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Radford University Policy and Procedures For Responding to Allegations of Research Misconduct

Last Revised: December 23, 2025

Last Reviewed: December 23, 2025

Required revisions made to comply with Final Rule: December 23, 2025

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Appendix A—Research Integrity Officer Responsibilities

RADFORD UNIVERSITY DRAFT POLICY AND PROCEDURES FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

I. Introduction

A. General Policy

To endorse high ethical standards in conducting research, the university has established this policy and procedure document. Under these policies and procedures, institutional members are to report any instances of observed, suspected, or apparent research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results). All allegations of misconduct of research are to be investigated and resolved in accordance with the procedures established herein.

This policy will further require that the institution educate its members on the subject of research integrity through, among other means, the development of a research integrity website that will include a link to the DHHS "The Lab: Avoiding Research Misconduct", which has been previously distributed throughout the institution.

Training and awareness on this subject will also be included in new faculty orientations and incoming graduate student trainings and/or orientations. Periodic, typically annual, reminders on this important topic will also be disseminated to faculty and students.

The Research Integrity Officer (RIO) and Research Integrity and Compliance Staff will be clearly designated on the Radford University website addressing Research Integrity and in any relevant training provided to faculty and/or students. These policies and procedures will also be posted on said website and/or similarly accessibly media.

B. Scope

This statement of policy and procedures is intended to carry out this institution's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93, and any other applicable laws or sponsor regulations. This document applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) involving:

- A person who, at the time of the alleged research misconduct, was employed by, was a student at, was an agent of, or was affiliated by contract or agreement with

this institution; and

- sponsor supported biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information,
- applications or proposals for sponsor support for biomedical or behavioral research, research training or activities related to that research or research training,
- any other research-related activity, whether or not the activity is sponsored, or
- plagiarism of research records produced in the course of sponsor supported research, research training or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for sponsor funds resulted in a grant, contract, cooperative agreement, or other form of sponsor support.

This statement of policy and procedures does not apply to authorship or collaboration disputes and applies only to allegations of research misconduct that occurred within six years of the date the institution or sponsor received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b) or other applicable laws.

The six-year time limitation does not apply if the respondent continues or renews any incident of alleged research misconduct that occurred before the six-year period through the use of, republication of, or citation to the portion(s) of the research record alleged to have been fabricated, falsified, or plagiarized, for the potential benefit of the respondent ("subsequent use exception").[OBJ] For alleged research misconduct that appears subject to this subsequent use exception, but Radford University determines is not subject to the exception, the institution will document its determination that the subsequent use exception does not apply and will retain this documentation for the later of seven years after completion of the institutional proceeding or the completion of any HHS proceeding.[i]

The six-year time limitation also does not apply if ORI or Radford University, following consultation with ORI, determines that the alleged research misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.[ii]

These policies and procedures do not supersede or establish an alternative to the PHS regulation or any existing regulations for handling research misconduct involving non-PHS supported research.[iii] They do not replace the PHS regulation, and in case of any conflict between this document and 42 CFR Part 93, the PHS regulation will prevail. They are intended to enable Radford University to comply with the requirements of the PHS regulation.

These policies and procedures do not supersede or establish an alternative to the PHS regulation or any existing regulations for handling research misconduct involving non-PHS supported research.[iv] They do not replace the PHS regulation, and in case of any conflict

between this document and 42 CFR Part 93, the PHS regulation will prevail. They are intended to enable Radford University to comply with the requirements of the PHS regulation.

When multiple institutions are involved in a research misconduct proceeding, one institution should be designated as the lead institution. The lead institution should obtain the research records from the other relevant institutions.

II. Definitions

Terms used have the same meaning as given in the Public Health Service Policies on Research Misconduct, 42 CFR Part 93, including:

*Accepted practices of the relevant research community***.** This term means those practices established by 42 CFR Part 93 and by PHS funding components, as well as commonly accepted professional codes or norms within the overarching community of researchers and institutions that apply for and receive PHS awards.[v]

Administrative action means (a) An sponsor action in response to a research misconduct proceeding taken to protect the health and safety of the public, to promote the integrity of sponsor supported biomedical or behavioral research, research training, or activities related to that research or research training and to conserve public funds; or (b) An sponsor action in response either to a breach of a material provision of a settlement agreement in a research misconduct proceeding or to a breach of any sponsor debarment or suspension.

*Administrative record***.** The administrative record comprises: the institutional record; any information provided by the respondent to ORI, including but not limited to the transcript of any virtual or in-person meetings under § 93.403(b) between the respondent and ORI, and correspondence between the respondent and ORI; any

additional information provided to ORI while the case is pending before ORI; and any analysis or additional information generated or obtained by ORI. Any analysis or additional information generated or obtained by ORI will also be made available to the respondent.[vi]

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 sponsor official.

Assessment. Assessment means a consideration of whether an allegation of research misconduct appears to fall within the definition of research misconduct; appears to involve PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training; and is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The assessment only involves the review of readily accessible information relevant to the allegation.[vii]

Charge letter means the written notice, as well as any amendments to the notice, that are sent to the respondent stating the findings of research misconduct and any sponsor administrative actions. If the charge letter includes a debarment or suspension action, it may be issued jointly by the ORI and the debarring official.

Complainant means a person who in good faith makes an allegation of research misconduct.

Debarment or *suspension* means the Government wide exclusion, whether temporary or for a set term, of a person from eligibility for Federal grants, contracts, and cooperative agreements under the applicable sponsor regulations.

Deciding Official (DO) means the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. The Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in the institution's 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.

Evidence means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

Fabrication. Fabrication means making up data or results and recording or reporting them.[viii]

Falsification. Falsification means 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.[ix]

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 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 part. 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.

Institution. Institution means any person who applies for or receives PHS support for any activity or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training. This includes, but is not limited to, colleges and universities, PHS intramural biomedical or behavioral research laboratories, research and development centers, national user facilities, industrial laboratories or other research institutes, research institutions, and independent researchers.[x]

Hearing means that part of the research misconduct proceeding from the time a respondent files a request for an administrative hearing to contest ORI findings of research misconduct and sponsor administrative actions until the time the ALJ issues a recommended decision.

Intentionally. To act intentionally means to act with the aim of carrying out the act.[xi]

Institutional Record comprises a) The records that the institution compiled or generated during the research misconduct proceeding, except records the institution did not consider or rely on. These records include, but are not limited to:

- Documentation of the assessment as required by § 93.306(c).
- If an inquiry is conducted, the inquiry report and all records (other than drafts

of the report) considered or relied on during the inquiry, including, but not limited to, research records and the transcripts of any transcribed interviews conducted during the inquiry, information the respondent provided to the institution, and the documentation of any decision not to investigate as required by § 93.309(c).

- If an investigation is conducted, the investigation report and all records (other than drafts of the report) considered or relied on during the investigation, including, but not limited to, research records, the transcripts of each interview conducted pursuant to § 93.310(g), and information the respondent provided to the institution.
- Decision(s) by the Deciding Official, such as the written decision from the Deciding Official under § 93.314.
- The complete record of any institutional appeal consistent with § 93.315.
- A single index listing all the research records and evidence that the institution compiled during the research misconduct proceeding, except records the institution did not consider or rely on.
- A general description of the records that were sequestered but not considered or relied on.

For PHS-supported projects, the institution must file the entire institutional record with ORI upon conclusion of the investigation (including documentation of the assessment; the inquiry report and all records considered or relied on during the inquiry; the investigation report and all records considered or relied on during the investigation; all transcripts; decisions by the Deciding Official; records of any appeals; an index listing all the research records and evidence that the institution compiled during the research misconduct proceeding; and a general description of the records that were sequestered but not considered or relied on.

Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of applicable law and these procedures.

Institution. Institution means any person who applies for or receives PHS support for any activity or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training. This includes, but is not limited to, colleges and universities, PHS intramural biomedical or behavioral research laboratories, research and development centers, national user facilities, industrial laboratories or other research institutes, research

institutions, and independent researchers.[xii]

Investigation means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.

Knowingly. To act knowingly means to act with awareness of the act.[xiii]

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.

Office of Research Integrity or *ORI* means the office to which the sponsor has delegated responsibility for addressing research integrity and misconduct issues related to supported activities.

Person means any individual, corporation, partnership, institution, association, unit of government, or legal entity, however organized.

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Plagiarism also includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contributions of the author. It does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology. Plagiarism does not include self-plagiarism or authorship or credit disputes, including disputes among former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct.

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.

PHS support. PHS support means PHS funding, or applications or proposals for PHS funding, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through funding for PHS intramural research; PHS grants, cooperative agreements, or contracts; subawards, contracts, or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements, or contracts.[xiv]

*Recklessly***.** To act recklessly means to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism.[xv]

Research Integrity Officer (RIO) means 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 applicable law, 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 policy.

Research misconduct proceeding means any actions related to alleged research misconduct taken under this part, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings, and administrative appeals.

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 the sponsor or an institutional official by a respondent in the course of the research misconduct proceeding.

Respondent means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

Retaliation for the purpose of this part means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to— (a) A good faith allegation of research misconduct; or (b) Good faith cooperation with a research misconduct proceeding.

*Suspension and Debarment Official***.** Suspension and Debarment Official or SDO means the HHS official authorized to impose suspension and debarment, which are the actions that Federal agencies take to disqualify persons deemed not presently responsible from doing business with the Federal Government.[xvi]

III. Rights and Responsibilities

A. Research Integrity Officer

As directed by the Senior Vice President for Academic Affairs and Provost or designee, the Associate Provost for Academic Affairs will serve as the RIO who will have primary responsibility for implementation of the institution's policies and procedures on research misconduct. A detailed listing of the responsibilities of the RIO is set forth in Appendix A. These responsibilities include the following duties related to research misconduct proceedings:

- Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;
- Receive allegations of research misconduct;
- Assess each allegation of research misconduct in accordance with Section V.A. of this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;
- Review allegations that are not sufficiently credible and specific with a standing member of the Inquiry Committee before dismissing the allegation and keep sufficiently detailed documentation of the assessment to permit a later review by ORI of reasons why Radford University did not conduct an inquiry;
- As necessary, take interim action and notify research sponsors of special circumstances, as required by applicable law;
- Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with Section V.C. of this policy and maintain it securely in accordance with this policy and applicable law and regulation;
- Provide confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy;
- Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- Appoint the chair and members of the inquiry and investigation committees, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;
- Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person

with such conflict is involved in the research misconduct proceeding;

- In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, respondents that are not found guilty, and committee members and counter potential or actual retaliation against them by respondents or other institutional members;

- Keep the Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;

    - Notify and make reports to ORI as required by applicable law;

    - Ensure that administrative actions taken by the institution and ORI are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and

    - Maintain records of the research misconduct proceeding and make them available to ORI in accordance with Section VIII.F. of this policy.

B. 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 complainant must be interviewed during an investigation and be given the transcript or recording of the interview for correction.

The RIO shall provide to the complainant for comment: (1) relevant portions of the inquiry report (within a timeframe that permits the inquiry to be completed within 60 days of its initiation); and (2) the draft investigation report or relevant portions of it. The institution must require that comments on the draft investigation report be submitted within 30 days of the date on which the complainant received the draft report. The institution must consider any comments made by the complainant on the draft investigation report and include those comments in the final investigation report.

C. Respondent

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

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

- The respondent will not be present during the witnesses' interviews but will be provided a transcript of the interview after it takes place.[xvii]
- Be provided copies of or supervised access to the sequestered research records.[xviii]
  - 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
  - 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 30 days of the date on which the copy was received and that the comments will be considered by the institution and addressed in the final report.

The respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. If admitting to research misconduct, the respondent will sign a written statement specifying the affected research records and confirming the misconduct was falsification, fabrication, and/or plagiarism; committed intentionally, knowingly, or recklessly; and a significant departure from accepted practices of the relevant research community.[xix] The respondent's destruction of research records documenting the questioned research is evidence of research misconduct where a preponderance of evidence establishes that the respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations.[xx] The respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the respondent claims to possess the records but refuses to provide them upon request.[xxi]

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 ORI.

As provided in applicable law, the respondent will have the opportunity to request an institutional appeal.

D. Deciding Official

The DO, the Radford University Provost and Senior Vice President for Academic Affairs, will receive the investigation report and, after consulting with the RIO and/or other institutional officials, decide the extent to which this institution accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate.

The DO shall ensure that the final investigation report, the findings of the DO and a description of any pending or completed administrative actions are provided to ORI, as required by applicable law.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All institutional members will report observed, suspected, or apparent research misconduct to the RIO or Research Integrity and Compliance Staff.

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 anonymously and/or 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. The RIO will keep sufficiently detailed documentation of the assessment to permit a later review by ORI (if needed) of reasons why Radford University did not conduct an inquiry;

At any time, an institutional member may have confidential discussions and consultations about concerns of possible misconduct with the RIO or Research Integrity and Compliance staff and will be counseled about appropriate procedures for reporting allegations.

B. Cooperation with Research Misconduct Proceedings

Institutional members will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations.

Institutional members, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

C. Confidentiality

The RIO shall, as required by applicable law: (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. Those who “need to know” may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions. The limitation on disclosure of the identity of respondents, complainants, and witnesses explicitly no longer applies once an institution has made a final determination of research misconduct findings. The RIO should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information. The RIO or Research Integrity and Compliance Office should provide confidentiality for witnesses when the circumstances indicate that the witnesses may be harassed or otherwise need protection.

D. Protecting complainants, witnesses, and committee members

Institutional members may not retaliate in any way against complainants, witnesses, or committee members.

Institutional members should immediately report any alleged or apparent retaliation against complainants, witnesses, or committee members to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

E. Protecting the Respondent

As requested, and as appropriate, the RIO and other institutional officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in applicable law and the policies and procedures of the institution. 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 counsel or personal adviser to interviews or meetings on the case.

F. Interim Administrative Actions and Notifying ORI of Special Circumstances (if applicable)

Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the sponsor supported research process. In the event of such a threat, the RIO will, in consultation with other institutional officials, as appropriate, and ORI, take appropriate interim action to protect against any such threat. Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:

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

- Sponsor resources or interests are threatened;
- Research activities should be suspended;
- There is a reasonable indication of possible violations of civil or criminal law;
- Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- The research misconduct proceeding may be made public prematurely and sponsor action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

V. Conducting the Assessment and Inquiry

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will immediately

assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether it is within the jurisdictional criteria of 42 CFR § 93.102(b) or other applicable law, and whether the allegation falls within the definition of research misconduct in 42 CFR § 93.103 or other applicable law. An inquiry must be conducted if these criteria are met.

The RIO shall refer any allegations that are not within the definition of research misconduct to the appropriate university officials or units for further review and/or action. Prior to dismissing an allegation on the basis that it is not sufficiently credible and specific; the RIO may review this determination with a member of the Standing Member Committee.

If the RIO or another designated institutional official determines that requirements for an inquiry are not met, they will keep sufficiently detailed documentation of the assessment to permit a later review by ORI of the reasons why Radford University did not conduct an inquiry.[xxii] The institution will keep this documentation and related records in a secure manner for seven years and provide them to ORI upon request.[xxiii]

The assessment period should be brief, preferably concluded within a week. In conducting the assessment, the RIO need not interview the complainant,

respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

The RIO shall, on or before the date on which the respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding, as provided in paragraph C. of this section.

B. Initiation and Purpose of the Inquiry

If the RIO determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. An inquiry is warranted if the allegation

(a) falls within the definition of research misconduct under 42 CFR Part 93, (b) is within the applicability criteria of § 93.102, and (c) is sufficiently credible and specific so that potential evidence of research misconduct may be identified.[xxiv] 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. If additional respondents are identified during an inquiry, Radford University is not required to conduct a separate inquiry for each new respondent.

C. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the RIO must make a good faith effort to notify the respondent in writing, if the respondent is known. 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, evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and sequester them in a secure manner, and retain them for seven years.[xxv] When original research records cannot be obtained, copies of records that are substantially equivalent to evidentiary value will fulfill the sequestration requirement. An exception is made 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 institution has a duty to obtain, inventory, and securely sequester evidence that extends to whenever additional items become known or relevant to the inquiry or investigation.[xxvi] The RIO may consult with ORI for advice and assistance in this regard.

D. Appointment of the Inquiry Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an inquiry committee of 3 or 5 voting members and designate the committee chair, drawn from the Standing Member Committee, as soon after the initiation of the inquiry as is practical, preferably within 10 days. Ad hoc non-voting members may be appointed and consulted as appropriate.

The inquiry committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry.

The purpose of the Standing Member Committee is to have a pool of pre-selected faculty members that have agreed to serve on Inquiry and/or Investigative Committees of a research misconduct proceeding.

The Standing Member Committee will consist of a minimum of five faculty members that have been appointed by the Research Integrity Officer in consultation with the Provost and other institutional officials as appropriate.

Standing members serve a three-year appointment and are limited to serving two consecutive terms, provided however that the terms of the initial standing members of the committee may be shorter or longer terms to allow for staggering terms of members.

The respondent will be notified of the proposed committee membership to give the respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. The period for submitting objections is limited to no more than 10 calendar days. The RIO will make the final determination of whether a conflict exists and shall reappoint members to the Inquiry Committee as necessary to mitigate the identified conflicts of interest.

E. Charge to the Committee and First Meeting

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

- Sets forth the time for completion of the inquiry;
- Describes the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial review of the

evidence, including the testimony of the respondent, complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;

- Ensures that all inquiry committee members understand their commission, keep the identities of respondents, complainants, and witnesses confidential, and conduct the research misconduct proceedings in compliance with the PHS regulation.

- States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that th allegation falls within the definition of research misconduct; and, (2) the allegation may have substance, based on the committee's review during the inquiry.

- Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and applicable law.

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.

F. Inquiry Process

The inquiry committee will normally interview the complainant, the respondent, and key witnesses as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence, including the testimony obtained during the inquiry. After consultation with the RIO, the committee members will decide whether an investigation is warranted based on the criteria in this policy and applicable law. The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining who committed the research misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the institution shall promptly consult with ORI to determine the next steps that should be taken. See Section IX.

If relevant, the Inquiry Committee will determine whether the Complainant's allegations of research misconduct were made in good faith. If the Inquiry Committee determines that there was an absence of good faith, the DO will

determine whether any administrative action should be taken against the person who failed to act in good faith.

G. Time for Completion

Radford University will complete the inquiry within 90 calendar days of initiating it unless circumstances warrant a longer period, in which it will sufficiently document the reasons for exceeding the time limit in the inquiry report.[xxvii]

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that includes the following information:

- the name, professional aliases, and positions of the respondent and complainant(s);
- a description of the allegation(s) of research misconduct;
- the sponsor support, including, grant numbers, grant applications, contracts and publications listing sponsor support;
- the composition of the inquiry committee including names, positions and subject matter expertise;
- transcripts of any interviews that were transcribed,
- a timeline and procedural history,
- an inventory of sequestered research records and how sequestration was conducted,
- any scientific or forensic analyses conducted,
- the basis for recommending that the allegation(s) warrant an investigation;
- the basis on which any allegation(s) did not merit further investigation;
- any comments on the draft report by the respondent or complainant,
- any institutional actions implemented, including internal communications or external communications with journals or funding agencies; and
- documentation of potential evidence of honest error or difference of opinion.

The RIO shall review the report for compliance with these procedures. Modifications should be made as mutually agreed by the RIO and the Inquiry Committee.

B. Notification to the Respondent and Complainant - Opportunity to Comment

The RIO shall notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within 10 days, and include a copy of or refer to applicable law and the institution's policies and procedures on research misconduct. The institution shall notify the complainant whether the inquiry found an investigation to be warranted and provide relevant portions of the inquiry report to the complainant for comment within 10 days. A confidentiality agreement should be a condition for access to the report.

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

C. Institutional Decision and Notification

1. Final Decision

The findings by the Inquiry Committee as contained in the final report constitute the final decision of the institution as to whether an investigation is warranted. The inquiry is completed when the Inquiry Committee makes this determination. The determination shall be by majority vote of the committee.

2. Notification to Research Sponsors

Within 30 calendar days of the Inquiry Committee's decision that an investigation is warranted, the RIO will provide ORI with the Inquiry Committee's written decision and a copy of the inquiry report. The RIO will also notify those institutional officials who need to know of the Inquiry Committee's decision. The RIO must provide the following information to ORI upon request: (1) the institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and the charges to be considered in the investigation.

3. Documentation of Decision Not to Investigate

If the Inquiry Committee decides that an investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the

reasons why an investigation was not conducted. These documents must be provided to ORI or other authorized sponsor personnel upon request. The RIO shall, if needed, provide guidance to the Respondent on actions to take to eliminate future allegations of research misconduct.

VII. Conducting the Investigation

A. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by majority vote of the inquiry committee 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. If additional respondents are identified during an inquiry, Radford University is not required to conduct a separate investigation for each new respondent. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation must be set forth in an investigation report.

B. Notifying Research Sponsor and Respondent; Sequestration of Research Records

Before the date on which the investigation begins, the RIO must: (1) for PHS-supported projects, notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report; and (2) for all projects, notify the respondent in writing of the allegations to be investigated.[xxviii]

The RIO must also give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.

The RIO will, prior to notifying respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry. When original research records cannot be obtained, copies of records that are

substantially equivalent to evidentiary value will fulfill the sequestration requirement. 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 need for additional sequestration of records for the investigation may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry. The institution will obtain the original or substantially equivalent copies of all research records and other evidence, inventory these materials, sequester them in a secure manner, and retain them for seven years after its proceeding. Or, after HHS proceedings, as applicable, for PHS-supported projects. [xxix]

C. Appointment of the Investigation Committee

The RIO will convene the Investigation Committee within 10 calendar days of the beginning of the investigation or as soon thereafter as practical.

The Investigation Committee is composed of five voting members, consisting of at least two (2) standing members appointed by the Research Integrity Officer, and other expert faculty members as needed to be appointed by the Research Integrity Officer who have the appropriate expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the investigation. The Research Integrity Officer shall appoint one of the standing members to serve as the chair of the Investigation Committee.

Additional ad hoc non-voting members may be appointed and consulted as appropriate.

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 expertise to evaluate the evidence and issues related to the allegation, interview the Respondent and Complainant, and conduct the investigation.

Individuals appointed to the Investigation Committee may also have served on the inquiry committee.

When necessary to secure the necessary expertise or to avoid conflicts of

interest, non-voting committee members may be selected from outside the institution. The Investigation Committee is authorized to use non-voting ad hoc consultants when necessary to evaluate specific allegations.

The RIO shall notify the Respondent in writing of the proposed committee membership. The Respondent shall have 10 calendar days to object to a proposed member based upon a personal, professional, or financial conflict of interest. The RIO shall make the final determination of whether a conflict exists and shall reappoint members to the Investigation Committee as necessary to mitigate the identified conflicts of interest.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

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

- Describes the allegations and related issues identified during the inquiry;
- Provides the committee with a copy of the Inquiry Report
- Identifies the respondent;
- Informs the committee that it must conduct the investigation as prescribed in paragraph E. of this section;
- Informs the committee that it is to complete the investigation within 180 days of beginning the investigation; however, an extension may be requested from the RIO for cause;
- Defines research misconduct;
- Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
- Informs the committee that in order to determine that the respondent committed research misconduct it must find that a preponderance of the evidence establishes that: (1) research misconduct, as defined in this policy, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (2) the research misconduct is a

significant departure from accepted practices of the relevant research community; and (3) the respondent committed the research misconduct intentionally, knowingly, or recklessly; and

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

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 statement of policy and procedures and any applicable law. The RIO will be present or available throughout the investigation to advise the committee as needed.

E. Investigation Process

The investigation committee and the RIO must:

- Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;

- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;

- Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation; and

- Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.

F. Time for Completion

The investigation is to be completed within 180 calendar days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment, and sending the final report to ORI. However, if the RIO determines that the investigation will not be completed within this 180-day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay (if applicable). For PHS-supported projects, the RIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.

VIII. The Investigation Report

A. Elements of the Investigation Report

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

- Describes the nature of the allegation of research misconduct, including identification of the respondent; The respondent's c.v. or resume may be included as part of the identification.
- Describes and documents the sponsor support, including, the numbers of any grants that are involved, grant applications, contracts, and publications listing sponsor support;
- Describes the specific allegations of research misconduct considered in the investigation;
- Composition of investigation committee, including names, positions and subject matter expertise.
- Includes a copy of the institutional policies and procedures under which the investigation was conducted;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed;
- Inventory of sequestered research records and other evidence, except records the institution did not consider or rely on.[xxx] This inventory will include manuscripts and funding proposals that were considered or relied on during the investigation. The inventory will also include a description of how any sequestration was conducted during the investigation.

- Transcripts of all interviews;
- Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS funding applications, progress reports, presentations, posters, or other research records that contain the allegedly falsified, fabricated, or plagiarized material.
- Any scientific or forensic analyses conducted;
- Any comments made by the respondent and complainant(s) on the draft investigation report and the committee's consideration of those comments.
- Includes a statement of findings for each separate allegation of research misconduct identified during the investigation.

  If the committee recommends a finding of research misconduct for an allegation, the investigation report will present a finding for each allegation. These findings will (a) identify the individual(s) who committed the research misconduct; (b) indicate whether the misconduct was falsification, fabrication, and/or plagiarism; (c) indicate whether the misconduct was committed intentionally, knowingly, or recklessly; (d) identify any significant departure from the accepted practices of the relevant research community and that the allegation was proven by a preponderance of the evidence; (e) summarize the facts and analysis supporting the conclusion and consider the merits of any explanation by the respondent; (f) identify the specific PHS support; and (g) state whether any publications need correction or retraction.[xxxi]

  If the investigation committee does *not* recommend a finding of research misconduct for an allegation, the investigation report will provide a detailed rationale for its conclusion.[xxxii]

  The investigation committee should also provide a list of any current support or known applications or proposals for support that the respondent has pending with PHS and non-PHS Federal agencies.[xxxiii]

B. Comments on the Draft Report and Access to Evidence

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 30 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.

2. Complainant

The institution shall provide the complainant a copy of the draft investigation report, or relevant portions of it, for comment. The complainant's comments must be submitted within 30 calendar days of the date on which he/she received the draft report, and the comments must be included and considered in the final report.

3. Confidentiality

In distributing the draft report, or portions thereof, to the respondent and complainant, 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. The RIO may require that the recipient sign a confidentiality agreement.

4. Final Investigation Report

The Investigation Committee will discuss the comments provided by the respondent and complainant and, as necessary, consult with the RIO and the DO. If necessary, the draft report will be modified in view of the comments and discussions. The RIO will assist the Investigation Committee in finalizing the investigation report, including ensuring that the respondent's and complainant's comments are considered by the committee and included as attachments to the report.

The final report will include the information as required above as well as the committee's positive or negative findings of research misconduct.

Such findings shall be determined by majority vote of the committee, and recommendations as to any institutional actions in the event of findings of misconduct.

C. Decision by Deciding Official

The RIO will transmit the final investigation report to the DO. The DO documents their determination in a written decision that includes whether research misconduct

occurred, and if so, what kind and who committed it, and a description of the relevant actions Radford University has taken or will take.[xxxiv] The DO's written decision becomes part of the institutional record.[xxxv]

If this determination varies from the findings of the investigation committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the DO may return the report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, 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 falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies. ORI findings are not required for institutional decisions regarding research misconduct to be considered final and warrant remediation under the institution's policy.

D. Appeals

A respondent found to have engaged in research misconduct may initiate an appeal process within 10 calendar days of his/her receipt of the Final Decision. Any appeal process shall be completed within 120 days of its filing unless otherwise allowed by law with approval of the research sponsor.

An appeal based upon the findings or administrative actions shall be in writing to the President of Radford University and shall specifically identify the subject matter of the appeal and provide basis or evidence to support the appeal.

The President will consult with the DO, the RIO, the Investigation Committee, and others as necessary in reviewing the respondent's basis for appeal. The President shall provide the respondent a written decision on the appeal and the actions to be taken. The decision of the President is the final resolution of the appeal.

E. Notice to ORI of Institutional Findings and Actions for PHS-supported projects

Unless an extension has been granted, the RIO must, within the 180 day period for completing the investigation or the day period for completion of any appeal, submit the following to ORI: (1) a copy of the final investigation report with all attachments and any appeal; (2) a statement of whether the institution accepts the findings of the

investigation report or the outcome of the appeal;

(3) a statement of whether the institution found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent.

For PHS-supported projects, the institution must file the entire institutional record with ORI upon conclusion of the investigation (including documentation of the assessment; the inquiry report and all records considered or relied on during the inquiry; the investigation report and all records considered or relied on during the investigation; all transcripts; decisions by the Deciding Official; records of any appeals; an index listing all the research records and evidence that the institution compiled during the research misconduct proceeding; and a general description of the records that were sequestered by not considered or relied on.

F. Maintaining Records for Review by ORI for PHS-supported projects

The RIO must maintain and provide to ORI upon request "records of research misconduct proceedings" as that term is defined by applicable law. Unless custody has been transferred to the sponsor or ORI or the sponsor has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any sponsor proceeding involving the research misconduct allegation. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or of the institution's handling of such an allegation.

IX. Completion of Cases; Reporting Premature Closures to ORI

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. F o r P HS - s u pp o r t e d p r oj e c t s , a s required by applicable law, the RIO must notify ORI in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except:

(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 ORI, as prescribed in this policy, 42 CFR § 93.315, and any other applicable laws.

X. Institutional Administrative Actions

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

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

XI. Other Considerations

A. Multiple Institutions and Multiple Respondents

If the alleged research misconduct involves multiple institutions, Radford University may work closely with the other affected institutions to determine whether a joint research misconduct proceeding will be conducted.[xxxvi] If so, the cooperating institutions will choose an institution to serve as the lead institution. In a joint research misconduct proceeding, the lead institution will obtain research records and other evidence pertinent to the proceeding, including witness testimony, from the other relevant institutions.[xxxvii] By mutual agreement, the joint research misconduct proceeding may include committee members from the institutions involved.[xxxviii] The determination of whether further inquiry and/or investigation is warranted, whether research misconduct occurred, and the institutional actions to be taken may be made by the institutions jointly or tasked to the lead institution.[xxxix]

If the alleged research misconduct involves multiple respondents, Radford University may either conduct a separate inquiry for each new respondent or add them to the ongoing proceedings.[xl] The institution must give additional respondent(s) notice of and an opportunity to respond to the allegations.[xli]

B. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, by resignation or

otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the institution’s responsibilities under applicable law.

If the respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps.

If the respondent refuses to participate in the process after resignation, the RIO and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence.

C. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI concurrence where required by applicable law, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation. Depending on the particular circumstances and the views of the respondent, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the respondent's personnel file.

Any institutional actions to restore the respondent's reputation should first be approved by the DO.

D. Protection of the Complainant, Witnesses and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the institution or ORI determines that research misconduct occurred, the RIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding. The DO will determine, after consulting with the RIO, and with the complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions

or reputations or to counter potential or actual retaliation against them. The RIO is responsible for implementing any steps the DO approves.

E. Allegations Not Made in Good Faith

If relevant, the DO will determine whether the complainant's allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the DO determines that there was an absence of good faith he/she will determine whether any administrative action should be taken against the person who failed to act in good faith.

At any time during the misconduct proceedings, Radford University will immediately notify ORI if any of the following circumstances arise:

1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
2. HHS resources or interests are threatened.
3. Research activities should be suspended.
4. There is reasonable indication of possible violations of civil or criminal law.
5. Federal action is required to protect the interests of those involved in the research misconduct proceeding.
6. HHS may need to take appropriate steps to safeguard evidence and protect the rights of those involved.[xlii]

Appendix A

Research Integrity Officer Responsibilities

I. General

The Research Integrity Officer (RIO) has lead responsibility for ensuring that the institution:

- Takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.
- Has written policies and procedures for responding to allegations of research misconduct and reporting information about that response to ORI,

as required by 42 CFR Part 93.

- Complies with its written policies and procedures and the requirements of 42 CFR Part 93.

- Informs its institutional members who are subject to 42 CFR Part 93 about its research misconduct policies and procedures and its commitment to compliance with those policies and procedures.

- Takes appropriate interim action during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the PHS supported research process.

II. Notice and Reporting to ORI and Cooperation with ORI

The RIO has lead responsibility for ensuring that the institution:

- Files an annual report with ORI containing the information prescribed by ORI.

- Sends to ORI with the annual report such other aggregated information as ORI may prescribe on the institution's research misconduct proceedings and the institution's compliance with 42 CFR Part 93.

- Notifies ORI immediately if, at any time during the research misconduct proceeding, it has reason to believe that health or safety of the public is at risk, HHS resources or interests are threatened, research activities should be suspended, there is reasonable indication of possible violations of civil or criminal law, federal action is required to protect the interests of those involved in the research misconduct proceeding, the institution believes that the research misconduct proceeding may be made public prematurely, or the research community or the public should be informed.

- Provides ORI with the written finding by the responsible institutional official that an investigation is warranted and a copy of the inquiry report, within 30 calendar days of the date on which the finding is made.

- Notifies ORI of the decision to begin an investigation on or before the date the investigation begins.

- Within 180 calendar days of beginning an investigation, or such additional days as may be granted by ORI, (or upon completion of any appeal made available by the institution) provides ORI with the investigation report, a statement of whether the institution accepts the

investigation's findings, a statement of whether the institution found research misconduct and, if so, who committed it, and a description of any pending or completed administrative actions against the respondent.

- Seeks advance ORI approval if the institution plans to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage.

- Cooperates fully with ORI during its oversight review and any subsequent administrative hearings or appeals, including providing all research records and evidence under the institution's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.

III. Research Misconduct Proceeding

A. General

The RIO is responsible for:

- Promptly taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner.

- Taking all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to their providing information, research records and evidence.

- Providing confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy.

- Determining whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and taking appropriate action, including recusal, to ensure that no person with such a conflict is involved in the research misconduct proceeding.

- Keeping the Deciding Official (DO) and others who need to know

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

- In cooperation with other institutional officials, taking all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and to counter potential or actual retaliation against them by respondents or other institutional members.

- Making all reasonable and practical efforts, if requested and as appropriate, 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.

- Assisting the DO in implementing his/her decision to take administrative action against any complainant, witness, or committee member determined by the DO not to have acted in good faith.

- Maintaining records of the research misconduct proceeding, as defined in 42 CFR § 93.317, in a secure manner for 7 years after completion of the proceeding, or the completion of any ORI proceeding involving the allegation of research misconduct, whichever is later, unless custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained.

- Ensuring that administrative actions taken by the institution and ORI are enforced and taking appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards, of those actions.

B. Allegation Receipt and Assessment

The RIO is responsible for:

- Consulting confidentially with persons uncertain about whether to submit an allegation of research misconduct.

- Receiving allegations of research misconduct.

- Assessing each allegation of research misconduct to determine if an inquiry is warranted because the allegation falls within the definition of research misconduct, is within the jurisdictional criteria of 42 CFR § 93.102(b) and is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

C. Inquiry

The RIO is responsible for:

- Initiating the inquiry process if it is determined that an inquiry is warranted.
- At the time of, or before beginning the inquiry, making a good faith effort to notify the respondent in writing, if the respondent is known.
- On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventorying the records and evidence and sequestering 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 the instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
- Appointing an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical.
- Preparing a charge for the inquiry committee in accordance with the institution's policies and procedures.
- Convening the first meeting of the inquiry committee and at that meeting briefing the committee on the allegations, the charge to the committee, and the appropriate procedures for conducting the inquiry, including the need for confidentiality and for developing a plan for the inquiry, and assisting the committee with organizational and other issues that may arise.
- Providing the inquiry committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging witness interviews and recording or transcribing those interviews.
- Being available or present throughout the inquiry to advise the committee as needed and consulting with the committee prior to its decision on whether to recommend that an investigation is warranted on the basis of the criteria in the institution's policies and procedures and 42 CFR § 93.307(d).

- Determining whether circumstances clearly warrant a period longer than 90 calendar days to complete the inquiry (including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted), approving an extension if warranted, and documenting the reasons for exceeding the 90 calendar day period in the record of the research misconduct proceeding.

- Assisting the inquiry committee in preparing a draft inquiry report, sending the respondent a copy of the draft report for comment (and the complainant if the

  institution's policies provide that option) within a time period that permits the inquiry to be completed within the allotted time, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent (and the complainant if the institution's policies provide that option), and ensuring that the comments are attached to the final inquiry report.

- Receiving the final inquiry report from the inquiry committee and forwarding it, together with any comments the RIO may wish to make, to the DO who will determine in writing whether an investigation is warranted.

- Within 30 days of a DO decision that an investigation is warranted, providing ORI with the written finding and a copy of the inquiry report, and notifying those institutional officials who need to know of the decision.

- Notifying the respondent (and the complainant if the institution's policies provide that option) whether the inquiry found an investigation to be warranted and including in the notice copies of or a reference to 42 CFR Part 93 and the institution's research misconduct policies and procedures.

- Providing to ORI, upon request, the institutional policies, and procedures under which the inquiry was conducted, the research records and evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents, and the allegations to be considered in the investigation.

- If the DO decides that an investigation is not warranted, securing, and maintaining for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted.

D. Investigation

The RIO is responsible for:

- Initiating the investigation within 30 calendar days after the determination by the DO that an investigation is warranted.

- Before the date on which the investigation begins: (1) for PHS-supported projects, notify ORI of the decision to begin the investigation and providing ORI a copy of the inquiry report; and (2) for all projects, notify the respondent in writing of the allegations to be investigated.

- Prior to notifying respondent of the allegations, taking 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.

- In consultation with other institutional officials as appropriate, appointing an investigation committee and committee chair as soon after the initiation of the investigation as is practical.

- Preparing a charge for the investigation committee in accordance with the institution's policies and procedures.

- Convening the first meeting of the investigation committee and at that meeting: (1) briefing the committee on the charge, the inquiry report and the procedures and standards for the conduct of the investigation, including the need for confidentiality and developing a specific plan for the investigation; and (2) providing committee members a copy of the institution's policies and procedures and 42 CFR Part 93.

- Providing the investigation committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging interviews with witnesses and recording or transcribing those interviews.

- Being available or present throughout the investigation to advise the committee as needed.

- On behalf of the institution, the RIO is responsible for each of the following steps and for ensuring that the investigation committee: (1) uses diligent efforts to conduct an investigation that includes an examination of all research records and evidence relevant to reaching a decision on the merits of the allegations and that is otherwise thorough and sufficiently documented; (2) takes reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical; (3) interviews 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 records or transcribes each interview, provides the recording or transcript to the interviewee for correction, and includes the recording or transcript in the record of the research misconduct proceeding; and (4) pursues 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 continues the investigation to completion.

- Upon determining that the investigation cannot be completed within 180 days of its initiation (including providing the draft report for comment and sending the final report with any comments to ORI), submitting a request to ORI for an extension of the 180-day period that includes updates and a statement of the reasons for the extension. If the extension is granted, the RIO will file periodic progress reports with ORI.

- Assisting the investigation committee in preparing a draft investigation report that meets the requirements of 42 CFR Part 93 and the institution's policies and procedures, sending the respondent (and complainant at the institution's option) a copy of the draft report for his/her comment within 30 days of receipt, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent (and complainant at the institution's option) and ensuring that the comments are included and considered in the final investigation report.

- Transmitting the draft investigation report to institutional counsel for a review of its legal sufficiency.

- Assisting the investigation committee in finalizing the draft investigation report and receiving the final report from the committee.

- Transmitting the final investigation report to the DO and: (1) if the DO determines that further fact-finding or analysis is needed, receiving the report back from the DO for that purpose; (2) if the DO determines whether or not to accept the report, its findings and the recommended institutional actions, transmitting to ORI within the time period for completing the investigation, a copy of the final investigation report with all attachments, a statement of whether the institution accepts the findings of the report, a statement of whether the institution found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the respondent; or (3) if the institution provides for an appeal by the respondent that could result in a modification

or reversal of the DO's finding of research misconduct, ensuring that the appeal is completed within 120 days of its filing, or seeking an extension from ORI in writing (with an explanation of the need for the extension) and, upon completion of the appeal, transmitting to ORI a copy of the investigation report with all attachments, a copy of the appeal proceedings, a statement of whether the institution accepts the findings of the appeal proceeding, a statement of whether the institution found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the respondent.

- When a final decision on the case is reached, the RIO will normally notify both the respondent and the complainant in writing and will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of involved journals, collaborators of the respondent, or other relevant parties should be notified of the outcome of the case.

- Maintaining and providing to ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including the results of all interviews and the transcripts or recordings of those interviews.

[i] §§ 93.104(b)(1) and 93.318.

[ii] § 93.104(b)(2).

[iii] § 93.102(c).

[iv] § 93.102(c).

[v] § 93.200.

[vi] § 93.202.

[vii] § 93.204.

[viii] § 93.211.

[ix] § 93.212.

[x] § 93.216.

[xi] § 93.221.

[xii] § 93.216.

[xiii] § 93.223.

[xiv] § 93.230.

[xv] § 93.231.

[xvi] § 93.241.

[xvii] § 93.310(g)(5).

[xviii] § 93.305(b).

[xix] §§ 93.103 and 93.317(b).

[xx] § 93.105(b)(1).

[xxi] § 93.105(b).

[xxii] § 93.306(c)(3).

[xxiii] § 93.318.

[xxiv] § 93.307(a)(1-3).

[xxv] §§ 93.305(a) and 93.318.

[xxvi] §§ 93.305(a)(2) and 93.318.

[xxvii] § 93.307(h).

[xxviii] § 93.310(a-c).

[xxix] § 93.318.

[xxx] § 93.313(e).

[xxxi] § 93.313(k)(1)(i-vii).

[xxxii] § 93.313(k)(2).

[xxxiii] § 93.313(k)(3).

[xxxiv] § 93.314.

[xxxv] § 93.220(a)(4).

[xxxvi] § 93.305(e).

[xxxvii] Id.

[xxxviii] Id.

[xxxix] Id.

[xl] § 93.305(d).

[xli] Id.

[xlii] § 93.305(g)(1-6).