RESEARCH AND SCHOLARLY MISCONDUCT POLICY

(Approved by the Faculty Senate on November 9, 2011 This policy is adapted from sample policy and procedures published by the United States Public Health Service Office of Research Integrity (ORI) in compliance with 42 CFR Part 93. This policy replaces "Research and Scholarly Misconduct Policies and Procedures" approved by the Faculty Senate on November 12, 2008.)

I. Introduction

A. General Policy

The University of Arkansas is committed to the highest integrity in research and scholarly activity. Actions which fail to meet this standard can undermine the quality of academic scholarship and harm the reputation of the University. This policy is designed to help ensure that all those associated with the University of Arkansas carry out their research and scholarly obligations in a manner that is consistent with the mission and values of the University, and provides a means of addressing instances of suspected research misconduct should they arise.

Principal investigators are responsible for maintaining ethical standards in the projects they direct and reporting any violations to the appropriate University official. Students charged with academic misconduct are subject to separate disciplinary rules governing students, however, such cases may also be reviewed under these policies if applicable

under the provisions stated below. The Research Integrity Officer, in consultation with the student's dean shall determine which policy is most appropriate in each case.

A charge of research misconduct is very serious, and will be reviewed carefully and thoroughly. Any allegation of research misconduct will be handled as confidentially and expeditiously as possible. Full attention will be given to the rights and responsibilities of all individuals involved. Charges of research misconduct which are determined not to be made in good faith, as provided for in this policy, may result in administrative action against the charging party.

B. Scope

This statement of policy and procedures is intended to carry out the responsibilities of the University of Arkansas, Fayetteville under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93 and the research misconduct policies of other funding agencies, as applicable to particular allegations.

This document applies to allegations of research misconduct (as defined below) involving:

- A person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by enrolled student status, contract or agreement with the University of Arkansas, Fayetteville; and

- is accused of plagiarism, fabrication, or falsification of research records produced in the course of research, research training or activities related to that research or research training. This includes any research formally proposed, performed, reviewed, or reported, or any document or record generated in connection with such research, regardless of whether an application or proposal for funds resulted in a grant, contract, cooperative agreement, or other form of support.

Severance of the respondent's relationship with the University, whether by resignation or termination of employment, completion of or withdrawal from studies, or otherwise, before or after initiation of procedures under this policy, will not preclude or terminate research misconduct procedures.

II. Definitions and Standard of Review

Charge. A written allegation of misconduct that triggers the procedures described in this policy.

Complainant. A person who submits a charge of research misconduct.

Deciding Official (DO). The Provost and Vice Chancellor for Academic Affairs who is the institutional official responsible for making determinations, subject to appeal, on allegations of research misconduct and any institutional administrative actions. The

Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in the institution's allegation assessment, inquiry, or investigation. Discussing concerns regarding suspected research misconduct, as provided for in Section IV.A. of this policy, shall not be considered direct prior involvement. If the Deciding Official is unable to serve as DO in a particular matter, the Chancellor may appoint an appropriate official to act as the DO for purposes of that matter.

Good Faith Charge. A charge of research misconduct made by a complainant who believes that research misconduct may have occurred. A charge is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the charge.

Inquiry. The process under the policy for information gathering and preliminary fact-finding to determine if a charge or apparent instance of research misconduct has substance and therefore warrants an investigation.

Investigation. The process under this policy for the formal examination and evaluation of all relevant facts to determine whether research misconduct has occurred, and, if so, the responsible person and the seriousness of the misconduct.

Investigator. Any person, including but not limited to any person holding an academic or professional staff appointment at the University of Arkansas, who is engaged in the design, conduct, or reporting of research.

ORI. The Office of Research Integrity within the U.S. Department of Health and Human Services.

PHS. The Public Health Service within the U.S. Department of Health and Human Services.

Preponderance of Evidence. Evidence which is of greater weight or more convincing than evidence to the contrary; evidence which shows that something more likely than not is true.

Recklessly. To act recklessly means that a person acts in such a manner that the individual consciously disregards a substantial and unjustifiable risk or grossly deviates from the standard of conduct that a reasonable individual would observe; reckless means more than mere or ordinary negligence.

Research. A systematic investigation designed to develop or contribute to generalizable knowledge. The term includes the search for both basic and applied knowledge and well as training methods by which such knowledge may be obtained.

Research Integrity Officer (RIO) means the the institutional official responsible for: (1) assessing allegations of research misconduct to determine if the allegations fall within the

definition of research misconduct, are covered by 42 CFR Part 93 or other applicable federal policies, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing inquiries and investigations; and (3) the other responsibilities described in this policy. The Provost shall appoint the Vice Provost for Research and Economic Development; Director of Research Compliance; or another senior faculty member or administrator with significant experience in federal and state regulations and University policies regarding the responsible conduct of research to serve as the RIO. If the Research Integrity Officer is unable to serve as RIO in a particular matter, the DO may appoint an appropriate official to act as the RIO for purposes of that matter.

Research Misconduct. Research misconduct means the 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.

Research misconduct does not include disputes regarding honest error or honest differences in interpretations or judgments of data, and is not intended to resolve bona fide scientific disagreement or debate. *Research misconduct* is also not intended to include "authorship" disputes such as complaints about appropriate ranking of co-authors in publications, presentations, or other work, unless the dispute constitutes plagiarism (as defined above).

Research Record. Any data, document, computer file, computer storage media, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of a charge of research misconduct. A *research record* includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; printed or electronic correspondence; memoranda of telephone calls; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

Respondent. The person against whom a charge of research misconduct is directed, or the person whose actions are the subject of an inquiry or investigation.

Standard of Review

A finding of research misconduct requires that:

a. There be a significant departure from accepted practices of the relevant research community; and

b. The research misconduct be committed intentionally, knowingly, or recklessly; and

c. The allegation be proven by a preponderance of the evidence.

This standard and related definitions are restated in the charge to the investigation committee located in section V.E. of this policy.

III. Rights and Responsibilities

A. Research Integrity Officer

The RIO will have primary responsibility for implementation of the institution's policies and procedures on research misconduct. These responsibilities include the following duties related to research misconduct proceedings:

- Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;
- Receive allegations of research misconduct;
- Assess each allegation of research misconduct in accordance with Section V.A. of this policy to determine whether the allegation falls within the definition of research misconduct and warrants an inquiry;
- As necessary, take interim action and notify ORI of special circumstances, in accordance with Section IV.H. 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 or other applicable law or regulations, or institutional policy;
- Notify the respondent and provide opportunities for him/her to review/ comment/respond to allegations, evidence, and committee reports in accordance with Section III.C. of this policy;
- Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- Appoint the chair and members of the inquiry and investigation committees, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;
- Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;
- In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith

complainants, witnesses, and committee members and counter potential or actual retaliation against them by respondents or other institutional members;
- Keep the Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;
- Notify and make reports to ORI or other applicable federal agencies as required by 42 CFR Part 93 or other applicable law or regulations;
- Ensure that administrative actions taken by the institution, ORI, or other appropriate agencies are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and
- Maintain records of the research misconduct proceeding and make them available to ORI or other appropriate agencies as applicable in accordance with Section VIII.F. of this policy.

B. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality to the extent permitted by law, 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 of the interview for comment. The complainant must be interviewed during an investigation, and be given the transcript of the interview for comment. The complainant may be provided for comment with (1) relevant portions of the inquiry report (within a timeframe that permits the inquiry to be completed within 60 days of its initiation); and (2) relevant portions of the draft investigation report. In reviewing reports, the complainant must adhere to time limits set by the corresponding committee for timely completion of the inquiry or investigation

C. Respondent

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

- A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry;
- An opportunity to comment on the inquiry report and have his/her comments attached to the report;
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to 42 CFR Part 93 or other applicable law or regulations and the institution's policies and procedures on research misconduct;
- Be notified in writing of the allegations to be investigated within a reasonable time after the determination that an investigation is warranted, but before the investigation begins (within 30 days after the institution decides to begin an investigation), and be notified in writing of any new allegations, not addressed in the inquiry or in the initial notice of investigation, within a reasonable time after the determination to pursue those allegations;

- Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;
- Have a good faith effort made to interview 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, have the witness suggest any corrections in the transcript, and have the recording or corrected transcript included in the record of investigation; and
- Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to any records or materials 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.
- Appeal the decision of the DO as provided in Section XIII.D.

The respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO and/or other institutional officials, the 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 resolution is approved by ORI or the appropriate federal agency, if required.

D. Deciding Official

The DO will receive the inquiry report and after consulting with the RIO and/or other institutional officials, decide whether an investigation is warranted under this policy, the criteria in 42 CFR § 93.307(d), or other applicable law or regulations. Any finding that an investigation is warranted must be made in writing by the DO and must be provided to ORI or other federal agencies, if required, 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 or other applicable agencies may assess the reasons why the institution decided not to conduct an investigation.

The DO will receive the investigation report and, after consulting with the RIO and/or other institutional officials, decide the extent to which this institution accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate. The DO shall ensure that the final investigation report, the findings of the DO and a description of any pending or completed administrative actions are provided to ORI, as required by 42 CFR § 93.315 or to other federal agencies as required by their respective misconduct policies.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All institutional members will report observed, suspected, or apparent research misconduct to the RIO, the DO, or their designees. Prior to submitting a formal charge, a potential complainant is encouraged to consult informally with the RIO, the DO, or their designees to consider whether the case involves questions of research misconduct, should be resolved by other University procedures, or does not warrant further action. Contact information for the RIO may be obtained from the Office of Research Compliance or the listing of Research Council members on the Faculty Senate website. If the circumstances described by the individual do not meet the definition of research misconduct, but further action is required, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, to the extent permitted by law, an institutional member may have confidential discussions and consultations about concerns of possible misconduct with the RIO, the DO, or their designees and will be counseled about appropriate procedures for reporting allegations and their obligation to cooperate in any inquiry or investigation that may occur.

B. Cooperation with Research Misconduct Proceedings

Institutional members shall 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, as required by 42 CFR § 93.108 or other applicable law or regulation: (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. Conflicts of interest

At each stage of handling an inquiry or subsequent investigation, all persons involved shall be vigilant to prevent any real or perceived conflict of interest, or personal conflicts or relationships between colleagues, from affecting the outcome of the proceedings and resolution of the charges. Possible conflicts of interest may include co-authorship of work within the recent past with any of the individuals directly involved with the alleged misconduct, or professional or personal relationship with the respondent beyond that of mere acquaintances or colleagues. Committee members shall not have had any personal,

professional or financial involvement with the matters at issue in the investigation that might create an appearance of bias or actual bias. If such relationships or involvement are present, the individual shall recuse himself or herself from any investigative or decisional role in the case. If any prospective committee member at any point in the process presents a conflict of interest, that committee member shall be replaced by another appointee. If the RIO has a conflict of interest, the DO shall appoint a replacement; if the DO has a conflict of interest, the Chancellor shall appoint a replacement. The RIO may use a written conflict of interest statement to implement this provision; a sample statement is referenced in the Appendix to this policy.

E. 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.

F. 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.

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, or other applicable federal policies, and the policies and procedures of the institution.

G. Advisor to the Respondent

The respondent may consult with an advisor, who may or may not be an attorney. The advisor may not be a principal or witness in the case. The advisor may accompany the respondent to proceedings conducted as a part of the research misconduct proceeding, but shall not speak on behalf of the respondent or otherwise participate in the proceedings. The advisor must maintain confidentiality and be available as needed to ensure that that all proceedings are completed on a timely basis.

H. Interim Administrative Actions and Notifying ORI or Other Federal Agencies 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 ORI or other federal agencies, if

applicable, 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, consult with appropriate University officials and legal counsel immediately if he/she has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- Federal 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 federal action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

Following such consultation, the institution shall take appropriate steps to address such conditions, such as by notifying ORI or other applicable agency.

H. Computation of Time

In this policy, any reference to days shall mean calendar days. Any period of time equal to ten days or fewer shall exclude University holidays. If a deadline falls on a weekend or University holiday, the deadline shall be the next University business day.

I. Procedural Changes

a. Deadlines. Due to the sensitive nature of allegations of misconduct, each case shall be resolved as expeditiously as possible. The nature of some cases may, however, render normal deadlines difficult to meet. If at any time an established deadline cannot be met, a report shall be filed with the DO setting out the reasons why the deadline cannot be met and estimating when that stage of the process will be completed. A copy of this report shall be provided to the respondent. If PHS funding is involved, an extension must be received from the Office of Research Integrity.

b. Other Procedural Changes. Particular circumstances in an individual case may dictate variation from the procedures set out in this policy in order to ensure fair and efficient consideration of the matter. Any change in the procedures must ensure fair treatment of the respondent. Any major deviations from the procedures described in this policy shall be made only with the written approval of the DO in consultation with the respondent. Any minor deviations from the procedures described in this policy shall not require the written approval of the DO.

J. Exclusive Process

The procedures described in this policy constitute the exclusive process for raising and resolving charges of research misconduct.

V. Conducting the Assessment and Inquiry

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified and further review is warranted. The RIO shall also determine whether the alleged misconduct is within the jurisdictional criteria of 42 CFR § 93.102(b), and whether the allegation falls within the definition of research misconduct in 42 CFR § 93.103. An inquiry must be conducted if these criteria are met. In conducting this assessment, the RIO may consult with the institution's legal counsel and other appropriate University officials. If a charge is frivolous, does not raise questions of research misconduct, is more appropriately resolved by other University procedures, or does not warrant further action, the RIO may, at his or her discretion, handle the matter informally or refer it to the appropriate person or process, and will notify the complainant and anyone else known to be aware of the charge.

The assessment period should be brief, preferably concluded within a week. In conducting the assessment, the RIO need not interview the complainant, respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified and further review is warranted. The RIO shall, on or before the date on which the respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding, as provided in paragraph C. of this section.

B. Initiation and Purpose of the Inquiry

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

C. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the RIO must make a good faith effort to notify the respondent in writing, if the respondent is known. With the approval of the respondent, the RIO will also notify the dean of the school or college in which the

respondent holds his or her primary appointment. If the inquiry subsequently identifies additional respondents, they must be notified in writing. On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. The RIO may consult confidentially with the institution's legal counsel and other appropriate University officials for advice and assistance in this regard. In addition, if necessary, the RIO may consult with ORI or other applicable federal agency.

D. Appointment of the Inquiry Committee

The RIO, in consultation with other institutional officials as appropriate, shall appoint an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical. The inquiry committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. The RIO shall notify the respondent of the proposed inquiry committee membership. The respondent may then submit a written objection to any appointed member of the inquiry committee based on bias or conflict of interest within seven days. If an objection is raised, the RIO shall determine whether to replace the challenged member with a qualified substitute. The RIO's decision shall be final. The RIO may, with the concurrence of the DO, appoint one or more experts to assist the inquiry committee if necessary to evaluate specific allegations. The RIO shall direct the members of the committee that the investigation and all information relating to the investigation shall be kept confidential.

E. Charge to the Committee and First Meeting

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

- Sets forth the time for completion of the inquiry;
- Describes the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
- States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR §

93.102(b), if applicable; 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), if applicable.

At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The RIO will be present or available throughout the inquiry to advise the committee as needed. Prior to the first meeting, the RIO shall also consult with legal counsel for the institution as to the need for counsel to provide legal advice to the committee at the first meeting and in subsequent phases of the inquiry, including, but not limited to, for the purpose of reviewing institutional policies governing research misconduct proceedings, confidentiality and potential conflicts of interest.

F. Inquiry Process

The inquiry committee shall interview the complainant and the respondent, and may interview 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 42 CFR § 93.307(d) as applicable. The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the institution shall promptly consult with ORI or other appropriate agencies, as as required, 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 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. The respondent will be notified of the extension.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that includes the following information: (1) the name and position of the respondent; (2) a description of the allegations of research

misconduct; (3) the PHS or other federal support, if any, including, for example, grant numbers, grant applications, contracts and publications listing support; (4) the basis for recommending or not recommending that the allegations warrant an investigation; (5) any comments on the draft report by the respondent or complainant. An outline for reports to be furnished to ORI is referenced in the Appendix to this policy.

Institutional counsel shall review the draft inquiry report prior to transmission of the draft to the respondent. Modifications shall be made as appropriate in consultation with the RIO and the inquiry committee. The inquiry report shall include the following information: 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, together with a copy of the draft inquiry report, and a copy of or reference to 42 CFR Part 93 or other applicable federal policies and the institution's policies and procedures on research misconduct. The report shall clearly be labeled "DRAFT" in bold and conspicuous type font. The RIO shall notify the respondent that the respondent shall have 10 days to comment on the draft inquiry report. The RIO shall also direct the respondent that the draft report shall be kept confidential.

On a case-by-case basis, the RIO may provide the complainant a copy of the draft inquiry report, or relevant portions of it, for comment. If so, the report shall clearly be labeled "DRAFT" in bold and conspicuous type font, and the complainant will be allowed no more than 10 days to submit comments to the RIO. The complainant shall be directed that the draft report shall be kept confidential.

Any comments that are submitted by the respondent or the complainant shall 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. The RIO shall notify the complainant in writing whether the inquiry found an investigation to be warranted.

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 and Respondent

Within 30 days of the DO's decision that an investigation is warranted, the RIO will provide ORI, if required, with the DO's written decision and a copy of the inquiry report. The RIO shall also provide a copy of the DO's written decision and a copy of the inquiry report to the respondent within 30 days of the DO's decision. Subject to confidentiality, the RIO will also notify those institutional officials, if any, who need to know of the DO's decision because they will be directly involved in the investigation or otherwise have a need to know because of their official duties. The RIO must provide the following information to ORI, if required, or other applicable federal agency upon request: (1) the institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the investigation.

3. Documentation of Decision Not to Investigate

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

VII. Conducting the Investigation

A. Initiation and Purpose

The investigation must begin within 30 days, after the determination by the DO that an investigation is warranted. The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation must be set forth in an investigation report.

B. Notifying ORI 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, if required; 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. 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 as soon after the beginning of the investigation as is practical. The investigation committee must consist of at least three individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee. When necessary to secure the necessary expertise or to avoid conflicts of interest, the RIO may select committee members from outside the institution, or, with concurrence of the DO, may appoint experts to assist the committee in particular aspects of the case. The RIO will notify the respondent of the proposed investigation committee membership and any appointed experts. If the respondent then submits a written objection to any appointed member or expert based on bias or conflict of interest within seven days, the RIO will determine whether to replace the challenged member or expert with a qualified substitute, and the decision of the RIO shall be final.

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;
- Reviews the definition of research misconduct as stated in this Policy;
- 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 any other applicable federal policies, such as 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 developing a specific investigation plan. The RIO shall also direct the members of the committee that the investigation and all information relating to the investigation shall be kept confidential. The investigation committee will be provided with a copy of this statement of policy and procedures and any applicable federal research misconduct policies. The RIO will be present or available throughout the investigation to advise the committee as needed. Prior to the first meeting, the RIO shall also consult with legal counsel for the institution as to the need for counsel to provide legal advice to the committee at the first meeting and in subsequent phases in the investigation, including, but not limited to, for the purpose of reviewing institutional policies governing research misconduct proceedings, confidentiality and potential conflicts of interest.

E. Investigation Process

The investigation committee and the RIO must:

- Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;

- Interview each respondent, complainant, and make a good-faith effort to interview any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation; and
- Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.

F. Time for Completion

The investigation is to be completed within 120 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, if applicable. However, if the RIO determines that the investigation will not be completed within this 120-day period, he/she will submit a written request for an extension to the DO and to ORI or other applicable federal agencies, setting forth the reasons for the delay. If the request for an extension is approved by the DO and applicable federal agencies, then the RIO will ensure that periodic progress reports are filed with the approving officials.

G. Amended Charges

If issues of research misconduct that fall outside of the charge arise during the course of the investigation, the committee shall so inform the RIO, including in its communication the evidence on which its concerns are based. The RIO in consultation with the DO and the investigation committee, will consider the issues raised and, in the RIO's discretion, provide the investigation committee with an amended charge. The respondent shall be notified of any such amendments.

VIII. The Investigation Report

A. Elements of the Investigation Report

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

- Describes the nature of the allegation of research misconduct, including identification of the respondent and the respondent's curriculum vitae;
- Describes and documents the federal support, if any, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing federal support;
- Describes the specific allegations of research misconduct considered in the investigation;

- Includes the institutional policies and procedures under which the investigation was conducted;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
- Includes a statement of findings for each allegation of research misconduct identified during the investigation. Each statement of findings must: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any 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 federal support, if any; (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 federal agencies.
- If the committee determines that any allegation of research misconduct is true, the report shall recommend appropriate institutional actions in response to the findings of research misconduct.

The report and other retained documentation must be sufficiently detailed as to permit a later assessment of the investigation. An outline for reports to be furnished to ORI is referenced in the Appendix to this Policy.

B. Comments on the Draft Report and Access to Evidence

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 report shall clearly be labeled "DRAFT" in bold and conspicuous type font. 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 considered and made a part of the final investigation record. The respondent shall be directed that the draft report shall be kept confidential.

On a case-by-case basis, the RIO may provide the complainant a copy of the draft investigation report, or relevant portions of it, for comment. If so, the report shall clearly be labeled "DRAFT" in bold and conspicuous type font, and the complainant will be allowed no more than 30 days from the date on which he/she received the draft report to submit comments to the RIO. The complainant's comments must be included and considered in the final report. The complainant shall be directed that the draft report shall be kept confidential.

C. Decision by Deciding Official

The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's and, if applicable, complainant'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, whether at this stage of after a subsequent appeal, the RIO will notify the respondent in writing. If the DO's findings are not appealed within ten days, the DO's findings shall become the institution's final decision. At the time of a final decision, whether at this stage or after an appeal, the RIO will also notify the complainant in writing of the final outcome of the case. After informing ORI or other applicable federal agency, as required, the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Appeals

The respondent, within ten days of receiving written notification of the decision of the DO, may file an appeal with the Chancellor. The appeal may result in (i) a reversal or modification of the DO's findings of research misconduct or determinations of institutional action, (ii) the Chancellor may direct the DO to return the report to the investigation committee with a request for further fact-finding or analysis, or (iii) other action the Chancellor deems appropriate. The appeal process must be completed within 120 days of the filing of the appeal unless an extension is granted by appropriate officials and federal agencies. The decision of the Chancellor shall be final.

E. Notice to Federal Agencies of Institutional Findings and Actions

Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation or the 120-day period for completion of an appeal, submit the following to any applicable federal agencies as required: (1) a copy of the investigation report with all attachments and any appeals; (2) the findings of research misconduct, including who committed the misconduct; (3) a statement of whether the institution accepts the findings of the investigation; and (4) a description of any pending or completed administrative actions against the respondent.

F. Maintaining Records for Review by Federal Agencies

If required, the RIO must maintain and provide to ORI, if required, or other applicable federal agencies upon request "records of research misconduct proceedings" as that term is defined by 42 CFR § 93.317 or other applicable policies, as appropriate. Unless

custody has been transferred to an appropriate federal agency or such agency 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 federal proceeding involving the research misconduct allegation. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI or other appropriate federal agency to carry out its review of an allegation of research misconduct or of the institution's handling of such an allegation.

IX. Completion of Cases; Reporting Premature Closures to Federal Agencies

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. A case may be closed at the inquiry stage if it is determined that an investigation is not warranted. A case may be closed at the investigation stage if there is a finding that no research misconduct was committed. If the alleged misconduct was in the jurisdiction of the ORI or other federal agency, then this finding must be reported to the applicable agency. An advance notification by the RIO to any applicable federal agency must be made 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 those noted above.

X. Institutional Administrative Actions

If the DO and any subsequent appeal determine that research misconduct is substantiated by the findings, then the DO will decide on the appropriate actions to be taken, after consultation with the RIO and the Chancellor. The administrative actions may include, but are not limited to, the following:

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

XI. Other Considerations

A. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise

limit any of the institution's responsibilities under 42 CFR Part 93 or the corresponding research misconduct policies of other federal agencies .

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 or other federal agencies, if required, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation. Depending on the particular circumstances and 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.

Appendix

A. Summary of Items that must be Reported or Submitted to the ORI in those Cases Covered by 42 CFR Part 93

(*Note:* This list is subject to modification based on adherence to current ORI regulations.)

- An annual report containing the information specified by ORI on the institution's compliance with the final rule. Section 93.302(b).
- Within 30 days of finding that an investigation is warranted, the written finding of the responsible official and a copy of the inquiry report. Sections 93.304(d), 93.309(a), and 93.310(a) and (b).
- Where the institution has found that an investigation is warranted, the institution must provide 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 for the investigation to consider. Section 93.309.
- Periodic progress reports, if ORI grants an extension of the time limits on investigations or appeals and directs that such reports be submitted. Sections 93.311(c) and 93.314(c).
- Following completion of the investigation report or any appeal: (1) a copy of the investigation report with all attachments and any appeals; (2) the findings of research misconduct, including who committed the misconduct; (3) a statement of whether the institution accepts the findings of the investigation; and (4) a description of any pending or completed administrative actions against the respondent. Section 93.315.
- Upon request, custody or copies of records relevant to the research misconduct allegation, including research records and evidence. Section 93.317(c).
- Notify ORI immediately of the existence of any of the special circumstances specified in Section 93.318.
- Any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or the institution's handling of such an allegation. Section 93.400(b).

B. Outline for an Inquiry/Investigation Report for ORI

(*Note:* A recommended outline for inquiry and investigation reports has been furnished by ORI and is available on the Research Compliance web site. Committee members should consult this outline in preparing reports. The outline is subject to modification based on adherence to current ORI regulations.)

C. Conflict of Interest Statement

(*Note*: A sample conflict of interest statement is available on the Research Compliance web site. This statement shall be provided to the RIO for use in implementing the conflict of interest portions of this policy.)