Regulation on Research Conduct

Interim

REG10.45.01 Current Version

Authority: Chancellor

History: Effective July 13, 2012. This interim regulation supersedes and replaces Part VII, Section III of the ECU Faculty Manual, ?Ethics in Research and Creative Activity.?

Related Policies: UNC Policy Manual 500.7

ECU Academic Integrity Policy -ECU Faculty Manual Part VI (Section II)

Additional Resources: National Science Foundation Research Misconduct Regulation 45 CFR 689

Public Health Service Research Misconduct Regulation 42 CFR 93

Research Compliance Administration Website

Contact Information: Office of Research Compliance Administration 252-328-9473

Table of Contents

1. Introduction
   1.1. General Policy
   1.2. Scope
2. Definitions
3. Rights and Responsibilities
   3.1. Research Integrity Officer
   3.2. Complainant
   3.3. Respondent

3.4. Deciding Official
4. General Policies and Principles
4.1. Responsibility to Report Misconduct
4.2. Cooperation with Research Misconduct Proceedings
4.3. Confidentiality
4.4. Protecting complainants, witnesses, and committee members
4.5. Protecting the Respondent and Use of Legal Counsel
4.6. Interim Administrative Actions
5. Conducting the Assessment and Inquiry
5.1. Assessment of Allegations
5.2. Initiation and Purpose of the Inquiry
5.3. Notice to Respondent; Sequestration of Research Records
5.4. Appointment of the Inquiry Panel
5.5. Charge to the Committee and First Meeting
5.6. Inquiry Process
5.7. Time for Completion
6. The Inquiry Report
6.1. Elements of the Inquiry Report
6.2. Notification and Opportunity to Comment
6.3. Institutional Decision and Notification
6.3.1. Decision by Deciding Official
6.3.2. Notification
6.3.3. Documentation of Decision Not to Investigate
7. Conducting the Investigation
7.1. Initiation and Purpose
7.2. Notifying Respondent; Sequestration of Research Records
7.3. Appointment of the Investigation Committee
7.4. Charge to the Committee and the First Meeting
7.4.1. Charge to the Committee
7.4.2. First Meeting
7.5. Investigation Process
7.6. Time for Completion
8. The Investigation Report
8.1. Elements of the Investigation Report
8.2. Comments on the Draft Report and Access to Evidence
8.2.1. Respondent
8.2.2. Complainant
8.2.3. Confidentiality
8.3. Decision by Deciding Official
8.4. Notice of Institutional Findings and Actions
8.5. Maintaining Records for Review by Federal Agencies
9. Completion of Cases; Reporting Premature Closures
10. Institutional Administrative Actions

11. Other Considerations
11.1. Termination or Resignation Prior to Completing Inquiry or Investigation
11.2. Restoration of the Respondent's Reputation
11.3. Protection of the Complainant, Witnesses and Committee Members
11.4. Allegations Not Made in Good Faith

1. Introduction

1.1. General Policy

All individuals associated with East Carolina University, including, but not limited to faculty, staff, postdoctoral scholars, and students, have the responsibility to seek honestly and to promulgate ethically the truth in all phases of work. This responsibility governs not only the production and dissemination of research and creative activities, but also all applications for funding, reports to funding agencies, and teaching and publication of teaching materials.

1.2. Scope

This regulation applies to allegations of research misconduct (fabrication, falsification, or plagiarism) involving individuals associated with East Carolina University, including, but not limited to, faculty, staff, postdoctoral scholars, and students. This regulation does not apply to authorship or collaboration disputes.

2. Definitions

2.1. Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. For the purposes of this Regulation, Research includes all basic, applied, and demonstration research in all academic and scholarly fields. Research fields include, but are not limited to, the arts, the basic sciences, liberal arts, applied sciences, social sciences, clinical sciences, the professions, and research involving human subjects or animals.

2.2. Research Misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting the results. Research misconduct does not include honest error or differences of opinion.

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

2.4. 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. The research record is the record of data or results that embody the facts resulting from the research inquiry and includes, but is not limited to research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, books, dissertations, and journal articles.

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

2.6. Allegation means a disclosure of possible research misconduct through any means of communication. The disclosure may be a written or oral statement or other communication to an ECU administrator or RIO.

2.7. Complainant means a person who in good faith makes an allegation of research misconduct. There may be more than one Complainant in a given case.

2.8. Respondent means a person against whom are made allegations of research misconduct. There may be more than one Respondent in a given case.

2.9. 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 been 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 made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under this definition. 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.

2.10. 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.

2.11. Research Record- 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 a federal agency having jurisdiction and authority or an institutional official by a respondent in the course of the research misconduct proceeding. A research record also includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports, laboratory notebooks, notes, correspondence, 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 human subject research files.

2.12. Research Integrity Officer (RIO) is the institutional official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by law, regulation, or research sponsor policy, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing inquires and investigations; and (3) the other responsibilities described in this Regulation. The RIO for ECU is the Director of the Office of Research Compliance Administration.

2.13. Deciding Official (DO) means the institutional official who makes final determinations on allegations of research misconduct. 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 inquiry, investigation, or allegation assessment. A DO's appointment of an individual to assess allegations of research misconduct, or to serve on an inquiry or investigation committee, is not considered to be direct prior involvement. The DO for ECU is the Vice Chancellor for Research and Graduate Studies. In the event that the Vice Chancellor for Research and Graduate Studies has a conflict of interest for a particular case then the Chancellor shall appoint a designee as the DO for that particular case.

3. Rights and Responsibilities

3.1. Research Integrity Officer

3.1.1. The RIO will have primary responsibility for implementation of this Regulation. These responsibilities include the following duties related to research misconduct proceedings:

3.1.1.1. Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;

3.1.1.2 Receive allegations of research misconduct;

3.1.1.3 Assess each allegation of research misconduct in accordance with Section 5.1 of this Regulation to determine whether it falls within the definition of research misconduct and warrants an inquiry;

3.1.1.4 As necessary, take interim action and notify sponsors of special circumstances, in accordance with Section 4.6 of this Regulation;

3.1.1.5 Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with Section 5.3. of this Regulation and maintain it securely in accordance with this Regulation and applicable law and regulation;

3.1.1.6 Provide confidentiality to those involved in the research misconduct proceeding as required by applicable law and university policy;

3.1.1.7 Notify the respondent and provide opportunities for him/her to review/ comment/respond to allegations, evidence, and committee reports in accordance with Section 3.3. of this Regulation;

3.1.1.8 Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;

3.1.1.9 Ensure that the Deciding Official appoints the chair and members of the inquiry and investigation committees, ensure that those committees are properly staffed, that the members are without conflicts, and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;

3.1.1.10 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;

3.1.1.11 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;

3.1.1.12 Keep the Deciding Official and others who need to know

apprised of the progress of the review of the allegation of research misconduct;

3.1.1.13 Notify and make reports to federal agencies as required by applicable law or regulation;

3.1.1.14 Take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of corrective actions; and

3.1.1.15 Maintain records of the research misconduct proceeding and make them available to federal agencies in accordance with Section 8.4 of this Regulation.

3.2. 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 RIO may provide to the complainant for comment: (1) relevant portions of the inquiry report (within a timeframe that permits the inquiry to be completed within sixty (60) calendar days of its initiation, unless an extension of time is granted in accordance with the terms of this Regulation); and (2) relevant portions of the draft investigation report. Any comments on the draft investigation report must be submitted within thirty (30) calendar days of the date on which the complainant received the draft report. The University must consider any comments made by the complainant on the draft investigation report and include those comments in the final investigation report. See Section 4.4 for rights and protections of the Complainant.

3.3. Respondent

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

3.3.1.1. A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry;

3.3.1.2. An opportunity to comment on the inquiry report and have his/her comments attached to the report;

3.3.1.3. Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to this Regulation;

3.3.1.4. 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 (usually within thirty (30) calendar 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;

3.3.1.5. 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;

3.3.1.6. Have interviewed during the investigation any witness who has been reasonably identified by the Respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation; and

3.3.1.7. Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within thirty (30) calendar 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.

3.3.2. 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 settlement is approved by any federal agency having authority and jurisdiction. See Section 4.4 for rights and protections of the Respondent.

3.4. Deciding Official

3.4.1. The DO will receive the inquiry report and after consulting with the RIO and/or other institutional officials, decide whether an investigation is warranted. Any finding that an investigation is warranted must be made in writing by the DO and, where required by applicable law or regulation, must be provided to any federal agency with authority and jurisdiction, together with a copy of the inquiry report, within thirty (30) calendar 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 seven (7)

years after termination of the inquiry, so that any federal agency with authority and jurisdiction may assess the reasons why the institution decided not to conduct an investigation.

3.4.2. The DO will receive the investigation report and, may request all other associated documentation, after consulting with the RIO and/or other institutional officials, decide the extent to which he/she accepts the findings of the investigation and, if research misconduct is found, refer the matter to the appropriate Vice Chancellor to 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 any federal agency with jurisdiction and authority, as required by law or regulation.

4. General Policies and Principles

4.1. Responsibility to Report Misconduct

4.1.1. All individuals associated with ECU, including, but not limited to, faculty, staff, postdoctoral scholars, and students, will report observed, suspected, or apparent research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the RIO to discuss the suspected research misconduct informally, which may include discussing it hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem, if any.

4.1.2. 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.

4.2. Cooperation with Research Misconduct Proceedings

All individuals associated with ECU, including, but not limited to, faculty, staff, postdoctoral scholars and students, will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. These individuals, including Respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

4.3. Confidentiality

The RIO shall: (1) limit disclosure of the identity of respondents and

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

4.4. Protecting complainants, witnesses, and committee members

Individuals associated with ECU, including, but not limited to, faculty, staff, postdoctoral scholars, and students, may not retaliate in any way against complainants, witnesses, or committee members. These persons 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.

4.5. Protecting the Respondent and Use of Legal Counsel

4.5.1. 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.

4.5.2. During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in this Regulation. 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 personal advisor or legal counsel to interviews or meetings on the case. The role of the respondent's legal counsel is restricted to advising the respondent(s) and he/she may not act in a representative capacity or otherwise actively participate in interviews, meetings, or hearings.

4.5.3. The University shall provide legal counsel to assist the RIO, DO, Inquiry Panel, and Investigation Committee. The role of counsel is to advise and not to act in a representative capacity or otherwise actively participate in interviews, meetings, or hearings; provided, however, University counsel may be present at such interviews, meetings, or

hearings, and must be present whenever respondent's legal counsel is present.

4.6. Interim Administrative Actions

4.6.1. Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, animal health, sponsor funds, equipment, or the integrity of the sponsored research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and any federal agency with jurisdiction and authority, take appropriate interim action to protect against any such threat. Interim action might include additional monitoring of the research process and the handling of equipment or sponsor funds, freezing or limiting access to fund accounts, reassignment of personnel or of the responsibility for the handling of equipment or sponsor funds, additional review of research data and results or delaying publication.

4.6.2. The RIO shall, at any time during a research misconduct proceeding, notify any federal agency with jurisdiction and authority immediately if he/she has reason to believe that any of the following conditions exist:

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

4.6.2.2. Federal resources or interests are threatened;

4.6.2.3. Research activities should be suspended;

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

4.6.2.5. Federal action is required to protect the interests of those involved in the research misconduct proceeding;

4.6.2.6. The research misconduct proceeding may be made public prematurely and federal agency action may be necessary to safeguard evidence and protect the rights of those involved; or

4.6.2.7. The research community or public should be informed.

5. Conducting the Assessment and Inquiry

5.1. Assessment of Allegations

5.1.1. Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether it is sufficiently

credible and specific so that potential evidence of research misconduct may be identified and whether the allegation falls within the definition of research misconduct. An inquiry must be conducted if these criteria are met.

5.1.2. The assessment period should be brief, concluded within a reasonable time period as warranted by the nature of the allegations, typically within seven (7) to twenty-one (21) calendar days. 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, copy as warranted, and sequester all research records and evidence needed to conduct the research misconduct proceeding, as provided in paragraph 5.3 of this section.

5.2. 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.

5.3. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the RIO must make a good faith effort to notify the respondent in writing, if the respondent is known. If the inquiry subsequently identifies additional respondents, they must be notified in writing. On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. The RIO will provide a receipt of sequestered items to the respondent(s) or other individuals who have information relating to the inquiry. The RIO may consult with any federal agency with jurisdiction and authority for advice

and assistance in this regard.

5.4. Appointment of the Inquiry Panel

The DO, in consultation with the RIO and other institutional officials as appropriate, will appoint an Inquiry Panel of at least three individuals, as soon after the initiation of the inquiry as is practical. The majority of the committee shall be faculty without administrative appointment. The Inquiry Panel 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 or other relevant expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. The committee members may be selected from inside or outside the University as warranted. The respondent will be notified in writing of the proposed committee membership and may object to a proposed member based upon a personal, professional, or financial conflict of interest. Any such objections must be submitted to the RIO no more than ten (10) calendar days from the date of the notification. The RIO will make the final determination of whether a conflict exists.

5.5. Charge to the Committee and First Meeting

5.5.1 The RIO will prepare a charge for the Inquiry Panel that:

5.5.1.1 Sets forth the time for completion of the inquiry;

5.5.1.2 Describes the allegation(s) and any related issues identified during the allegation assessment;

5.5.1.3 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 or were responsible;

5.5.1.4 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, (2) the allegation(s) may have substance, based on the committee's review during the inquiry.

5.5.1.5 Informs the Inquiry Panel that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this Regulation and applicable law or regulation.

5.5.2 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.

5.6. Inquiry Process

The Inquiry Panel may interview the complainant, the respondent, and key witnesses as well as examining relevant research records and materials. Then the Inquiry Panel 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 Regulation. 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, as required by applicable law or regulation, the institution shall promptly consult with any federal agency with jurisdiction and authority, if any, to determine the next steps that should be taken. See Section 9.

5.7. 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 sixty (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 calendar day period. The respondent will be notified in writing of the extension.

6. The Inquiry Report

6.1. Elements of the Inquiry Report

6.1.1. 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 identification of any sponsor support, including, for example, grant numbers, grant applications, contracts and publications; (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.

6.1.2. Institutional counsel should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the Inquiry Panel. The inquiry report should include: the names and titles of the committee members and experts who conducted the inquiry; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; and whether any other actions should be taken if an investigation is not recommended.

6.2. Notification to the Respondent and Complainant and Opportunity to Comment

6.2.1. The RIO shall notify the respondent and the complainant whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment(s) usually within fourteen (14) calendar days, and include a copy of or refer to this Regulation. The complainant will receive only a copy of the portions of the draft inquiry report that address the claimant's role and opinions in the investigation for comment. The complainant shall execute in advance a written confidentiality agreement in a form approved by the Office of the University Attorney as a condition for access to the report.

6.2.2. Any comments that are submitted by the respondent and the claimant, respectively, will be attached to the final inquiry report. Based on the comments, the Inquiry Panel may revise the draft report as appropriate and prepare it in final form. The committee will deliver the final report to the RIO.

6.3. Institutional Decision and Notification

6.3.1. 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.

6.3.2. Notification to External Federal Agencies

Within thirty (30) calendar days of the DO's decision that an investigation is warranted, as required by applicable law or regulation, the RIO will provide any federal agency with authority and jurisdiction

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. As required by applicable law or regulation, the RIO must provide the following information to such 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 allegations to be considered in the investigation.

6.3.3. Documentation of Decision Not to Investigate

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

7. Conducting the Investigation

7.1. Initiation and Purpose

The investigation must begin within thirty (30) calendar days after the determination by the DO that an investigation is warranted. The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged research misconduct involves clinical trials, potential harm to human subjects, 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.

7.2. Notifying Respondent; Sequestration of Research Records

7.2.1. As required by applicable law or regulation, on or before the date on which the investigation begins, the RIO must: (1) notify any federal agency with jurisdiction and authority of the decision to begin the investigation and provide such federal agency a copy of the inquiry report; and (2) notify the respondent in writing of the allegations to be investigated. The RIO must also give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the

inquiry or in the initial notice of the investigation.

7.2.2. 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 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.

7.3. Appointment of the Investigation Committee

The DO, in consultation with the RIO and other institutional officials as appropriate, will appoint an investigation committee of at least five (5) individuals, as soon after the beginning of the investigation as is practical. The investigation committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific or other relevant expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation. The majority of the committee should be faculty without administrative appointment. Individuals appointed to the investigation committee may also have served on the Inquiry Panel. When necessary to secure the necessary expertise or to avoid conflicts of interest, the DO may select committee members from outside the University. The respondent will be notified of the proposed committee membership and given an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. If so, the respondent must submit objections in writing to the RIO no more than ten (10) calendar days from the date of the notification. The RIO will make the final determination of whether a conflict exists.

7.4. Charge to the Committee and the First Meeting

7.4.1. Charge to the Committee

The RIO will define the subject matter of the investigation in a written charge to the committee that:

7.4.1.1 Describes the allegations and related issues identified during the inquiry;

7.4.1.2 Identifies the respondent(s);

7.4.1.3 Informs the committee that it must conduct the investigation as prescribed in paragraph 7.5 of this section;

7.4.1.4 Defines research misconduct;

7.4.1.5 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;

7.4.1.6 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 Regulation, 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

7.4.1.7 Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this Regulation and applicable law or regulation.

7.4.2. First Meeting

The RIO will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of this Regulation and any applicable federal law or regulation governing the investigation. The RIO will be present or available throughout the investigation to advise the committee as needed.

7.5. Investigation Process

The investigation committee and the RIO must:

7.5.1. 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;

7.5.2. Take reasonable steps to ensure an impartial and unbiased

investigation to the maximum extent practical;

7.5.3. 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; and

7.5.4. 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.

7.6. Time for Completion

The investigation is to be completed within one-hundred twenty (120) calendar days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and, as required by applicable law or regulation, sending the final report to any federal agency with jurisdiction and authority. However, if the RIO determines that the investigation will not be completed within this time period, as required by applicable law or regulation, he/she will submit to any federal agency with jurisdiction and authority a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress reports are filed with such agency, if the agency grants the request for an extension and directs the filing of such reports. If no federal agency is involved, any request for extension of time must be approved in writing by the DO and the respondent notified in writing of such approval.

8. The Investigation Report

8.1. Elements of the Investigation Report

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

8.1.1. Describes the nature of the allegation of research misconduct, including identification of the respondent;

8.1.2. Describes and documents any relevant external sponsor support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing the sponsor support;

8.1.3. Describes the specific allegations of research misconduct

considered in the investigation;

8.1.4. Includes the University policies and procedures under which the investigation was conducted;

8.1.5. Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and

8.1.6. 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 sponsor support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the respondent has pending with any federal agencies.

8.2. Comments on the Draft Report and Access to Evidence

8.2.1. 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 thirty (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.

8.2.2. Complainant

The RIO must give the complainant a copy of the portions of the draft investigation report that address the claimant’s role and opinions in the investigation for comment. The complainant will be allowed thirty (30) calendar days from the date 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 execute in advance a written confidentiality agreement in a form approved by the Office of the University Attorney as a condition for access to the report.

8.2.3. Confidentiality

In distributing the draft report, or portions thereof, to the respondent, the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality.

8.3. Decision by Deciding Official

8.3.1. The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's(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.

8.3.2. When a final decision on the case has been reached, the RIO will normally notify both the respondent and the complainant in writing. After informing ORI, the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which relevant 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.

8.4. Notice of Institutional Findings and Actions

In accordance with applicable law or regulation, unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation, submit the following to any federal agency with jurisdiction and authority: (1) a copy of the final investigation report with all attachments; (2) a statement of whether the institution accepts the findings of the investigation report; (3) a statement of whether the institution found research misconduct and, if so, who committed the research misconduct; and (4) a description of any pending or completed administrative actions against the respondent.

8.5. Maintaining Records for Review by Federal Agencies

In accordance with applicable law or regulation, the RIO must maintain and provide to any federal agency with jurisdiction and authority upon request records of research misconduct proceedings. Unless custody has been transferred to the federal agency or the federal 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 seven (7) years after completion of the proceeding or the completion of any federal agency proceeding involving the research misconduct allegation. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by the federal agency to carry out its review of an allegation of research misconduct or of the institution's handling of such an allegation.

9. 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. In accordance with applicable law or regulation, the RIO must notify any federal agency with jurisdiction and authority 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 the federal agency, as prescribed in this Regulation.

10. Institutional Administrative Actions

If the DO determines that research misconduct is substantiated by the findings, he or she will refer the case to the appropriate Vice Chancellor to decide on the appropriate actions to be taken, after consultation with the RIO and the DO. The administrative actions may include:

10.1. Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;

10.2. 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;

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

10.4. Other action appropriate to the research misconduct, including, but not limited to, the imposition of sanctions, up to and including termination from employment.

11. Other Considerations

11.1. Termination or Resignation Prior to Completing Inquiry or Investigation

11.1.1. 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 University's responsibilities to investigate the alleged research misconduct.

11.1.2. 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 allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence.

11.2. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including concurrence of any federal agency with jurisdiction and authority, where required by law or regulation, the RIO must undertake 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.

11.3. Protection of the Complainant, Witnesses and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the institution 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.

11.4. 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 refer the matter to the appropriate Vice Chancellor to determine whether any administrative action should be taken against the person who failed to act in good faith.