Tulane University Policies and Procedures for Responding to Allegations of Research Misconduct Involving Public Health Service-Funded Research

(Based on the ORI Model Policy issued October 20, 2006)

I. Introduction

A. General Policy and Applicability

It is the responsibility of all researchers to conduct their professional activities according to high standards of scholarship. Their responsibility to the community at large demands that they be honestly and sincerely devoted to the ideals of discovery and dissemination of truth and knowledge. Research misconduct undermines the academic enterprise. Institutions engaged in research have a responsibility, not only to provide an environment that promotes integrity, but also to establish and enforce policies and procedures that deal effectively and expeditiously with allegations or evidence of research misconduct.

This policy applies to all employees, students or other persons within the organizational control of Tulane University at the time of the performance of research funded by the Public Health Service (PHS). The primary goal of this policy is to ascertain the truth regarding allegations while assuring professional and humane treatment of the parties involved.

The PHS Office of Research Integrity must be informed at any stage of an inquiry or investigation if:
(a) there is an immediate health hazard involved;
(b) there is an immediate need to protect Federal funds or equipment
(c) there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is/are the subject of
the allegations as well as his/her co-investigators and associates, if any;
(d) it is probable that the alleged incident is going to be reported publicly;
(e) the allegation involves a public health sensitive issue, e.g., a clinical trial; or
(f) there is a reasonable indication of possible criminal violation.

In the instance set forth in the preceding clause (f), the PHS Office of Research Integrity must be informed within 24 hours. The Office of Research Integrity must also be informed if any inquiry or investigation involving a PHS grantee or grant applicant is terminated prior to completion.

The procedures defined in this policy involve four stages:
a. An inquiry to determine which allegations or related issues warrant further investigation;
b. If warranted after such inquiry, an investigation to collect and thoroughly examine evidence;
c. A formal finding; and
d. Appropriate disposition of the matter.

This policy operates in conjunction with existing Tulane policies for employment and academic conduct. (See Dismissal Procedure, Art. VI.) Recommendations for discipline resulting from investigations conducted under this policy will be administered pursuant to provisions H.3.d and e.1 as contained in the Faculty Research Misconduct policy and/or the disciplinary actions contained in the Staff Handbook.

With regard to the institutional review process for dealing with allegations of fraud, Tulane is committed to:
1. Ensuring that the process used to resolve allegations of research misconduct do not damage the research process.

2. Investigating and resolving all charges. All respondents to allegations of research fraud must cooperate with the division, Dean or chief administrator undertaking inquiries or investigations into allegations of research fraud. Even if the respondent leaves Tulane before the case is resolved, Tulane shall continue examination of the allegations and reach a conclusion. Further, Tulane shall cooperate with the processes of other involved institutions to resolve such problems.

3. Treating all parties with justice and fairness and being sensitive to their reputations and vulnerabilities. Anyone receiving any allegation of research misconduct shall provide confidentiality for the individual who comes forward with an allegation of research misconduct and shall take appropriate steps to protect the complainant against retaliation. Any individuals engaging in acts of malice or of retaliation shall be disciplined in accordance with appropriate institutional policies. Institutional officials shall work to assure that allegations of research fraud have been brought in good faith and are not motivated by malicious intent.

4. Preserving the highest attainable degree of confidentiality compatible with an effective and efficient response. Strict confidentiality shall be maintained of all information gathered in an inquiry or investigation. This may include seeking assurances of the confidential treatment of such information prior to notifying sponsors of research. If confidentiality is breached, the institutional official responsible for the inquiry or investigation shall take reasonable steps to minimize damage to reputations that may result from inaccurate reports.

5. Maintaining the integrity of the process by painstaking avoidance of real or apparent conflict of interest. The institutional official in charge of each stage of the process shall be responsible for assuring no real or apparent conflict of interest, bearing on the case in question, is possessed by individuals chosen to assist in the inquiry and investigative process.
6. Resolving charges in as expeditious a manner as possible.
7. Documenting the pertinent facts and actions at each stage of the process.
8. After resolving allegations, discharging its responsibilities both internally – to all involved individuals – and externally – to the public, the sponsors of research, the scientific literature, and the scientific community, to the extent that it is appropriate and allowable. When allegations are not confirmed, the University shall undertake diligent efforts to restore the reputations of persons alleged to have engaged in this conduct, as well as to protect the positions and reputations of those who, in good faith, made such allegations.

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 and is based on the model policy issued by ORI on October 20, 2006. This policy applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) involving:
1. 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
2. (a) PHS-supported biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information;
   (b) Applications or proposals for PHS support for biomedical or behavioral research, research training or activities related to that research or research training;
   OR
   (c) Plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application

* Sections based on 42 CFR Part 93 have endnotes indicating the applicable section.
or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.²

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 the institution or HHS 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 HHS official.³
B. Complainant means a person who in good faith makes an allegation of research misconduct.⁴
C. Deciding Official (DO) means the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. The Deciding Official is either the Senior Vice President for Academic Affairs or the Senior Vice President for Health sciences, depending upon the academic unit of the person accused of misconduct.
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.⁵
E. 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 research misconduct proceeding by carrying out the duties assigned impartially for 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.\textsuperscript{6}

F. **HHS** means the United States Department of Health and Human Services.

G. **Inquiry** means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of 42 CFR §§ 93.307-93.309.\textsuperscript{7}

H. **Institutional member** means a person who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. 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 sub awardees, and their employees.\textsuperscript{8}

I. **Institutional Representative** means the person(s) who assess allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct be identified; and oversees inquiries.

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.\textsuperscript{9}

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.\textsuperscript{10}

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.\textsuperscript{11}

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.\textsuperscript{12}

N. \textbf{PHS support} means PHS funding, or applications or proposals therefore, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: Funding for PHS intramural research, PHS grants, cooperative agreements, or contracts or sub grants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.\textsuperscript{13}

O. \textbf{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.\textsuperscript{14}

P. \textbf{Research Integrity Officer (RIO)} means the institutional official responsible for: (1) overseeing investigations; and (2) the other responsibilities described in this policy. 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.
Q. 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.\(^{15}\)

R. Research misconduct proceeding means any actions related to alleged research misconduct that is within 42 CFR Part 93, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings and administrative appeals.\(^{16}\)

S. 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 HHS or an institutional official by a respondent in the course of the research misconduct proceeding.\(^{17}\)

T. Respondent means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.\(^{18}\)

U. 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.\(^{19}\)

III. Rights and Responsibilities

A. Research Integrity Officer (RIO)

The Associated Senior Vice President for Research will serve as the Research Integrity Officer (RIO). S/he will have primary responsibility for overseeing and implementing the institution’s policies and procedures on research misconduct.
The RIO will have broad authority to administer these policies if an investigation is warranted. The RIO may, at his/her discretion, designate all or some of his/her duties throughout the inquiry and investigation process.

The RIO (or his/her designee) has 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 and refer it to the appropriate Dean for a determination regarding whether an investigation is warranted.
• As necessary, take interim action and notify ORI 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 investigation committees; ensure that the committee is 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 ORI as required by 42 CFR Part 93;
• Ensure that administrative actions taken by the institution and ORI 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 in accordance with Section VIII.F. of this policy.

B. Institutional Representative
The Dean or Chief administrator of the division in which the respondent researcher resides will serve as the Institutional Representative. The Institutional Representative will perform the following duties:
• Ensure that a written inquiry report is prepared;
• 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.
• Notify the RIO if an inquiry is determined to be required and give the RIO a copy of the inquiry report;
• May appoint a small ad hoc committee to provide advice relevant to the inquiry stage. Such a committee shall include individuals with the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. It is the responsibility of the Dean to insure that the inquiry is conducted in a fair and just manner. The Dean may delegate any or all of the above responsibilities for gathering information to a member of his/her staff;
• If the Institutional Representative determines that an investigation is warranted, the matter, along with all information and materials gathered, will be referred to the DO for further proceedings under this policy.

• The IR will provide confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law and institutional 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;

• Keep a detailed written record of all proceedings that will be given to the RIO at the conclusion of the inquiry.

C. 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.20

D. 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;21
• An opportunity to comment on the inquiry report and have his/her comments attached to the report;22
• Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to 42 CFR Part 93 and the institution’s policies and procedures on research misconduct;23
• 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;\textsuperscript{24}

- 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;\textsuperscript{25}

- 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;\textsuperscript{26} 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.\textsuperscript{27}

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 ORI.\textsuperscript{28}

E. Deciding Official
The Deciding Official 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 ORI, 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 ORI may assess the reasons why the institution
decided not to conduct an investigation.\textsuperscript{29}
The Deciding Official will receive the investigation report from the investigation committee and, after consulting with the RIO and other appropriate officials, decide the extent to which Tulane University 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 ORI, as required by 42 CFR § 93.315.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All institutional members have a duty to report observed, suspected, or apparent research misconduct to the RIO or the Institutional Representative. Any employee who receives an allegation of research misconduct must report it immediately to an Institutional Representative. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact an Institutional Representative 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 under this policy, and Institutional Representative or 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 an Institutional Representative, the RIO or the University Research Compliance Officer 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
As required by 42 CFR § 93.108, the RIO shall be responsible for ensuring that all persons involved in the misconduct proceedings: (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.

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
As 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. 30

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 chose to consult with personal legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice. However, not outside legal or personal representative will be allowed to participate in any research misconduct proceeding, meeting or interview.

F. Interim Administrative Actions and Notifying ORI 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 PHS supported research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and ORI, take appropriate interim action to protect against any such threat. Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI 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;
- HHS resources or interests are threatened;
- Research activities should be suspended;
- There is a reasonable indication of possible violations of civil or criminal law;
- Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

V. Conducting the Assessment and Inquiry

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the Institutional Representative will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether it is within the jurisdictional criteria of 42 CFR § 93.102(b), and whether the allegation falls within the definition of research
misconduct in this policy and 42 CFR § 93.103. An inquiry must be conducted if these criteria are met. The assessment period should be brief, and barring exceptional circumstances, should be completed within one week. In conducting the assessment, the Institutional Representative 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 Institutional Representative 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 criteria for an inquiry are met, the Institutional Representative will initiate the inquiry process. The Institutional Representative shall inform the RIO of this determination prior to initiating 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. The inquiry stage is designed to separate allegations deserving of further investigation from frivolous, unjustified, or clearly mistaken allegations.

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.\textsuperscript{35} The RIO may consult with ORI for advice and assistance in this regard.

D. Appointment of the Inquiry Committee

The Institutional Representative will appoint an inquiry committee and committee chair within 10 days of the initiation of the inquiry or as soon thereafter as practical. The inquiry committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and 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.\textsuperscript{36}

E. Charge to the Committee and First Meeting

The Institutional Representative 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 42 CFR § 93.102(b); 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 Institutional Representative 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 Institutional Representative will be present or available throughout the inquiry to advise the committee as needed.

F. Inquiry Process

The inquiry committee will have all investigative powers necessary to determine whether a allegation of research misconduct should be investigated further. These powers include, but are not limited to interviewing the complainant, the respondent and key witnesses, and examining relevant research records and materials. After consultation with the RIO, the committee members will decide whether an investigation is warranted based on an evaluation of the evidence obtained during the inquiry, the criteria in this policy and 42 CFR § 93.307(d). The focus of the inquiry committee is not to decide whether research misconduct occurred, 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 ORI to determine the next steps that should be taken.

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

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 PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support; (4) the basis for
(5) any comments on the draft report by the respondent or complainant. The inquiry report should also include the names and titles of the committee members and experts who conducted the inquiry; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; 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 by the Respondent within 14 days and include a copy of or refer to 42 CFR Part 93 and the institution’s policies and procedures on research misconduct. The RIO may notify the complainant whether the inquiry found an investigation to be warranted. 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 ORI

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

B. Notifying ORI and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the RIO must: (1) notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report; and (2) notify the respondent in writing of the allegations to be investigated. 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 days of the beginning of the investigation or as soon 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. The Faculty Senate Grievance Committee may be appointed to serve as the investigation committee with additional members added as need to provide additional expertise.

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 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;\(^ {44} \)

• Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;\(^ {45} \)

• 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;\(^ {46} \) 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.\(^ {47} \)

F. Time for Completion
The investigation is to be completed within 120 days of the first meeting of the investigation committee, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to ORI. However, if the RIO determines that the investigation will not be completed within this 120-day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.\textsuperscript{48}

\textbf{VIII. The Investigation Report}

\textbf{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 PHS support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS 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 ORI 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.\textsuperscript{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 PHS 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 non-PHS federal agencies.50

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.51

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 ORI, 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. Notice to ORI of Institutional Findings and Actions
Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation submit the following to ORI: (1) a copy of the final investigation report with all attachments (2) a statement of whether the institution accepts the findings of the investigation report (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.52

E. Maintaining Records for Review by ORI
The RIO must maintain and provide to ORI upon request “records of research misconduct proceedings” as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation.53 The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or of the institution’s handling of such an allegation.54
IX. Completion of Cases; Reporting Premature Closures to ORI

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify ORI in 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 ORI, 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:

• 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 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 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 ORI concurrence where required by 42 CFR Part 93, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent’s reputation. 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 ORI determines that research misconduct occurred, the RIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding. 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.
ENDNOTES

1 42 CFR § 93.214
2 42 CFR § 93.102
3 42 CFR § 93.201
4 42 CFR § 93.203
5 42 CFR § 93.208
6 42 CFR § 93.210
7 42 CFR § 93.212
8 42 CFR § 93.214
9 42 CFR § 93.215
10 42 CFR § 93.217
11 42 CFR § 93.219
12 42 CFR § 93.220
13 42 CFR § 93.221
14 42 CFR § 93.224
15 42 CFR § 93.103
16 42 CFR § 93.223
17 42 CFR § 93.224
18 42 CFR § 93.225
19 42 CFR § 93.226
20 42 CFR § 93.310(g)
21 42 CFR §§ 93.304(c), 93.307(b)
22 42 CFR §§ 93.304(e), 93.307(f)
23 42 CFR § 308(a)
24 42 CFR § 310(c)
25 42 CFR § 310(g)
26 42 CFR § 310 (g)
27 42 CFR §§ 93.304(f), 93.312(a)
28 42 CFR § 93.316
29 42 CFR § 93.309(c)
30 42 CFR § 93.304(k)
31 42 CFR § 93.304((h)
32 42 CFR § 93.318
33 42 CFR § 93.307(a)
34 42 CFR § 93.307(c)
35 42 CFR §§ 93.305, 93.307(b)
36 42 CFR § 93.304(b)
37 42 CFR § 93.307(g)
38 42 CFR § 93.309(a)
39 42 CFR § 93.308(a)
40 42 CFR § 93.309(a) and (b)
41 42 CFR § 93.310(a)
42 42 CFR § 93.310(b) and (c)
43 42 CFR § 93.310(d)
44 42 CFR § 93.310(e)
45 42 CFR § 93.310(f)
46 42 CFR § 93.310(g)
47 42 CFR § 93.310 (h)
48 42 CFR § 93.311
49 42 CFR § 93.313
50 42 CFR § 93.313(f)
51 42 CFR §§ 93.312(a), 313(g)
52 42 CFR § 93.315
53 42 CFR § 93.317 (b)
54 42 CFR §§ 93.300(g), 93.403(b) and (d)
55 42 CFR § 93.316(a)
56 42 CFR § 93.304(k)

57 42 CFR § 93.304(l)