverse action taken against a complainant, witness, or committee member by this institution or one of its institutional members in response to (1) a good faith allegation of research misconduct; or (2) good faith cooperation with a research misconduct proceeding.

III. Rights and Responsibilities

A. Research Integrity Officer

The Provost will appoint the RIO who will have primary responsibility for implementation of the institution’s policies and procedures on research misconduct. The RIO will be an institutional official who is well qualified to administer the procedures and is sensitive to the varied demands made on those who conduct research, those who are accused of research misconduct, those who make good faith allegations of research misconduct, and those who may serve on inquiry and investigation committees.

The responsibilities of the RIO include but are not necessarily limited to 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 the external funding source 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 42 CFR § 93.108, other applicable law, and institutional policy;
- 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;
- Appoint 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;
- 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 Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;
- Notify and make reports to the external funding source (for PHS funded research, this shall be conducted as required by 42 CFR Part 93).

- Ensure that administrative actions taken by the institution and the external funding source 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 the external funding source 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 and 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.

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 notify the respondent 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 and this or any other applicable USD policy or procedure governing research misconduct;
- 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 (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, within a reasonable time 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

- 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.

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 institutional legal counsel, the Deciding Official 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 the external funding source.

D. Deciding Official

The DO will receive the inquiry report and after consulting with the RIO, decide whether an investigation is warranted under the criteria in 42 CFR § 93.307(d). Any finding that an investigation is warranted must be made in writing by the DO and must be provided to external funding source, together with a copy of the inquiry report meeting the requirements of 42 CFR § 93.309, 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 the external funding source 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 other appropriate 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 the any pending or completed administrative action are provided to the external funding source (to ORI as required by 42 CFR § 93.315 if the research is funded by PHS).

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All institutional members will report observed, suspected, or apparent research misconduct to the RIO. Any official who receives an allegation of research misconduct must report it immediately to the RIO. 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 to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. The contact information for the RIO may be obtained through the Provost's office. 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 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 may use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information. The university will make reasonable efforts to provide confidentiality to the extent feasible for witnesses when the circumstances indicate that the witnesses may be harassed or otherwise need protection.

D. Protecting 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 against complainants, witnesses or committee members to the RIO, who shall review the matter and, as necessary, 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

If requested and 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 the policies and procedures of the institution. Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice, but may not bring counsel or a personal adviser to interviews or meetings on the case.

F. Interim Administrative Actions and Notifying the External Funding Source 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, external funds and equipment, or the integrity of the externally-supported research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and the external funding source, take appropriate interim action to protect against any such threat. Interim action might include additional monitoring of the research process and the handling of external funds and equipment, reassignment of personnel or of the responsibility for the handling of external funds and equipment, additional review of research data and results or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify the external funding source 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;
- The external sources 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, whether it is within the jurisdictional criteria of this policy, and whether the allegation falls within the definition of research misconduct in this policy. An inquiry must be conducted if these criteria are met.

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. 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, he or she will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.

C. Notice to Respondent; Sequestration of Research Records

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. 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, 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. The RIO may consult with the external funding agency for advice and assistance in this regard.

D. Appointment of the Inquiry Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair within 10 business days of the initiation of the inquiry or as soon thereafter as practical. The inquiry committee shall have three members. 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 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. The RIO will establish a procedure for notifying the respondent of the proposed committee membership to give the respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. The period for submitting objections shall be limited to no more than 10 calendar days. The RIO will make the final determination of 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 is within the jurisdictional criteria of this policy; 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 and 42 CFR § 93.309(a).

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 as well as examining 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 and 42 CFR § 93.307(d). 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, the institution shall promptly consult with the external funding source to determine the next steps that should be taken. See Section III.C.

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 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.³⁷ The respondent will be notified of the extension.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that includes the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) the external support, including, for example, grant numbers, grant applications, contracts and publications listing external support; (4) the basis for recommending or not recommending that the allegations warrant an investigation; (5) 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. The inquiry report should include: the names and titles of the committee members and experts who conducted the inquiry; a list of the research records reviewed; a list of witnesses (provided, however, that the name of a witness may be omitted if the university has agreed to make reasonable efforts to the extent feasible to protect the witness' confidentiality) excluding those witnesses to whom confidentiality has been granted); and whether any other actions should be taken if an investigation is not recommended.

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 or refer to 42 CFR Part 93 and the institution's policies and procedures on research misconduct.

Any comments that are submitted 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 DO, who will determine in writing whether an investigation is warranted. The inquiry is completed when the DO makes this determination.

2. Notification to the External Funding Source

Within 30 calendar days of the DO's decision that an investigation is warranted, the RIO will provide the external funding source 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 the external funding source upon request: (1) the institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed,

transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the investigation.

3. Documentation of Decision Not to Investigate

If the DO decides that an investigation is not warranted, the 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 the external funding source of the reasons why an investigation was not conducted. These documents must be provided to authorized external funding source personnel 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 will be set forth in an investigation report.

B. Notifying External Funding Source and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the RIO must: (1) notify the external funding source of the decision to begin the investigation and provide it with 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 proceeding that were not previously sequestered during the inquiry. 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. 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 other institutional officials as appropriate, will appoint an investigation committee and the committee chair within 10 business days of the beginning of the investigation or as soon thereafter as practical. The investigation committee shall have five members. 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. When necessary to secure the necessary expertise or to avoid conflicts of interest, the RIO may select committee members from outside the institution. The RIO will establish a procedure for notifying the respondent of the proposed committee membership to give the respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. The period for submitting objections shall be limited to no more than 10 calendar days. The RIO will make the final determination of 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 and 42 CFR § 93.313.

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 policy 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 120 calendar 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 the external funding source. However, if the RIO determines that the investigation will not be completed within this 120-day period, he/she will submit to the external funding source a written request for an extension, setting forth the reasons for the delay.

The RIO will ensure that periodic progress reports are filed with the external funding source, if it grants the request for an extension and 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 external support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing external support;
- 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 the external funding source previously;
- Identifies and summarizes the research records and evidence reviewed 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.⁴⁹ 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 effort by respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion; (3) identify the specific external 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 with external funding sources.

B. Comments on the Draft Report and Access to Evidence

1. Respondent

The RIO must give the respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed 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. Confidentiality

In distributing the draft report, or portions thereof, to the respondent, 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 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 the external funding source, 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 may appeal a final decision by the DO that research misconduct occurred. The appeal must be submitted in writing to the President within 30 days of the date on which the respondent was notified of the DO's final decision. A copy of the appeal may be provided to university officials who have a need to know of the appeal, as well as to the external funding source.

The appeal shall describe with specificity why the respondent believes the final decision by the DO was not warranted. The President will provide the decision on the appeal within 120 calendar days of the receipt of the written appeal by the President's office, unless the external funding source finds good cause for an extension, based upon USD's written request for an extension that explains the need for the extension. If the external funding source grants an extension, it may direct the filing of periodic progress reports.

If granted, the appeal by the respondent may result in a reversal or modification of the institution's findings of research misconduct, or other relief as deemed by the President to be appropriate under the circumstances.

E. Notice to External Funding Source 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 the external funding source: (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 the External Funding Source

The RIO must maintain and provide to the external funding source upon request records of research misconduct proceedings. Unless custody has been transferred to the external funding source or it 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 external funding source proceeding involving the research misconduct allegation.⁵³ The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by the external funding source to carry out its review of an allegation of research misconduct or of the institution's handling of such an allegation.

IX. Completion of Cases; Reporting Premature Closures to the External Funding Source

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify the external funding source 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, 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 the external funding source, as prescribed in this policy and 42 CFR § 93.315.55.

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, but are not limited to, the following:

- 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 and/or special monitoring of future work,
- A letter of reprimand, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment, following the procedures of the disciplinary policy that applies to the respondent;
- Restitution of funds to external funding source as appropriate; and
- Other action appropriate to the 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 or 42 CFR Part 93.

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 concurrence of the external funding source where required by 42 CFR Part 93 or this policy, the RIO will, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation. 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.

C. Protection of the Complainant, Witnesses and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the institution or the external funding source determines that research misconduct occurred, the RIO will undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual

retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding. The DO will determine, after consulting with the 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

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/she will determine whether any administrative action should be taken against the person who failed to act in good faith.

(January 31, 2007)