

# MUSC POLICIES AND PROCEDURES FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

(revised June 2007)

## TABLE OF CONTENTS

- I. [INTRODUCTION](#)
  - II. [DEFINITIONS](#)
  - III. [RESPONSIBILITIES AND RIGHTS](#)
  - IV. [GENERAL POLICIES AND PRINCIPLES](#)
  - V. [CONDUCTING THE ASSESSMENT AND INQUIRY](#)
  - VI. [THE INQUIRY REPORT](#)
  - VII. [CONDUCTING THE INVESTIGATION](#)
  - VIII. [THE INVESTIGATION REPORT](#)
  - IX. [PREMATURE COMPLETION OF CASES](#)
  - X. [INSTITUTIONAL ADMINISTRATIVE ACTIONS](#)
  - XI. [OTHER CONSIDERATIONS](#)
- 

### I. INTRODUCTION

#### I.A. General Policy

The principles that govern scientific research long have been established and applied in the discovery of new knowledge. The faculties and administrators at the Medical University of South Carolina (MUSC) and its teaching hospitals (hereafter referred to as the institution) have a central and critical responsibility to maintain these high ethical standards. Validity and accuracy in proposing, collecting, reporting, and reviewing of data are intrinsically essential to the scientific process. Dishonesty in these endeavors is contrary to the very nature of research; that is, the pursuit of truth.

The goal of this document is to present the guidelines and the procedures that will be used in dealing with alleged misconduct by researchers. "Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." It does not include honest error or differences of opinion. [42 CFR § 93.103] The use of this document to address other forms of misconduct by faculty and staff would be at the discretion of the dean of the college in which a faculty member holds a primary appointment or in which the staff member is employed and subject to relevant regulations and procedures.

Primary responsibility for the integrity of all scientific research rests with the individual researcher. The researcher accepts this responsibility with the understanding that the commission of misconduct in the research process is a major breach of contract between the researcher and the institution.

The Medical University of South Carolina will make every effort, consistent with Federal and State laws, and University policy, to support and protect the confidentiality of those bringing an allegation of misconduct in good faith, those against whom the allegation is made, and any research subjects, except at needed to carry out the research misconduct proceedings.

[\[back to Table of Contents\]](#)

### II. DEFINITIONS

**"Allegation"** means a disclosure of possible research misconduct through any means of

communication. The disclosure may be by written or oral statement or other communication to an institutional or HHS official.” 42 CFR § 93.201

**Burden of proof** refers to the responsibilities of certain parties in a misconduct investigation to prove something by a preponderance of evidence.

1. The institution or HHS has the burden of proof for making a finding of misconduct if either establishes “that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the respondent’s conduct constitutes a significant departure from accepted practices of the relevant research community.” [42 CFR § 93.106(b)(1)] The records are those that would adequately document the research in question.
2. The respondent has the burden of proof to prove any and all affirmative defenses s/he raises. [42 CFR §93.106(b) (2)]
3. The respondent has the burden of proof to prove that any mitigating factors are relevant to a decision to impose administrative actions. [42 CFR §93.106(b)(3)]

**“Complainant** means a person who in good faith makes an allegation of research misconduct.” [42 CFR § 93.203] This individual may commonly be referred to as a whistle-blower. More than one person may be involved.

**Confidentiality** means that the disclosure of the identity of the respondent, complainants, and the revealing of evidence from which the identity of research subjects may be determined must be limited to those with a need to know including ORI for the conduct of the research misconduct proceedings. [42 CFR § 93.108] The Research Integrity Officer may use confidentiality agreements or other mechanisms to ensure that recipients of identifying information do not disclose it to other individuals.

**Conflict of interest** means the real or apparent interference of one person’s interests with the interests of another person, where potential bias may occur due to unresolved personal, professional, or financial conflicts of interest. There should be no conflict of interest between any individual responsible for carrying out any part of the research misconduct proceeding and the complainant, respondent, or witnesses. [42 CFR § 93.300(b)]

**Deciding Official (DO)** means the institutional official who makes final determinations on reports of inquiries and investigations into allegations of misconduct and any responsive institutional actions. The Dean of the college in which the allegation is made would normally be the deciding official. In the event the Dean is involved in the allegation, or the allegation involves an individual not associated with the college, or if the allegation involves individuals from more than one college, The Vice President for Academic Affairs and Provost is the Deciding Official.

**“Evidence** means any document, tangible item, or testimony offered or obtained during a misconduct proceeding that tends to prove or disprove the existence of an alleged fact.” [42 CFR § 93.208]

**Good faith** [42 § 93.210)

1. A complainant or witness is acting in good faith if s/he believes that what they are saying in their allegation or testimony is true based on the information that they have available to them at the time and that a reasonable person in their position would have this same belief.
2. A committee member is acting in good faith if s/he is honest and not influenced by any type of conflict of interest in performing their duties to help the University fulfill its responsibilities as described in 42 CFR Part 93.

**Health and Human Services (HHS)** means United States Department of Health and Human Services.

**Inquiry** means the initial gathering and review of the evidence used to determine if an allegation warrants an investigation. [42 CFR § 93.212 and 93.307 (d)]. The scope of the inquiry is limited with

respect to interviews and analyses and does not include a determination of whether or not misconduct has occurred.

**Institutional member** or members means a person who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees. [42 CFR § 93.214]

**Investigation** means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred and, if so, to determine the person(s) responsible and the seriousness of the misconduct. Recommendations for actions for appropriate action may be included in misconduct findings. A decision may also be made not to make a finding of misconduct. [42 CFR § 93.215] Findings are made based on a preponderance of the evidence. The respondent has the burden of proof for any affirmative defenses (including honest error or difference of opinion) raised.

**Notice** means a written communication served in person, sent by mail or its equivalent to the last known street address, facsimile number or e-mail address of the addressee." [42 CFR § 93.216]

**Office of Research Integrity (ORI)** is the HHS office responsible for PHS related research integrity and misconduct issues. [42 CFR § 93.217]

**“Preponderance of 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.” [42 CFR § 93.219]. This is the standard of proof applied to research misconduct findings.

**Public Health Service (PHS)** a unit of the HHS that includes the Office of Public Health and Science and multiple operating divisions and offices. [42 CFR § 93.220]. Funding components of the PHS are defined in 42 CFR § 93.209.

**PHS support** means PHS funding, or applications or proposals for the same for biomedical or behavioral research or research training or activities related to these, that may be provided through various PHS funding instruments e.g. grants, cooperative agreements or contracts. [42 CFR § 93.221]

**Research** means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to knowledge. Additional details as it applies to public health are described in 42 CFR § 93.222.

**Research evidence** includes any written or non-written account or object that may provide information regarding the alleged scientific misconduct. Evidence includes, but is not limited to, grant or contract applications (both funded and unfunded); grant or contract progress or other reports; laboratory records (both physical and electronic) such as laboratory notebooks; notes; internal reports; correspondence; videos; photographs; digital images; x-ray film; gels; slides; biologic materials; computer files and printouts; manuscripts (both final and draft versions); publications (print and on-line); abstracts; theses; oral and poster presentations; equipment use logs; laboratory procurement records; animal facility records, human and animal subject protocols; monitoring (including auditor) reports; consent forms; medical charts; and patient research files.

**Research Integrity Committee (RIC)** means the standing committee at the Medical University of South Carolina charged with conducting inquiries and investigations of research misconduct and maintaining confidentiality concerning the proceedings. Members must be thorough, competent, objective and fair in their actions. No member serving on an inquiry or investigation committee should have real or apparent personal, professional, or financial conflict of interest with the complainant,

respondent, or witnesses. The RIC submits reports of inquiries and investigations to the RIO who, after review, forwards them to the deciding official for the case. It also serves as a resource to the constituent colleges regarding policies and procedures for handling alleged scientific misconduct.

**Research Integrity Officer (RIO)** means the institutional official appointed by the Associate Provost for Research who initially assesses allegations of misconduct to determine if an inquiry is warranted and oversees any resulting inquiries and investigations. This individual performs various intermediary functions in conjunction with this oversight. As required, the RIO will be in contact with ORI during the course of research misconduct proceedings involving PHS supported research. In addition, the RIO will contact ORI as needed for consultation and advice e.g. technical assistance.

**“Research misconduct** means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. (a) Fabrication is making up data or results and recording or reporting them. (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. (c) Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit. (d) Research misconduct does not include honest error or differences of opinion.” [42 CFR § 93.103] In order for a finding of misconduct to be made by the investigation committee intentional, knowing, or reckless commitment of the misconduct and “significant departure from accepted practices of the relevant research community” must be shown by a preponderance of the evidence.

**Research misconduct proceeding** includes assessment, inquiries, investigations, ORI oversight reviews, and other actions related to the allegation of research misconduct. [42 CFR § 93.223]

**Research record** means the record of the data or results embodying the facts of a scientific inquiry and anything provided by the respondent during a misconduct proceeding. [42 CFR § 93.224] The composition of this record is described in research evidence.

**Respondent** means the individual against whom an allegation of research misconduct has been made. More than one person may be involved. [42 CFR § 93.225]

**Retaliation** means an adverse action (e.g. affecting employment or institutional status) taken against a complainant, witness, or committee member (inquiry or investigation) by an institution or an institutional member in response to a good faith allegation of research misconduct or cooperation with a misconduct proceeding. [42 CFR § 93.226]

[\[back to Table of Contents\]](#)

### III. RIGHTS AND RESPONSIBILITIES

#### III.A. Research Integrity Officer

The Research Integrity Officer is responsible for implementation of the institution’s research misconduct policies and procedures. This individual must be capable of maintaining confidentiality and sensitive to the various individuals who are involved in research misconduct proceedings. Responsibilities range from pre-allegation advising of individuals to: receiving and assessing allegations; sequestering research evidence; making necessary notifications of and reports to participants in proceedings, institutional officials and the ORI; maintaining the research record and making it available as required; ensuring that members of the Research Integrity Committee have no unresolved conflicts of interest that could impact on misconduct proceedings; assisting with the restoration of reputation of individuals and protection from retaliation of individuals needing this; and ensuring that actions taken by the institution and ORI are enforced and communicated to other involved parties including, but not limited

to, sponsors, professional societies, licensing boards, and law enforcement agencies.

### **III.B. Complainant**

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. The role of this individual after the allegation is made is limited principally to serving as a witness.

The complainant will be interviewed by the inquiry and investigation committees and have the opportunity to review portions of the inquiry and investigation reports pertinent to his/her allegations and testimony. S/he will be informed of the results of the inquiry and investigation, and protected from retaliation. Additional sections of the draft inquiry and investigation reports also will be given to this person for comment, at the discretion of the Research Integrity Officer, if pertinent information may be obtained.

The complainant must submit any comments on reports in a timely manner i.e. that will permit completion of the inquiry within 60 days (specific number of days to be determined on a case by case basis) and within 30 days of receipt of the draft investigation report. Comments received from the complainant will be included in the final investigation report.

### **III.C. Respondent**

The respondent is responsible for maintaining confidentiality and cooperating with the inquiry and investigation.

The respondent(s) will be notified in writing of the:

- allegations of research misconduct, the initiation of an inquiry, the outcome of the inquiry, the decision to conduct an investigation before beginning it
- policies and procedures of the institution regarding allegations of research misconduct
- right to object to an inquiry or investigation committee member based on a conflict of interest. This must be done within seven days of notification of the composition of the committee. The institution will make the final determination of the existence of a conflict.
- right to be interviewed by and present evidence to the inquiry and investigation committees
- nature of any new allegations that were not addressed in the inquiry or included in the initial notice of the investigation, but which will be pursued during the course of the investigation
- right to review and make written comments on the draft inquiry and investigation reports
- right to have comments on the draft inquiry report attached to the report
- right to have comments on the draft investigation report considered before the final report is written
- right to receive advice during recesses from a legal counselor or personal advisor when interviewed during the inquiry and investigation. That individual, however, may not be a principal or witness in the case, and may not represent or speak for the respondent or question anyone at inquiry or investigation sessions.
- right to receive copies of or reasonable, supervised access when appropriate to research records that have been sequestered [42 CFR § 93.305(b)]
- right to copies of or supervised access to evidence on which the investigation report is based.

The respondent must submit any comments reports in a timely manner i.e. that will permit completion of the inquiry within 60 days (specific number of days to be determined on a case by case basis) and on the draft investigation report within 30 days of the receipt of the report.

The respondent has the responsibility of burden of proof by preponderance of evidence for any defenses raised including those of honest error or difference of opinion.

The respondent may admit that research misconduct has occurred and that s/he has committed it. The institutional review of the allegation may then be terminated by the Deciding Official after consultation with the RIO and University Counsel and if the ORI approves the acceptance of admission and any proposed settlement in cases involving PHS support.

If a finding of research misconduct is not made, the respondent has the right to receive institutional assistance [42 CFR § 93.304 (k)] in restoring his or her reputation.

### **III.D. Deciding Official (DO)**

The DO will receive the inquiry report and, in consultation with the RIO, determine if an investigation is warranted [based on criteria in 42 CFR § 93.307(d)]. If this determination is made, the DO will ensure that ORI is provided with this decision in writing, along with a copy of the final inquiry report [fulfilling criteria in 42 CFR §93.309] within 30 days of the finding.

The DO will receive the investigation report and in consultation with the RIO and other appropriate officials, decide the extent to which the institution will accept the findings. If misconduct has been found, the responsible person(s) identified, and this finding is accepted, the DO will decide what, if any, administrative actions are appropriate. The DO will ensure that ORI is provided with the final investigation report including all attachments, the decision of the DO regarding the findings, and a detailing of any pending or completed administrative action [42 CFR § 93.315].

The DO will also ensure that records of research misconduct proceedings are maintained in a secure manner for seven years following completion of the proceedings under subparts D and E of 42 CFR Part 93, whichever is later. This will not apply if custody of the records has been transferred to ORI or ORI has advised the institution in writing that records do not need to be retained. The DO will make provisions for copies of these to be provided to ORI as requested for additional analysis, inquire, investigation, review, or other proceedings described in subparts D and E in cases where PHS support is involved. Responsibility for maintaining the records may be delegated to the RIO

[\[back to Table of Contents\]](#)

## **IV. GENERAL POLICIES AND PRINCIPLES**

### **IV.A. Reporting Misconduct**

All institutional members have the responsibility to report observations of possible research misconduct to the RIO, Dean, Chair, Program Director, or to the confidential, compliance hotline [1-800-296-0269]. All individuals receiving such allegations should contact the RIO regarding it in a timely manner so that these institutional policies and procedures can be followed.

An individual may contact [843-792-3370] or meet with the RIO to informally discuss the situation. This may be done anonymously and/or hypothetically. If the RIO determines that the circumstances described do not meet the definition of research misconduct, the RIO will refer the individual to other officials or offices with responsibilities for resolving such problems.

The RIO is also available to confidentially discuss concerns about possible misconduct and to provide counsel about appropriate procedures for reporting allegations.

### **IV.B. Cooperating with Research Misconduct Proceedings**

All institutional members should cooperate with the RIO, institutional officials, and the inquiry and

investigation committees in research misconduct proceedings. This includes providing information, research records, and evidence, serving as a witness, and maintaining confidentiality. The institution will take reasonable and practical steps to ensure cooperation of its respondents and other institutional members. [42 CFR § 300 (f)]

#### **IV.C. Maintaining Confidentiality**

The RIO will limit disclosure of identifying information except on a need to know basis for misconduct proceedings and in response to requests by the ORI. This limited disclosure is required for: identity of respondents and complainants and, except as otherwise prescribed by law, records or evidence from which research subjects might be identified. Written confidentiality agreements may be required to ensure that the recipient of identifying information does not make further disclosure. Confidentiality will also be provided for witnesses, if indicated, to protect them against possible harassment or retaliation.

#### **IV.D. Protecting the Complainant, Witnesses, and Committee Members**

The RIO will monitor the treatment of individuals bringing allegations of misconduct, those interviewed during the misconduct proceedings, and those serving on inquiry and investigation committees for retaliation by institutional members against these individuals. This retaliation may affect the terms and conditions of their employment or other status at the institution. Institutional members should immediately report alleged or apparent retaliation to the RIO who will review and take appropriate action.

#### **IV.E. Protecting the Respondent**

Upon receiving an allegation of scientific misconduct, the Research Integrity Officer will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether PHS support or PHS applications for funding are involved, and whether the allegation falls under the PHS definition of scientific misconduct.

#### **IV.F. Notifying the ORI of Special Circumstances and Taking Interim Administrative Actions**

The RIO will notify the ORI immediately if PHS supported research is involved and if, at any time during the misconduct proceedings, any of the seven conditions listed in 42 CFR § 93.318 are thought to exist.

In conjunction with this, the institution will take appropriate interim administrative action to protect against a threat of harm to public health or safety, federal funds and equipment, integrity of the research process, or rights and interest of individuals involved in the research misconduct proceedings. These actions will be taken regardless of the source of research support. [42 CFR § 93.304(h)]

[\[back to Table of Contents\]](#)

### **V. CONDUCTING THE ASSESSMENT AND INQUIRY**

#### **V.A. Assessment of Allegations**

After receiving the allegation of misconduct, the RIO will assess it and determine within seven days if it meets the definition of research misconduct as defined in II. V. of this document and if it is sufficiently credible and specific so that sufficient evidence may be identified to proceed with an inquiry.

#### **V.B. Sequestration of Evidence**

At the time that or shortly before the respondent is notified of the allegation, the RIO shall obtain

custody of, inventory, and sequester in a secure location the research evidence thought necessary to conduct the research proceeding. [42 CFR § 93.305(a)]. This will be accomplished with the assistance of other individuals e.g. the RIC Chair, RIC Administrator, and Chair of the respondent's department.

### **V.C. Notification of the Respondent**

At the time of sequestration of evidence, the RIO will notify the respondent in writing of the allegation, provide him/her with a copy of the inventory of material secured, and copies of the applicable policies and procedures. A similar notification will be made to additional respondents that are identified.

### **V.D. Configuration of the Committee**

The RIO will contact the members of the RIC regarding their ability to serve as the inquiry committee. The respondent will also be provided with a list of members. Members themselves or respondents may request removal from the committee if there are unresolved conflicts of interest. Replacement and/or additional members should be appointed as needed replace those with real or apparent conflicts of interest and to provide appropriate scientific expertise to conduct the inquiry. The RIO in consultation with the RIC, and other institutional officials as appropriate, will appoint other members.

### **V.E. Presentation of the Charge to the Committee**

At the first meeting of the inquiry committee to address the allegation of research misconduct in question, the RIO will present the charge. The charge will include the allegations and the purpose and scope of the inquiry. The committee will also be informed of its responsibility to prepare a written report that meets the requirements of this policy and 42 CFR § 93.309(a). The RIO will discuss the charge with the committee, answer questions, assist with the development of plans to conduct the inquiry within the time limit, and emphasize the need to maintain confidentiality.

### **V.F. Conduct of the Inquiry**

The inquiry committee will interview individuals who can provide pertinent information normally beginning with the complainant, then the respondent, and finally other witnesses. Relevant research evidence is also examined. Testimonies and evidence are evaluated to determine if there is sufficient evidence of possible research misconduct to recommend that an investigation be conducted. Throughout this process the RIO and institutional counsel will be present or available to provide advice.

### **V.G. Time for Completion**

The inquiry process including preparation of the final inquiry report and decision of the DO regarding conduct of an investigation must be completed within 60 calendar days of the initiation of the inquiry i.e. the date of the first meeting of the inquiry committee. If additional time is required, the extension must be approved by the RIO and documentation of the reasons included in the report. Both the complainant and respondent will be notified of any extension.

[\[back to Table of Contents\]](#)

## **VI. THE INQUIRY REPORT**

### **VI.A. Elements**

The inquiry report should include the following information:

- names and positions of the committee members and any experts

- name and position of the respondent(s)
- list of the allegations
- grant support in particular PHS support to include grant numbers, applications, related contracts and publications listing support
- list of the research evidence reviewed
- list of individuals interviewed and summaries of each testimony
- the committee's recommendation on conducting an investigation
- the evidence supporting the recommendation
- other actions that should be taken if an investigation is not recommended
- reasons for extension of the inquiry beyond 60 days, if applicable
- complainant and respondent comments on the draft report or portions thereof

These comments may be used to prepare the final report.

The RIO and institutional counsel should review the final report. Modifications should be made if necessary and appropriate.

### **VI.B. Notification of the Respondent and Complainant**

The entire draft inquiry report must be provided to the respondent for review while the complainant may be permitted to review the committee recommendation, his/her own testimony, and other portions of the report if useful feedback might be obtained. All comments should be returned within 7 calendar days of receipt.

### **VI.C. Institutional Decision and Notification**

1. The RIO will transmit the final report including any comments to the DO who will then determine if an investigation is warranted.
2. The RIO will then provide the DO's written decision to the respondent, the complainant, and all appropriate institutional officials.
3. The RIO will provide the final report within 30 days to the ORI in cases where PHS support is involved and the DO has made the written decision that an investigation is warranted. The decision to open an investigation must be made on or before the date that the investigation begins. [42 CFR § 93.304(d)]. Additional information will be provided upon request. [42 CFR § 93.309(b)] as will notification of any special circumstances that may exist. [42 CFR § 93.309(d)]

### **VI.D. Record Retention**

- 1 Decision to conduct an investigation – All records and evidence must be retained for use in the subsequent investigation.
- 2 Decision to not conduct an investigation - Sufficiently detailed documentation of inquiries must be retained in a secure place for a minimum of seven years in the event that the ORI wishes to assess a decision not to investigate.

### **VI.E. Protection of Reputations**

If the decision is made to not proceed to the investigation stage, the RIO must take all reasonable and practical steps, if requested and as appropriate, to restore a respondent's reputation. [42 CFR § 93.304(k)]

[\[back to Table of Contents\]](#)

## **VII. CONDUCTING THE INVESTIGATION**

## **VII.A. Initiation and Purpose**

The investigation must begin within 30 calendar days after the DO has determined that, based on the findings of the inquiry, that the investigation is warranted. The purpose of the investigation is to examine the evidence in depth to determine if misconduct has been committed, by whom, and to what extent. In addition, the investigation will determine if there are additional instances of possible research misconduct that would justify broadening the scope of the investigation beyond that covered in the initial allegation. If clinical trials are involved and there is the potential for harm to human subjects or the general public, or if the research forms the basis for public policy, clinical practice, or public health practice, expansion of the scope is particularly important. The investigation must result in a report of its findings. [42 CFR § 93.310 and § 93.313]

## **VII.B. Sequestration of Evidence**

Prior to notifying the respondent of the allegations, the RIO will take all reasonable and practical steps to obtain custody of, inventory, and sequester in a secure location any research evidence that was not previously sequestered during the inquiry stage becomes known or relevant including that thought to be needed to investigate any additional allegations or instances of possible misconduct that have resulted in broadening of the scope of the investigation. [42 CFR § 93.310(d)]

## **VII.C. Notifications [42 CFR § 93.310(b) and (c)]**

On or before the initiation date of the investigation, the RIO shall make the following notifications:

1. The ORI Director shall be notified of the decision to begin the investigation. A copy of the inquiry report should accompany the notification.
2. The respondent shall be notified of the decision to begin an investigation and the allegations to be investigated including any new allegations not addressed in the inquiry. This notification must be written.
3. In addition, the respondent will be given a list of any additional proposed members of the committee and given no more than 7 calendar days to object to a member because of a conflict of interest. The institution will make the final determination of the existence of a conflict.

## **VII.D. Configuration of the Committee**

The RIO will contact members of the inquiry committee regarding their ability to serve on the investigation committee. Replacement and/or additional members should be appointed as needed to replace those unable to serve e.g. because of conflict of interest concerns and to provide any additional expertise needed to address issues that resulted in a broadened scope for the investigation.

Other members will be appointed by the RIO in consultation with the inquiry committee and other institutional officials as appropriate.

## **VII.E. Presentation of the Charge to the Committee**

At the first meeting of the investigation committee, the RIO will present the charge after review of the inquiry report. The charge will include the initial allegations as well as any additional allegations and issues identified during the course of the inquiry; and the purpose and scope of the investigation. The original and any additional respondents will be identified. The committee also will be informed of its responsibility to conduct the investigation as described in VII.F. and to prepare a written report that meets the requirements of this policy and 42 CFR § 93.309(a). The RIO will discuss the charge with the committee, answer questions, assist with the development of plans to conduct the inquiry within the time limit, and emphasize the need to maintain confidentiality.

## **VII.F. Conduct of the Investigation**

The investigation committee will take the following steps to conduct an investigation that is thorough, impartial, unbiased, confidential, and permits the writing of the final report as described in VIII. Throughout this process the RIO and institutional counsel will be present or available to provide advice. The committee will:

1. Interview each respondent, complainant, and other individuals who may be able to give relevant information as determined from the interview and as identified by the respondent. Each individual will be provided with a recording or transcript of his/her interview for review and correction. The corrected testimony will be made part of the record of the investigation.
2. Examine research evidence pertinent to each allegation so that the decision made regarding each allegation is supported by a preponderance of the evidence.
3. Pursue additional issues/allegations that might arise/be received during the course of the investigations as described in VII F. 1 and 2.

## **VII.G. Time for Completion**

The investigation process including preparation of the final report and sending it to ORI is to be completed within 120 days of the start of the process if research involving PHS support is concerned. Should the RIO determine that additional time is needed, s/he may submit a written request for an extension to ORI. This request must include the reason(s) for the delay. If an extension is granted, the RIO will ensure that periodic progress reports are filed as directed. [42 CFR § 93.311]

[\[back to Table of Contents\]](#)

## **VIII. THE INVESTIGATION REPORT**

### **VIII.A. Elements**

The investigation report must include the following information: [42 CFR § 93.313] nature and specifics of the allegations included in the charge to the committee

- PHS support including grant numbers, applications, and related contracts and publications listing this support
- list of research evidence secured along with identification of an a summary of that which was reviewed
- statement of finding for each individual allegation that includes the type of misconduct (falsification, fabrication, or plagiarism), and whether it was intentional, knowing or done in reckless disregard; summarized supportive facts and analyses including the merits or reasonable respondent explanations; individual(s) responsible for the misconduct; PHS support both current and known applications; pending proposals with non-PHS federal agencies; and if correction or retraction of any publications is needed.
- comments made by the respondent and complainant on the draft report.

Other items to be included in the investigation report are:

- names and positions of the committee members and any experts
- name and position of each respondent
- reasons for extension of the investigation beyond 120 days
- recommended institutional actions

The RIO and institutional counsel should review the final report. Modifications should be made if necessary and appropriate.

### **VIII.B. Notification of the Respondent and Complainant**

The respondent must be provided with the draft report along with a copy of or supervised access to the evidence on which the report is based. All comments must be returned within 30 days of the date on which the report was received. These comments must be considered in the final report and a copy of them attached to the report. [42 CFR §93.312(a)].

The investigation committee in consultation with the RIO will determine on a case-by-case basis to provide complainant with a copy of the draft report or portions thereof for review. If provided, all comments must be returned within 30 days of the date on which the report was received. These comments must be considered in the final report and a copy of them attached to the report. [42 CFR §93.312(b)]

Both respondent and, if applicable, complainant will be reminded that the draft reports are confidential and may be asked to sign a confidentiality agreement or to come to the office of the RIO to review the report.

### **VIII.C. Institutional Decision and Notification**

1. The RIO will transmit the final report including any comments to the DO.
2. The DO will provide in writing his/her final decision that has been made based on the preponderance of the evidence and on behalf of the institution regarding acceptance of the report, its findings, and recommended institutional actions. If the determinations differ from that in the investigation report, the DO will explain the basis of his/her decision. The DO may also return the report to the investigation committee with a request for further fact-finding or analysis.
3. The RIO will provide the DO's determination in writing to the respondent, and complainant. If there has been a finding of misconduct, the respondent will also be informed that an institutional appeals process is not available.
4. In cases where PHS support is involved and within the 120 days allotted for completion of the investigation unless an extension has been granted, the RIO will provide ORI with the final report including all attachments, the determination of the DO, and any pending or completed administrative actions against the respondent.

### **VIII.D. Cooperation with the ORI including Record Provision and Retention**

The institution will continue to cooperate with ORI during any oversight review as described under 42 CFR Subpart D or hearings and appeals as described under 42 CFR Subpart E. [42 CFR § 93.304(m)]

If requested, the RIO must provide the ORI with records of misconduct proceedings as defined in 42 CFR § 93.317(a). This includes transcripts or recordings of all interviews and their results. In addition, the RIO is responsible for providing other information, documentation, evidence, or clarifications requested by ORI for its review of institutional research misconduct proceedings or its own review of an allegation of misconduct. [42 CFR § 93.300(g), 93.403(b) and (d). These records must be securely retained for at least seven years following completion of the institutional research misconduct proceeding or related PHS proceeding unless ORI has provided written advisement that the records no longer need to be retained or custody of these records has already been transferred to HHS. [42 CFR § 93.317(b)]

[\[back to Table of Contents\]](#)

## **IX. PREMATURE COMPLETION OF CASES**

If the institution plans to terminate an inquiry or investigation for any reason without completing all the requirements of the PHS regulation, 42 CFR § 93 if PHS support is involved, the RIO must notify the

ORI in advance for consultation and advice. Reasons may include admission of guilt by the respondent, settlement with the respondent, or any other reason other than 1) closure at the inquiry stage because an investigation is not warranted or 2) a finding of no misconduct at the investigation stage.

[\[back to Table of Contents\]](#)

## **X. INSTITUTIONAL ADMINISTRATIVE ACTIONS**

The Medical University of South Carolina will take appropriate administrative actions against individuals for whom the DO has supported a finding of misconduct made by the investigation committee. These actions may be taken following recommendations of this committee and in consultation with the RIO. Possible actions may include:

- withdrawal or correction of all pending or published abstracts and papers emanating from the research in which the research misconduct was found
- removal of the individual(s) responsible for the misconduct from a particular project, letter or reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment or release from an academic program
- restitution of funds to the grantor agency as appropriate
- other actions appropriate to the research misconduct

These actions are separate from any actions that may be taken by or sanctions imposed as HHS administrative actions. These latter actions along with the findings of research misconduct will be described in the written charge letter sent to the respondent in misconduct cases involving PHS support. It may be issued jointly by the ORI and the debarring official. [42 CFR § 93.202]

[\[back to Table of Contents\]](#)

## **XI. OTHER CONSIDERATIONS**

### **XI.A. Termination of Institutional Employment or Resignation Prior to Completing Inquiry or Investigation**

A respondent may terminate his position by resignation or otherwise at any point in the misconduct proceedings after the allegation has been reported. This does not preclude or terminate those proceedings or limit any institutional responsibilities. It is expected that the respondent will participate in the process, but if the individual refuses, the RIO and any inquiry or investigation committee will use their best efforts to reach a conclusion. Any failure to cooperate and the effect that this had will be noted in any reports.

[\[back to Table of Contents\]](#)

### **XI.B. Restoration of the Respondent's Reputation**

If there is a finding of no research misconduct with ORI concurrence, if required by 42 CFR § 93, the RIO must undertake all reasonable and practical efforts to restore the respondent's reputation if requested to do so by that individual. [42 CFR § 93.304(k)]. Actions should first be approved by the DO and may include notifying all individuals aware of or involved in the investigation of the finding, publicizing the finding in any forum in which the allegation had previously been publicized, and removing reference to the allegation from the respondent's personnel file.

### **XI.C. Protection of the Complainant, Witnesses, and Committee Members**

The RIO will also take reasonable and steps to protect the complainant and others who have acted in good faith in making allegations or in participating in or cooperating with inquiries and investigations. These steps should be taken throughout the research misconduct proceeding and upon its completion regardless of the final outcome. Both the position and reputation of these individuals should be protected and steps should be taken to counter potential or actual retaliation against them. [42 CFR § 93.304(l)] After consultation with the RIO and involved parties, the DO will determine what steps need to be taken. The RIO will implement approved actions.

### **XI.D. Allegations Not Made in Good Faith**

If the DO determines the absence of good faith on the part of the complainant, witness or inquiry or investigation committee member, s/he will determine if any administrative action should be taken against the person who failed to act in good faith.

[\[back to Table of Contents\]](#)