Responding to Allegations of Research Misconduct

Summary/Purpose: Policy and procedures for research misconduct.

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UM POLICY FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

I. Introduction

A. General Policy

Advances in and benefits from science, engineering, and all other fields of research depend on the reliability of the Research Record. The entire scientific enterprise relies on the integrity of researchers in proposing research and collecting, analyzing, and reporting research data.

Research Misconduct has consequences for the individual, the institution, and the entire research enterprise. It can cost researchers, staff, and students their careers. It can do serious harm to the reputation of the University. Sustained public trust in the research enterprise requires confidence in the Research Record and in the processes involved in its ongoing development. Research Misconduct can harm the institutions that fund and publish research, because it violates the public trust, and it is the public that ultimately funds the research enterprise.

The primary responsibility for maintaining standards of intellectual integrity rests with individual scholars and with the departments in which they work. It is the goal of the University of Mississippi to continue to foster a culture of responsible conduct of research by making all involved with research and future researchers aware of ethical research practices and the consequences of failure to adhere to those practices.

Optimally, such practices are modeled and disseminated by all senior researchers to their research students and staff and to students in their academic classrooms. However, the institution has a major role to play in three respects: (1) providing an environment for open inquiry in which research can be conducted appropriately, (2) declaring the standards which must not be abrogated, and (3) enforcing the standards on those occasions where violations may have occurred.

The purpose of this document is to set forth the policies and procedures by which the University of Mississippi seeks to maintain and enforce such standards through impartial fact-finding and fair adjudication of Allegations of Research Misconduct.

Much of the following policy and procedures aims to protect the positions and reputations of Good Faith Complainants, witnesses and committee members involved in Research Misconduct cases.

B. The University of Mississippi prohibits Research Misconduct as defined in II.R. below.

C. Scope

This policy is intended to carry out the University of Mississippi's ethical obligation to encourage the responsible conduct of research and to enforce its obligations under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. The United States Department of Health and Human Services (HHS) mandates that specific research misconduct policy provisions and procedures apply to PHS-supported research, and these form much of the basis for this policy, including reporting procedures. The University will comply with reporting procedures for all other funding agencies, although these are not specified in this policy.

This policy applies to Allegations of Research Misconduct involving any 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 the University.[1] This includes, but is 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, subawardees, and their employees.

This policy and associated procedures do not apply to collaboration or authorship disputes, with the exception of II.R.7 and II.R.8. They apply only to Allegations of Research Misconduct that occurred within six years of the date the University 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.[2]

B. *Complainant* means a person who in Good Faith makes an Allegation of Research Misconduct.[3]

C. *Deciding Official* (DO) means the institutional official who makes final determinations on Allegations of Research Misconduct and any institutional administrative actions. The University of Mississippi's Deciding Official is the Vice Chancellor for Research.

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.[4]

[1] Content based on 42 CFR Part 93 have endnotes referencing the applicable section.

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 knowledge of 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 the University meet its responsibilities under this policy and 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.[5]

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

G. *HHS Research Misconduct* means that subset of Research Misconduct relating to PHS-supported research activities for which HHS has prescribed particular standards, procedures, and reporting to ORI under 42 CFR Part 93 and as more particularly described throughout this policy. *HHS Research Misconduct* includes fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, in the context of (1) 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, (2) applications or proposals for PHS support for biomedical or behavioral research, research training or activities related to that research or research training, or (3) 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 or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.[6] For purposes of this definition:

1. *Fabrication* is making up data or results and recording or reporting them.

2. *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.

3. *Plagiarism* is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

4. *Research Misconduct* does not include honest error or differences of opinion.[7]

H. *Inquiry* means preliminary information-gathering and preliminary fact-finding that meet the criteria and follow the procedures of 42 CFR §§ 93.307-93.309.[8]

I. *Institutional Member* means a person who is employed by, is an agent of, or is affiliated by contract or agreement with the University of Mississippi. 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.[9]

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.[10]

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

L. *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.[11]

M. *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.[12]

N. *Public Health Service* or *PHS* means the unit within the Department of Health and Human Services 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.[13]

O. *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: PHS grants, cooperative agreements, or contracts or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.[14]

P. *Records of Research Misconduct Proceedings* means: (1) the Research Records and Evidence secured for the Research Misconduct Proceeding pursuant to this policy or 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.[15]

Q. *Research Integrity Officer* (RIO) means the institutional official responsible for: (1) assessing Allegations of Research Misconduct to determine if they fall within the definition of Research Misconduct and warrant an Inquiry on the basis that the Allegation is sufficiently credible and specific so that potential evidence of Research Misconduct may be identified; and (2) overseeing Inquiries and Investigations; and (3) the other responsibilities described in this policy. The University of Mississippi's Research Integrity Officer is the Executive Director for Research Integrity and Compliance.

R. *Research Misconduct* means:

1. Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results

    a. *Fabrication* is making up data or results and recording or reporting them.
    b. *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.
    c. *Plagiarism* is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
    d. *Research Misconduct* does not include honest error or differences of opinion.[16]

2. Violation of any criminal or civil law in obtaining, analyzing or reporting data.

3. Applying for federal funding while under federal suspension or debarment, or knowingly utilizing as a co-principal investigator, technician, or consultant a person who is suspended or debarred.

4. Failure to maintain a record of primary data with the intent to deceive; e.g. destroying laboratory notebooks (whether written or electronic), survey forms, microscope reference slides, computer or other machine printouts with the intent to deceive.

5. Failure to report known or suspected acts of misconduct on the part of others, including the act of knowingly withholding or destroying Evidence which would be crucial in an Investigation of misconduct.

6. Abuse of confidentiality when gathering or reporting data; e.g., releasing data gathered during privileged communication.

S. *Research Misconduct Proceeding* means any actions related to alleged Research Misconduct that is within this policy, including but not limited to, assessments, Inquiries, Investigations, ORI oversight reviews, hearings and administrative appeals.[17]

T. *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.[18]

U. *Respondent* means the person against whom an Allegation of Research Misconduct is directed or who is the subject of a Research Misconduct Proceeding.[19]

V. *Retaliation* means an adverse action taken against a Complainant, witness, or committee member by the University 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.[20]

III. Rights and Responsibilities

A. Research Integrity Officer

The Executive Director of Research Integrity and Compliance will serve as the RIO who will have primary responsibility for implementation of the institution's policies and procedures on Research Misconduct. The RIO will be well qualified to administer the procedures and 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.

A detailed listing of the responsibilities of the RIO is set forth in Appendix A. These responsibilities include the following duties related to Research Misconduct Proceedings:

1. Consult confidentially with persons uncertain about whether to submit an Allegation of Research Misconduct;

2. Receive Allegations of Research Misconduct;

3. 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;

4. As necessary, take interim action and notify ORI of special circumstances, in accordance with Section IV.F. of this policy;

5. Sequester research data and Evidence pertinent to the Allegations 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;

6. Provide confidentiality for those involved in the Research Misconduct Proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy;

7. Notify the Respondent and provide opportunities for him/her to review, comment, and respond to Allegations, Evidence, and committee reports in accordance with Section III.C. of this policy;

8. Inform Respondents, Complainants, and witnesses of the procedural steps in the Research Misconduct Proceeding;

9. 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;

10. 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;

11. 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;

12. Keep the Deciding Official and others who need to know apprised of the progress of the review of the Allegation of Research Misconduct;

13. Notify and make reports to ORI as required by 42 CFR Part 93;

14. 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

15. Maintain records of the Research Misconduct Proceeding and make them available to ORI in accordance with Section VIII.E. 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.[21]

As determined on a case-by-case basis, the RIO may provide to the Complainant for comment: (1) relevant portions of the Inquiry report; and (2) the draft Investigation report or relevant portions of it. The RIO will ensure that any comments made by the Complainant on the draft Investigation report are fully considered by the Investigation committee and that those comments are included in the final Investigation report.

C. Respondent

1. Responsibilities
   a. Maintaining confidentiality
   b. Cooperating with the conduct of an Inquiry and Investigation

2. The Respondent is entitled to:
   a. A good faith effort from the RIO to notify him or her in writing at the time of or before beginning an Inquiry;[22]
   b. An opportunity to comment on the Inquiry report and have his/her comments attached to the report;[23]
   c. 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 University's policies and procedures on Research Misconduct;[24]
   d. 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 Deciding Official decides an Investigation is warranted), and be notified in writing of any new Allegation, not addressed in the Inquiry or in the initial notice of Investigation, within a reasonable time after the determination to pursue those Allegations;[25]
   e. 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;[26]
   f. Have the Investigation committee interview 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;[27] and
   g. 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 1) any comments must be submitted within 30 days of receipt of the draft report and 2) that the comments will be considered by the Investigation committee and addressed in the final report.[28]

3. Admission to Allegations

   a. The Respondent will be given the opportunity to admit that Research Misconduct occurred and that he or 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. For HHS Research Misconduct, the Deciding Official may do this if the institution's acceptance of the admission and any proposed settlement is approved by ORI.[29]
   b. Admissions of Allegations must be written, specify the Research Misconduct in detail, and be signed in the presence of witnesses

c. A Respondent's admission to specific Allegations will not limit the scope of findings made against the Respondent nor limit the review of additional research activity of the Respondent for evidence of a broader set of misconduct issues.

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. For HHS Research Misconduct, the written finding that an Investigation is warranted 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. ORI may later assess the reasons why the University decided not to conduct an Investigation for HHS Research Misconduct. [30]

The DO will receive the Investigation report and, after consulting with the RIO and other appropriate officials, decide the extent to which the University accepts the findings of the Investigation and, if Research Misconduct is found, decide what, if any, institutional administrative actions are appropriate. For HHS Research Misconduct, the DO shall ensure that the final Investigation report, the findings of the DO and a description of 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 will report observed, suspected, or apparent Research Misconduct to the RIO. Any official who receives an Allegation of Research Misconduct must report it immediately. 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 at 662-915-5458, to discuss the suspected Research Misconduct informally, which may include discussing it hypothetically. The RIO will determine whether situations fall within the definition of Research Misconduct. If the circumstances described by the individual do not meet the definition of Research Misconduct, the RIO will refer the individual to other offices or officials with responsibility for resolving the problem.

At any time, an Institutional Member may have discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting Allegations. Discussions can be confidential, but only if the Institutional Member is not called to provide testimony in an Inquiry or Investigation. Inquiries, Investigations, and follow-up procedures are also confidential but include more individuals (e.g., respondents, committee members, and University and HHS officials).

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 will require written confidentiality agreements to ensure that the recipient does not make any further disclosure of identifying information. If feasible, the University will provide confidentiality 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

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.[31]

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 University. 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 and may bring the counsel or personal adviser to interviews or meetings on the case. Lawyers or personal advisers present at interviews and meetings will be restricted to advising (as opposed to representing) the Respondent.

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 research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and, for HHS Research Misconduct, with ORI, and take appropriate interim action to protect against any such threat.[32] 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. For HHS Research Misconduct, 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:

1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;

2. HHS resources or interests are threatened;

3. Research activities should be suspended;

4. There is a reasonable indication of possible violations of civil or criminal law;

5. Federal action is required to protect the interests of those involved in the Research Misconduct Proceeding;

6. 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

7. The research community or public should be informed.[33]

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 1) it is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified, thus meriting an Inquiry, and 2) whether the Allegation of Research Misconduct alleges HHS Research Misconduct within the jurisdictional criteria of 42 CFR § 93.102(b), thus requiring reporting to ORI.
The assessment period should as brief as possible. 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.[34]

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.[35] The RIO may consult with ORI 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 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.[36] The RIO will notify the Respondent of the proposed committee membership. If the Respondent submits a written objection to any appointed member of the Inquiry committee or expert based on personal, professional, or financial conflict of interest within 5 business days of receiving notice, the RIO will determine whether to replace the challenged member or expert with a qualified substitute.

E. Charge to the Committee and First Meeting

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

1. Sets forth the time for completion of the Inquiry;

2. Describes the Allegations and any related issues identified during the assessment;

3. 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;

4. 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, for HHS Research Misconduct, 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;

5. 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, for HHS Research Misconduct, 42 CFR § 93.309(a).

At the committee's first meeting, the RIO will review the charge with the committee, discuss the Allegation, 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 and the University Attorney 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 examine relevant Research Records and materials. Then the Inquiry committee will evaluate the Evidence, including the testimony obtained during the Inquiry. After consultation with the RIO, the committee members will decide whether an Investigation is warranted based on the criteria in this policy and, for HHS Research Misconduct, 42 CFR § 93.307(d). The scope of the Inquiry neither requires nor normally includes deciding whether misconduct definitely occurred, determining definitely who committed the Research Misconduct, or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of Research Misconduct is made by the Respondent, misconduct may be determined at the Inquiry stage if all relevant issues are resolved. In that case, for HHS Research Misconduct, the institution shall promptly consult with ORI to determine the next steps that should be taken. See Section IX.

G. Time for Completion

The Inquiry, including preparation of the final Inquiry report and the decision of the DO on whether an Investigation is warranted, must be completed within 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. the names and titles of the committee members and experts who conducted the Inquiry;

3. a description of the Allegations of Research Misconduct;

4. any PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support;

5. a list of the Research Records reviewed;

6. the basis for recommending or not recommending that the Allegations warrant an Investigation;

7. any comments on the draft report by the Respondent or Complainant; and

8. whether any other actions should be taken if an Investigation is not recommended.[38]

The University Attorney will review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the Inquiry committee.

B. Notification to the Respondent and Opportunity for Respondent and Complainant to Comment on the Draft Inquiry Report

1. Notification to Respondent

   The RIO will notify the Respondent whether the Inquiry found an Investigation to be warranted, provide the Respondent with a copy of the draft Inquiry report for comment, and include a copy of or refer to 42 CFR Part 93 and the University's policies and procedures on Research Misconduct.[39]

2. Respondent and Complainant Comments on Draft Inquiry Report

   The RIO may provide the Complainant, if he or she is identifiable, with the decision on whether the Inquiry found an Investigation to be warranted and may provide portions of the draft Inquiry report that address the Complainant‘s role and opinions in the Inquiry. Access to the report will be conditioned upon a signed confidentiality agreement with the Complainant.

3. Receipt of Comments and Final Inquiry Report

   Within 14 business days of their receipt of the draft report or excerpts from the draft report, the Complainant and Respondent will provide their comments, if any, to the Inquiry committee. Any comments that the Complainant or Respondent submits on the draft report will become part of the final Inquiry report and record. Based on the comments, the Inquiry committee may revise the report as appropriate and then submit 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 and state in writing whether an Investigation is warranted. The Inquiry is completed when the DO makes this determination in writing.

2. Notification to ORI for HHS Research Misconduct

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:

a. the institutional policies and procedures under which the Inquiry was conducted;

b. the Research Records and Evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and

c. the charges to be considered in the Investigation.[40]

3. Documentation of Decision and Records Retention

The RIO shall secure and maintain sufficiently detailed documentation of the Inquiry for 7 years after the termination of the Inquiry. For HHS Research Misconduct, if the DO's written determination is that an Investigation is not warranted, these documents must be provided to ORI or other authorized HHS personnel upon request for a later assessment by ORI of the reasons why an Investigation was not conducted.

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.[41] 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 ORI for HHS Research Misconduct; Notifying the Respondent; Sequestration of Research Records

For HHS Research Misconduct, on or before the date on which the Investigation begins, the RIO must notify the ORI Director of the decision to begin the Investigation and provide ORI a copy of the Inquiry report.

For all Research Misconduct, the RIO must notify the Respondent in writing of the Allegations to be investigated. The RIO must also give the Respondent written notice of any new Allegations of Research Misconduct within a reasonable amount of time of deciding to pursue Allegations not addressed during the Inquiry or in the initial notice of the Investigation.[42]
The RIO will, prior to notifying the Respondent of the Allegation, 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 encompasses 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 University'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.[43]

C. Appointment of the Investigation Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an Investigation committee and committee chair within 10 business days of the beginning of the Investigation or as soon thereafter as 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. When necessary to secure the necessary expertise or to avoid conflicts of interest, the RIO may select committee members from outside the University. The RIO will notify the Respondent of the proposed committee

membership within 5 business days after appointing the committee. If the Respondent submits a written objection to any appointed member of the Investigation committee or expert based upon a personal, professional, or financial conflict of interest within 5 business days of receipt of notification of the committee, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

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:

a. Describes the Allegations and related issues identified during the Inquiry;
b. Identifies the Respondent;
c. Informs the committee that it must conduct the Investigation as prescribed in paragraph E. of this section;
d. Defines Research Misconduct;
e. 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;
f. 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
g. Informs the committee that it must prepare or direct the preparation of a written Investigation report that meets the requirements of this policy and, for HHS Research Misconduct, the requirements of 42 CFR § 93.313.

2. First Meeting

The RIO will convene the first meeting of the Investigation committee, with the assistance of the University Attorney, 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 and the University Attorney will be present or available throughout the Investigation to advise the committee as needed.

E. Investigation Process

The Investigation committee and the RIO must:

1. 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]

2. Take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical;[45]

3. 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

4. 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 beginning it, including conducting the Investigation, preparing the report of findings, providing the draft report for comment, and, for HHS Research Misconduct, sending the final report to ORI.

For HHS Research Misconduct, if the RIO determines that the Investigation will not be completed within this 120-day period, the RIO 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.[48]

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:

1. Describes the nature of the Research Misconduct, including identification of the Respondent (the Respondent's c.v. or resume may be included as part of the identification);

2. For HHS Research Misconduct, 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;

3. Describes the specific Allegations of Research Misconduct considered in the Investigation;

4. Includes the University's policies and procedures under which the Investigation was conducted;

5. Identifies and summarizes the Research Records and Evidence reviewed and identifies any Evidence taken into custody but not reviewed; and

6. Includes a statement of findings for each Allegation of Research Misconduct identified during the Investigation.[49] Each statement of findings must:

   a. identify whether the Research Misconduct was falsification, fabrication, plagiarism, or other type of University of Mississippi-defined Research Misconduct, and whether it was committed intentionally, knowingly, or recklessly;
   b. 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 the 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;
   c. for HHS Research Misconduct, identify the specific PHS support;
   d. identify whether any publications need correction or retraction;
   e. identify the person(s) responsible for the misconduct; and
   f. 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 calendar 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. Complainant

   On a case-by-case basis, the University may provide the Complainant a copy of the draft Investigation report, or relevant portions of it, for comment. Any comments from the Complainant must be submitted within 30 calendar days of the date on which he/she received the draft report and the comments must be included and considered in the final report. §§ 93.312(b) and 93.313(g)

3. University Attorney

   The draft Investigation report will be reviewed by the University Attorney for legal sufficiency, and comments will be incorporated into the report as appropriate.

4. Confidentiality

   In distributing the draft report, or portions thereof, to the Respondent and Complainant, 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, such as requiring the recipient to sign a confidentiality agreement and/or to come to his or her office to review the report.

C. Decision by Deciding Official

1. Deciding Official Responses to the Investigation Report

   The RIO will assist the Investigation committee in finalizing the draft Investigation report, including ensuring that the Respondent's comments and, when provided, the Complainant's comments, are included and considered, and transmit the final Investigation report to the DO, who will determine in writing: (1) whether the University 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.

2. Guidelines for Determining Institutional Actions

   The appropriate administrative action is commensurate with the seriousness of the misconduct. The DO will consider the following guidelines and mitigating and aggravating factors, which are used by HHS (§ 93.408), in determining

administrative actions and their terms. The DO may consider other factors as appropriate in each case. The existence or nonexistence of any factor is not determinative:

a. Knowing, intentional, or reckless.
   Were the Respondent's actions knowing or intentional or was the conduct reckless?
b. Pattern.
   Was the Research Misconduct an isolated event or part of a continuing or prior pattern of dishonest conduct?
c. Impact.
   Did the misconduct have significant impact on the proposed or reported Research Record, research subjects, other researchers, institutions, or the public health or welfare?
d. Acceptance of responsibility.
   Has the Respondent accepted responsibility for the misconduct by—
   (1) Admitting the conduct;
   (2) Cooperating with the Research Misconduct Proceedings;
   (3) Demonstrating remorse and awareness of the significance and seriousness of the Research Misconduct; and
   (4) Taking steps to correct or prevent the recurrence of the Research Misconduct.
e. Failure to accept responsibility.
   Does the Respondent blame others rather than accepting responsibility for the actions?
f. Retaliation.
   Did the Respondent retaliate against Complainants, witnesses, committee members, or other persons?
g. Present responsibility.
   Is the Respondent presently responsible to conduct PHS or other supported or unsupported research?
h. Other factors.
   Other factors appropriate to the circumstances of a particular case.

3. Notification

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 for HHS Research Misconduct, 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, in addition to PHS agencies.

D. Notice to ORI of Institutional Findings and Actions for HHS Research Misconduct

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 University accepts the findings of the Investigation report;

3. a statement of whether the University found misconduct and, if so, who committed the misconduct; and

4. a description of any pending or completed administrative actions against the Respondent.[52]

Notice to non-PHS funding agencies will be made according to those agencies' reporting requirements.

E. Maintaining Records, Including Subsequent Review by ORI

1. For HHS Research Misconduct, 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 University's handling of such an Allegation.[54]

2. For all other Research Misconduct, 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 other funding agency proceeding involving the Research Misconduct Allegation.[55]

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.

For HHS Research Misconduct, the RIO must notify ORI in advance if there are plans to close a case at the Inquiry or Investigation 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.[56]

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:

1. Withdrawal or correction of all pending or published abstracts and papers emanating from the research where Research Misconduct was found;

2. 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;

3. Restitution of funds to the grantor agency as appropriate; and

4. 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 University 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 University'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 University 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 Allegation, 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 will, at the request of the Respondent, undertake all reasonable and practical efforts to restore the Respondent's reputation.[57] 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 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 University or, for HHS Research Misconduct, the ORI 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.[58] 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.

Approved by the University of Mississippi Executive Management Council October 29, 2007

Appendix A

Research Integrity Officer Responsibilities

I. General

The Research Integrity Officer (RIO) has lead responsibility for ensuring that the University:

- Takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages Research Misconduct, and deals promptly with Allegations or evidence of possible Research Misconduct.

- Has written policies and procedures for responding to Allegations of Research Misconduct and reporting information about that response to ORI, as required by 42 CFR Part 93.

- Complies with its written policies and procedures and the requirements of 42 CFR Part 93.

- Informs its Institutional Members who are subject to 42 CFR Part 93 about its Research Misconduct policies and procedures and its commitment to compliance with those policies and procedures.

- Takes appropriate interim action during a Research Misconduct Proceeding to protect public health, federal funds and equipment, and the integrity of any PHS supported research process.

II. Notice and Reporting to ORI and Cooperation with ORI - for HHS Research Misconduct

The RIO has lead responsibility for ensuring that the University:

- Files an annual report with ORI containing the information prescribed by ORI.

- Sends to ORI with the annual report such other aggregated information as ORI may prescribe on the University's Research Misconduct Proceedings and the University's compliance with 42 CFR Part 93.

- Notifies ORI immediately if, at any time during the Research Misconduct Proceeding, it has reason to believe that health or safety of the public is at risk, HHS resources or interests are threatened, research activities should be suspended, there is 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 University believes that the Research Misconduct Proceeding may be made public prematurely, or the research community or the public should be informed.

- Provides ORI with the written finding by Deciding Official (the responsible University official) that an Investigation is warranted and a copy of the Inquiry report, within 30 days of the date on which the finding is made.

- Notifies ORI of the decision to begin an Investigation on or before the date the Investigation begins.

- Within 120 days of beginning an Investigation, or such additional days as may be granted by ORI, provides ORI with the Investigation report, a statement of whether the University accepts the Investigation's findings, a statement of whether the University found Research Misconduct and, if so, who committed it, and a description of any pending or completed administrative actions against the Respondent.

- Seeks advance ORI approval if the University plans to close a case at the Inquiry, Investigation, or appeal stage on the basis that the Respondent has admitted guilt, a settlement with the Respondent has been reached, or for any other reason, except the closing of a case at the Inquiry stage on the basis that an Investigation is not warranted or a finding of no misconduct at the Investigation stage.

- Cooperates fully with ORI during its oversight review and any subsequent administrative hearings or appeals, including providing all Research Records and Evidence under the University's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant Evidence.

III. Research Misconduct Proceeding

A. General

The RIO is responsible for:

- Promptly taking all reasonable and practical steps to obtain custody of all Research Records and Evidence needed to conduct the Research Misconduct Proceeding, inventory the records and Evidence, and sequester them in a secure manner.

- Taking all reasonable and practical steps to ensure the cooperation of Respondents and other Institutional Members with Research Misconduct Proceedings, including, but not limited to their providing information, Research Records and Evidence.

- Providing confidentiality to those involved in the Research Misconduct Proceeding as required by 42 CFR 93.108, other applicable law, and University policy.

- Determining whether each person involved in handling an Allegation of Research Misconduct has an unresolved personal, professional or financial conflict of interest and taking appropriate action, including recusal, to ensure that no person with such a conflict is involved in the Research Misconduct Proceeding.

- Keeping the Deciding Official (DO) and others who need to know apprised of the progress of the review of the allegation of Research Misconduct.

- In cooperation with other University officials, taking all reasonable and practical steps to protect or restore the positions and reputations of Good Faith Complainants, witnesses, and committee members and to counter potential or actual Retaliation against them by Respondents or other Institutional Members.

- Making all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in Research Misconduct, but against whom no finding of Research Misconduct is made.

- Assisting the DO in implementing his/her decision to take administrative action against any Complainant, witness, or committee member determined by the DO not to have acted in Good Faith.

- Maintaining records of the Research Misconduct Proceeding, as defined in 42 CFR 93.317, in a secure manner for 7 years after completion of the proceeding, or the completion of any ORI proceeding involving the Allegation of Research Misconduct, whichever is later, unless custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained.

- Ensuring that administrative actions taken by the University and ORI are enforced and taking appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards, of those actions.

B. Receipt and Assessment

The RIO is responsible for:

- Consulting confidentially with persons uncertain about whether to submit an Allegation of Research Misconduct.

- Receiving Allegations of Research Misconduct.

- Assessing each Allegation of Research Misconduct to determine if an Inquiry is warranted because the Allegation falls within the definition of Research Misconduct, is within the jurisdictional criteria of 42 CFR 93.102 (b) - for HHS Research Misconduct, and is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified.

C. Inquiry

The RIO is responsible for:

- Initiating the Inquiry process if it is determined that an Inquiry is warranted.

- At the time of, or before beginning the Inquiry, making a Good Faith effort to notify the Respondent in writing, if the Respondent is known.

- On or before the date on which the Respondent is notified, or the Inquiry begins, whichever is earlier, taking all reasonable and practical steps to obtain custody of all Research Records and Evidence needed to conduct the Research Misconduct Proceeding, inventorying the records and Evidence and sequestering 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 the instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

- Appointing an Inquiry committee and committee chair as soon after the initiation of the Inquiry as is practical.

- Preparing a charge for the Inquiry committee in accordance with the University's policies and procedures.

- Convening the first meeting of the Inquiry committee and at that meeting briefing the committee on the Allegation, the charge to the committee, and the appropriate procedures for conducting the Inquiry, including the need for confidentiality and for developing a plan for the Inquiry, and assisting the committee with organizational and other issues that may arise.

- Providing the Inquiry committee with needed logistical support, e.g., expert advice, including forensic analysis of Evidence, and clerical support, including arranging witness interviews and recording or transcribing those interviews.

- Being available or present throughout the Inquiry to advise the committee as needed and consulting with the committee prior to its decision on whether to recommend that an Investigation is warranted on the basis of the criteria in the University's policies and procedures and 42 CFR 93.307 (d), as applicable.

- Determining whether circumstances clearly warrant a period longer than 60 days to complete the Inquiry (including preparation of the final Inquiry report and the decision of the DO on whether an Investigation is warranted), approving an extension if warranted, and documenting the reasons for exceeding the 60-day period in the record of the Research Misconduct Proceeding.

- Assisting the Inquiry committee in preparing a draft Inquiry report, sending the Respondent a copy of the draft report for comment and sending the Complainant a copy of sections of the draft report for comment within a time period that permits the Inquiry to be completed within the allotted time, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the Respondent and the Complainant, and ensuring that the comments are attached to the final Inquiry

report.

- Receiving the final Inquiry report from the Inquiry committee and forwarding it, together with any comments the RIO may wish to make, to the DO who will determine in writing whether an Investigation is warranted.

- Within 30 days of a DO decision that an Investigation is warranted, providing ORI with the written finding and a copy of the Inquiry report, as applicable, and notifying those University officials who need to know of the decision.

- Notifying the Respondent and the Complainant whether the Inquiry found an Investigation to be warranted and including in the notice copies of or a reference to 42 CFR Part 93, as applicable, and the University's Research Misconduct policies and procedures.

- For HHS Research Misconduct, providing to ORI, upon request, the University's policies and procedures under which the Inquiry was conducted, the Research Records and Evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents, and the charges to be considered in the Investigation.

- If the DO decides that an Investigation is not warranted, securing and maintaining for 7 years after the termination of the Inquiry sufficiently detailed documentation of the Inquiry to permit a later assessment by ORI of the reasons why an Investigation was not conducted for HHS Research Misconduct.

D. Investigation

The RIO is responsible for:

- Initiating the Investigation within 30 calendar days after the determination by the DO that an Investigation is warranted.

- On or before the date on which the Investigation begins: (1) for HHS Research Misconduct, notifying ORI of the decision to begin the Investigation and providing ORI a copy of the Inquiry report; and (2) notifying the Respondent in writing of the Allegations to be investigated.

- Prior to notifying Respondent of the Allegation, taking 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.

- In consultation with other University officials as appropriate, appointing an Investigation committee and committee chair as soon after the initiation of the Investigation as is practical.

- Preparing a charge for the Investigation committee in accordance with the University's policies and procedures.

- Convening the first meeting of the Investigation committee and at that meeting: (1) briefing the committee on the charge, the Inquiry report and the procedures and standards for the conduct of the Investigation, including the need for confidentiality and developing a specific plan for the Investigation; and (2) providing committee members a copy of the University's policies and procedures and, where applicable, 42 CFR Part 93.

- Providing the Investigation committee with needed logistical support, e.g., expert advice, including forensic analysis of Evidence, and clerical support, including arranging interviews with witnesses and recording or transcribing those interviews.

- Being available or present throughout the Investigation to advise the committee as needed.

- On behalf of the University, the RIO is responsible for each of the following steps and for ensuring that the Investigation committee: (1) uses diligent efforts to conduct an Investigation that includes an examination of all Research Records and Evidence relevant to reaching a decision on the merits of the Allegations and that is otherwise thorough and sufficiently documented; (2) takes reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical; (3) interviews 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 records or transcribes each interview, provides the recording or transcript to the interviewee for correction, and includes the recording or transcript in the record of the Research Misconduct Proceeding; and (4) pursues 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 continues the Investigation to completion.

- For HHS Research Misconduct, upon determining that the Investigation cannot be completed within 120 days of its initiation (including providing the draft report for comment and sending the final report with any comments to ORI), submitting a request to ORI for an extension of the 120-day period that includes a statement of the reasons for the extension. If the extension is granted, the RIO will file periodic progress reports with ORI as determined by ORI.

- Assisting the Investigation committee in preparing a draft Investigation report that meets the requirements of 42 CFR Part 93, where applicable, and the University's policies and procedures, sending the Respondent and Complainant a copy of the draft report for comment within 30 days of receipt, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the Respondent and Complainant, and ensuring that the comments are included and considered in the final

Investigation report.

- Transmitting the draft Investigation report to the University Attorney for a review of its legal sufficiency.

- Assisting the Investigation committee in finalizing the draft Investigation report and receiving the final report from the committee.

- Transmitting the final Investigation report to the DO and: (1) if the DO determines that further fact-finding or analysis is needed, receiving the report back from the DO for that purpose; (2) if the DO determines whether or not to accept the report, its findings and the recommended institutional actions, transmitting to ORI (where applicable) within the time period for completing the Investigation, a copy of the final Investigation report with all attachments, a statement of whether the University accepts the findings of the report, a statement of whether the University found Research Misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the Respondent.

- When a final decision on the case is reached, the RIO will normally notify both the Respondent and the Complainant in writing and will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of involved journals, collaborators of the Respondent, or other relevant parties should be notified of the outcome of the case.

- For HHS Research Misconduct, maintaining and providing to ORI upon request all relevant Research Records and records of the University's Research Misconduct Proceeding, including the results of all interviews and the transcripts or recordings of those interviews.

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[1] 42 CFR § 93.214
[2] 42 CFR § 93.201
[3] 42 CFR § 93.203
[4] 42 CFR § 93.208
[5] 42 CFR § 93.210
[6] 42 CFR § 93.102
[7] 42 CFR § 93.103
[8] 42 CFR § 93.212
[9] 42 CFR § 93.214
[10] 42 CFR § 93.215
[11] 42 CFR § 93.217

[12] 42 CFR § 93.219
[13] 42 CFR § 93.220
[14] 42 CFR § 93.221
[15] 42 CFR § 93.224
[16] 42 CFR § 93.103
[17] 42 CFR § 93.223
[18] 42 CFR § 93.224
[19] 42 CFR § 93.225
[20] 42 CFR § 93.226
[21] 42 CFR § 93.310(g)
[22] 42 CFR §§ 93.304(c), 93.307(b)
[23] 42 CFR §§ 93.304(e), 93.307(f)
[24] 42 CFR § 308(a)
[25] 42 CFR § 310(c)
[26] 42 CFR § 310(g)
[27] 42 CFR § 310(g)
[28] 42 CFR §§ 93.304(f), 93.312(a)
[29] 42 CFR § 93.316
[30] 42 CFR § 93.309(c)
[31] 42 CFR § 93.304(k)
[32] 42 CFR § 93.304(h)
[33] 42 CFR § 93.318
[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 § 93.317(b)
[56] 42 CFR § 93.316(a)
[57] 42 CFR § 93.304(k)
[58] 42 CFR § 93.304(l)