Part 1: General Policies, Definitions, and Principles

**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.

**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 though 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 CRF § 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]

**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 it 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 CRF § 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

**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)]