**Part 2: Inquiries and Investigations**

**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.

**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)]

**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]

**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)]

**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.

**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]

**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 cooperation and the effect that this had will be noted in any reports.

**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.