Policy and Procedures for Responding to Allegations of Research Misconduct

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LIBERTY UNIVERSITY
POLICY AND PROCEDURES FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

I. Introduction

A. Applicability

This policy applies to all research conducted at Liberty University ("Liberty") and research supported by outside organizations, including the Public Health Service, the National Science Foundation, and any other governmental entity. This policy applies to any person employed by, subject to the rules and policies of, or affiliated with Liberty including, but not limited to all "Researchers," as defined in Section II.

B. Scope

This statement of policy and procedures is intended to carry out Liberty University's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. 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 an agent of, or was affiliated by contract or agreement with Liberty University.

- (1) PHS 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; (2) applications or proposals for PHS support for biomedical or behavioral research, research training, or activities related to that research or research training; or (3) plagiarism of research records produced in the course of PHS 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 PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support 42 CFR § 93.102.

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 that Liberty or HHS received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

C. Foreword

Most researchers conduct themselves in a manner that is above reproach and take great pride in the reliability of their own research. Any instance of research misconduct, however, presents a serious threat to the integrity of research processes, the reputation of Liberty University, and the credibility of the research community as a whole. All Researchers at Liberty are expected to engage in research and research activities that maintain a level of ethical and moral behavior supportive of and consistent with the Christian mission of Liberty. Research misconduct will not be tolerated at Liberty. Each and every Researcher must bear responsibility for monitoring and evaluating the procedures and related activities which the Researcher conducts, supervises, or participates. Each Researcher is expected to be familiar with, and act in accordance with, this policy and all applicable local, state, and federal laws. Researchers must adhere to commonly accepted practices and standards governing research activities and report each act of research misconduct which is known or believed to have occurred.

All actions undertaken pursuant to this policy will proceed promptly and with due regard for the reputations and rights of all persons involved. However, because of the inherent unfairness and difficulties presented by any attempt to assess stale evidence, allegations of misconduct based on events that occurred six or more years ago will not be subject to review under this policy unless (1) the Respondent continues or renews any incident of alleged research misconduct that occurred outside the six-year limit through the citation, republication or other use for the potential benefit of the Respondent of the research record that is the subject of the allegation; or (2) it is determined that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

II. Definitions

Terms used have the same meaning as given them in the Public Health Service Policies on Research Misconduct, 42 CFR Part 93.200-227.

(1) **Allegation:** Any written or oral statement or other indication of possible research misconduct made to a Liberty official.

(2) **Complainant:** A person who make an allegation of research misconduct.

(3) **Conflict of Interest:** The real or apparent conflict of one person's interests with the interests of another person or entity, where the potential bias may occur due to prior or existing personal or professional relationships.

(4) **Deciding Official:** The Liberty official who makes final determination on allegations of research misconduct and any responsive Liberty actions.

(5) **Evidence:** 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.

(6) **Falsification:** 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.

(7) **Good Faith Allegation:** An allegation made with the honest belief that research misconduct may have occurred.

(8) **Inquiry:** Gathering information and conducting initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

(9) **Investigation:** The formal examination and evaluation of all relevant evidence to determine if research misconduct has occurred, and if so, to determine the responsible person and the seriousness of the research misconduct.

(10) **Notice:** A written communication served in person, sent by mail or its equivalent to the last known street address, facsimile, or e-mail address of the addressee.

(11) **ORI:** The Office of Research Integrity in the U.S. Department of Health and Human Services (DHHS). ORI is responsible for the research misconduct and research integrity activities of the U.S. Public Health Services (PHS).

(12) **PHS:** The U.S. Public Health Service, an operating component of the DHHS.

(13) **PHS Regulations:** The Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of research misconduct, which is set forth at 42 CFR, Part 33 (Public Health Service Policies on Research Misconduct).

(14) **PHS Support:** Includes PHS grants, contracts, or cooperative agreements or applications/proposals for same.

(15) **Plagiarism:** The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(16) **Research Integrity Officer:** The Liberty official responsible for making an inquiry into allegations of research misconduct and determining when such allegations warrant an investigation. The Research Integrity Officer will be responsible for communication to all persons and agencies involved during the inquiry and investigation unless otherwise provided below. The Research Integrity Officer is appointed by the Provost.

(17) **Research Misconduct:** Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. As described in 42 CFR Section 93.103: Fabrication is making up data or results and recording or reporting them. Research misconduct does not include honest error or differences of opinion.

(18) **Research Record:** Any data, document, computer file, computer diskette, or any other written or non-written account or object that may be reasonably expected to provide evidence or information regarding the proposed, conducted, and/or reported research that constitutes the subject of an allegation of research misconduct. A research record includes, but is not limited to: grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; audio tape; photographs; x-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

(19) **Researcher:** Any person employed by, subject to the rules and policies of, or affiliated with, Liberty including, but not limited to:

a. **Faculty:** Those bearing a title including the terms "Assistant Professor," "Associate Professor," "University Professor," "Distinguished Professor,"

"Professor," "Assistant Research Professor," "Associate Research Professor," "Research Professor," "Visiting Scholar," "Academic Professional," "Senior Lecturer," or "Lecturer" (part-time or full-time). Any individual with emeritus standing is considered to be a faculty member for the purposes of this Policy as long as that individual is actively associated with Liberty or is utilizing Liberty facilities.

b. **Students:** Anyone seeking a degree and/or research experience at Liberty including, but not limited to, undergraduate students, graduate students, and part-time students.

c. **Staff:** Non-faculty, non-student employees of Liberty.

(20) **Respondent(s):** The person(s) against whom an allegation of research misconduct is directed or the person(s) whose actions are the subject of an inquiry or investigation. There can be more than one Respondent in any inquiry or investigation.

(21) **Retaliation:** Any action taken by Liberty or its designees that adversely affects the employment or other institutional status of a Complainant, who, acting in good faith, has made an allegation of research misconduct; a witness; or an investigation committee member. Adverse actions taken against any individual who has cooperated in good faith with an investigation of alleged misconduct also constitute retaliation.

III. Rights and Responsibilities

A. Research Integrity Officer

The Research Integrity Officer (RIO) will have primary responsibility for implementation of the procedures set forth in this document. The RIO will be an institutional official who is well-qualified to handle the procedural requirements involved with implementing these procedures and who is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report allegations of misconduct in good faith. A detailed listing of the responsibilities of the RIO is set forth in Appendix A. At Liberty University, the Research Integrity Officer is the Associate Dean for Research, Liberty University College of Osteopathic Medicine or his/her designee. The RIO will:

- 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;

- As necessary, take interim action and notify ORI of special circumstances, in accordance with Section IV.F. of this policy;

- 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;

- Notify the Respondent and provide opportunities for him/her to review/ comment/respond to allegations, evidence, and committee reports in accordance with Section III.C. of this 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, 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 42 CFR Part 93;

- 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. The Complainant may have an opportunity to testify before the inquiry and investigation committees and be informed of the results of the inquiry and investigation. It is the responsibility of Liberty University to ensure that the Complainant is protected from retaliation.

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 (42 CFR § 93.304(c), 93.307(b));

- An opportunity to comment on the inquiry report and have his/her comments attached to the report (42 CFR § 93.304(e), 93.307(f));

- 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 and the institution's policies and procedures on research misconduct (42 CFR § 308(a));

- 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 (42 CFR § 310(c));

- 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 (42 CFR § 310(g));

- 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 (42 CFR § 310(g)); 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 (42 CFR §§ 93.304(f), 93.312(a)).

The Respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO and/or other institutional officials, the Deciding Official may terminate the institution's review of an allegation that has been admitted, if the institution's acceptance of the admission and any proposed settlement is approved by ORI (42 CFR § 93.316).

The Respondent will be informed of the allegations prior to or when an inquiry is opened and notified in writing of the final determinations and resulting actions. The Respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to have the advice of counsel. The Respondent is responsible for cooperating with the conduct of an inquiry or investigation. If the Respondent is not found to have committed research misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation.

D. Deciding Official

The DO will receive the inquiry report and after consulting with the RIO and/or other institutional officials, decide whether an investigation is warranted under the criteria in 42 CFR § 93.307(d). Any finding that an investigation is warranted must be made in writing by the DO and must be provided to ORI, together with a copy of the inquiry report meeting the requirements of 42 CFR § 93.309, within 30 days of the finding. If it is found that an investigation is not warranted, the DO and the RIO will ensure that detailed documentation of the inquiry is retained for at least 7 years after termination of the inquiry, so that ORI may assess the

reasons why the institution decided not to conduct an investigation (42 CFR § 93.309(c).

The DO will receive the investigation report and, after consulting with the RIO and/or other institutional officials, decide the extent to which Liberty University 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 42 CFR § 93.315.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All employees or individuals associated with Liberty University should report observed, suspected, or apparent research misconduct to the Research Integrity Official (RIO). If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the RIO to discuss the suspected research misconduct informally, which may include discussing it 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.

At any time, employee or individual associated with Liberty may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

B. Preliminary Assessment of Allegations

Upon receiving an allegation of research misconduct, the Research Integrity Officer will assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether external sponsors are involved, and whether the allegation falls under the definitions of research misconduct contained in this Policy.

C. Cooperation with Research Misconduct Proceedings

All employees or individuals associated with Liberty University will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees, including Respondents, have an obligation to provide evidence relevant of research misconduct allegations to the RIO or other institutional officials officially engaged in an inquiry or investigation.

D. Confidentiality

The RIO shall, as required by 42 CFR § 93.108: (1) limit disclosure of the identity of Respondents and Complainants to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding. The RIO should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

E. Protecting Complainants, witnesses, and committee members

Employees and individuals associated with Liberty University may not retaliate in any way against Complainants, witnesses, or committee members.

The Research Integrity Officer (RIO) will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The RIO will make reasonable and practical efforts to counter potential and/or actual retaliation against these persons in the terms and conditions of their employment or other status at Liberty University and will review instances of alleged retaliation for appropriate action. Employees should immediately report any alleged or apparent retaliation to the RIO.

Liberty will protect the privacy of those who report misconduct in good faith to the extent practicable. For example, if a Complainant requests anonymity, Liberty will make every effort to honor the request in accordance with applicable policies and regulations, as well as state and local laws. Liberty will undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations; to counter any potential or actual retaliation; and to protect and restore the position and reputation of any person against whom retaliation is directed.

F. Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the Respondent(s) in thoroughly carrying out the inquiry or investigation, and confidentiality to the extent possible without compromising public health and safety. During the research misconduct proceeding, the Research Integrity Officer (RIO) is responsible for ensuring that Respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and the policies and procedures of Liberty University.

Respondents accused of research misconduct may consult with legal counsel, or a non-lawyer personal advisor (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal advisor to interviews or meetings on the case with advance notice to the inquiry/investigation committee.

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 (42 CFR § 93.304(k)).

G. Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceeding, the Research Integrity Officer (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 PHS supported research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and the ORI, take appropriate interim action to protect against any such threat (42 CFR § 93.304(h)). 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 the 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;
- HHS 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 HHS action may be necessary to safeguard evidence and protect the rights of those involved; or

- The research community or public should be informed (42 CFR § 93.318).

H. Using a Consortium or Other Person for Research Misconduct Proceedings

(a) Liberty University may use the services of a consortium or person that it reasonably determines to be qualified by practice and experience to conduct research misconduct proceedings.

(b) A consortium may be a group of institutions, professional organizations, or mixed groups, which will conduct research misconduct proceedings for other institutions.

(c) A consortium or person acting on behalf of Liberty University must follow the requirements of this part in conducting research misconduct proceedings.

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), and whether the allegation falls within the definition of research misconduct in 42 CFR § 93.103 (42 CFR § 93.307(a)). An inquiry must be conducted if these criteria are met.

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. 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 (42 CFR § 93.307(c)).

C. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the Research Integrity Officer (RIO) must make a good faith effort to notify the Respondent in writing, if the Respondent is known. If the inquiry subsequently identifies additional Respondents, they must be notified in writing. On or before the date on which the Respondent is notified, or the inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments (42 CFR §§ 93.305, 93.307(b)). The RIO may consult with ORI for advice and assistance in this regard.

D. Appointment of the Inquiry Committee

The Research Integrity Officer (RIO), in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical. 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 (42 CFR § 93.304(b)).

The institution will notify the Respondent of the proposed committee membership and 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 shall be no more than 10 calendar days. The institution will make the final determination regarding the existence of a conflict.

E. Charge to the Committee and First Meeting

The Research Integrity Officer (RIO) will prepare a charge for the inquiry committee that:

- Sets forth a timeline 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;
- States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b); 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 42 CFR § 93.309(a).

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. The RIO will also 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 Research Integrity Officer (RIO), the committee members will decide whether an investigation is warranted based on the criteria in this policy and 42 CFR § 93.307(d). The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct, or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the Respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the institution shall promptly consult with ORI to determine the next steps that should be taken. See Section IX.

G. Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the Deciding Official on whether an investigation is warranted, must be completed within 60 calendar days of initiation of the inquiry, unless the Research Integrity Officer (RIO) determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period (42 CFR § 93.307(g)). The RIO will notify the Respondent in writing in the event that an extension to the 60-day period is warranted; such letter shall outline the rationale for the extension.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written Inquiry Report must be prepared that includes the following information:

(1) The name and position of the Respondent;

(2) The name and title of the committee members and experts, if any;

(3) A description of the allegations of research misconduct;

(4) The PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support;

(5) A summary of the inquiry process used;

(6) A list of the research records reviewed;

(7) Summaries of any interviews;

(8) A description of the evidence in sufficient detail to demonstrate the basis for recommending or not recommending that the allegations warrant an investigation; and

(9) Any comments on the draft report by the Respondent or Complainant (42 CFR § 93.309(a)). University counsel may review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the inquiry committee.

B. Notification to the Respondent and Opportunity to Comment

The Research Integrity Officer (RIO) shall notify the Respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment and rebuttal within 10 calendar days, and include a copy of or refer to 42 CFR Part 93 and the institution's policies and procedures on research misconduct (42 CFR § 93.308(a)). A confidentiality agreement shall 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. Decision by Deciding Official

The Research Integrity Officer will transmit the final inquiry report and any comments to the Deciding Official (DO), who will determine in writing whether an investigation is warranted. The inquiry is completed when the DO makes this determination.

2. Notification to Office of Research Integrity

Within 30 calendar days of the Deciding Official's (DO) decision that an investigation is warranted, and prior to the initiation of an investigation, the Research Integrity Officer (RIO) will provide the Office of Research Integrity with the DO's written decision and a copy of the inquiry report (42 CFR §9 3.304(d)). The RIO will also notify those institutional officials who need to know of the DO'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

(3) The charges to be considered in the investigation.

3. Documentation of Decision Not to Investigate

If the Deciding Official decides that an investigation is not warranted, the Research Integrity Officer 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 HHS personnel upon request.

VII. Conducting the Investigation

A. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the Deciding Official that an investigation is warranted (42 CFR § 93.310). The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations.

This is particularly important where the alleged research misconduct involves clinical trials 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. Under 42 CFR § 93.313 the findings of the investigation must be set forth in an investigation report.

B. Notifying ORI and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the Research Integrity Officer (RIO) must:

(1) Notify the ORI Director, in writing, of the decision to begin the investigation and provide ORI a copy of the inquiry report containing the information required by 42 CFR § 93.309(a); and

(3) Notify the Respondent in writing of the allegations to be investigated.

The RIO must also give the Respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation (42 CFR § 93.310(b) and (c)).

Upon request from the ORI, the RIO shall promptly send ORI:

(1) A copy of Liberty University's policies and procedures under which the inquiry was conducted;

(2) The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and

(3) The charges for the investigation to consider.

The RIO will, immediately and prior to notifying the Respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry. The need for additional sequestration of records for the investigation may occur for any number of reasons, including the 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 (42 CFR § 93.310 (d)).

C. Appointment of the Investigation Committee

The Research Integrity Officer (RIO), in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within thirty (30) days after determining that an investigation is warranted. The investigation committee must consist of individuals who do not have real or apparent conflicts of interest in the case and have the necessary expertise to: evaluate the evidence and issues related to the allegations; interview the Respondent, Complainant, and witnesses; and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, or other qualified persons, and they may be internal or external to the University. The investigation committee may solicit expert consultation from an outside party (e.g., scientific expert, forensic expert, etc.) as needed. Individuals appointed to the investigation committee may also have served on the inquiry committee.

The RIO will notify the Respondent of the proposed committee membership within five (5) days of its appointment. If the Respondent submits a written objection to any appointed member of the investigations committee or expert, the RIO will determine whether to replace the challenged member with a qualified substitute.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The Research Integrity Officer (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;
- Defines research misconduct;
- Identifies the Respondent;

The charge will state the committee is to evaluate the evidence and testimony of the Respondent, Complainant, and key witnesses to determine whether, based on a preponderance of evidence, research misconduct occurred and, if so, to what extent, who was responsible, and the level of seriousness. The charge must also inform the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and 42 CFR § 93.313.

In order for the committee 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.

2. First Meeting

The RIO, with possible assistance of University counsel, 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, 42 CFR Part 93, and, where external sponsors' funding is involved, the sponsor's regulations. The RIO will be present or available throughout the investigation to advise the committee as needed.

E. Investigation Process

The investigation committee will be appointed and the investigation process initiated within 30 days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation. The investigation will normally involve examination of all documentation including, but not limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls.

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 (42 CFR § 93.310(e));

- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical (42 CFR § 93.310(f));

- 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 (42 CFR § 93.310(g)); 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 (42 CFR § 93.310(h)).

F. Time for Completion

The investigation is to be completed within 120 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 the Provost, the Vice Provost, and the ORI. However, if the Research Integrity Officer (RIO) determines that the investigation will not be completed within this 120-day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay. 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 (42 CFR § 93.311).

VIII. The Investigation Report

A. Elements of the Investigation Report

The investigation committee and the Research Integrity Officer are responsible for preparing a written draft report of the investigation, to be submitted to the external sponsor, if any. The report will:

- Describe the specific allegations of research misconduct considered in the investigation;

- Describe the nature of the allegation of research misconduct, including identification of the Respondent;

- Describe and document the PHS support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support;

- Include the institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously;

- Identify and summarize the research records and evidence reviewed and identify any evidence taken into custody but not reviewed; and

- State the findings and explain the basis for the findings.

The report will include the actual text or an accurate summary of the view of any individual(s) found to have engaged in misconduct as well as a description of any sanctions imposed and administrative actions taken by the institution. Finally, the report must include a statement of findings for each allegation of research misconduct identified during the investigation (42 CFR § 93.313). Each statement of findings must:

(1) Identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly;

(2) Summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the Respondent, including any effort by Respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion;

(3) Identify the specific PHS support;

(4) Identify whether any publications need correction or retraction;

(5) Identify the person(s) responsible for the misconduct; and

(6) list any current support or known applications or proposals for support that the Respondent has pending with non-PHS federal agencies (42 CFR § 93.313).

B. Comments on the Draft Report and Access to Evidence

The Research Integrity Officer (RIO) will provide the Respondent with a copy of the draft investigation report for comment or rebuttal and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The Respondent

will be allowed thirty (30) days from the date he/she received the draft report to review and comment on the draft report. Comments should be submitted to the RIO. The Respondent's comments must be included and considered in the final report (42 §§ CFR 93.312(a), 93.313(g)).

In distributing the draft report, or portions thereof, to the Respondent, the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may require that the recipient sign a confidentiality agreement.

C. Institutional Review and Decision

The Research Integrity Officer (RIO) will assist the investigation committee in finalizing the draft investigation report, including ensuring that the Respondent's comments are included and considered, and transmit the final investigation report to the Deciding Official (DO), who will determine in writing:

(1) Whether the institution accepts the investigation report, its findings, and the recommended institutional actions; and

(2) The appropriate institutional actions in response to the accepted findings of research misconduct. If this determination varies from the findings of the investigation committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the DO may return the report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, the RIO will 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.

D. Transmittal of the Final Investigation Report

Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation submit the following to ORI and any external sponsors, as required:

(1) A copy of the final investigation report with all attachments;

(2) A statement of whether the institution accepts the findings of the investigation report;

(3) A statement of whether the institution found misconduct and, if so, who committed the misconduct; and

(4) A description of any pending or completed administrative actions against the Respondent (42 CFR § 93.315).

E. Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within one hundred twenty (120) days of its initiation, with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of the findings, making the draft report available to the subject of the investigation for comment, submitting the report to the Research Integrity Officer for approval, and submitting the report to the appropriate regulatory agency when required. If the Research Integrity Officer approves an extension for good cause, the reason for the extension will be entered into the records of the case and the report.

F. Maintaining Records for Review by ORI

The Research Integrity Officer (RIO) must maintain and provide to ORI upon request "records of research misconduct proceedings" as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI 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 PHS proceeding involving the research misconduct allegation (42 CFR § 93.317(b)). 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 (42 CFR §§ 93.300(g), 93.403(b) and (d)).

XIV. Special Requirements for Cases Involving PHS Funding

A. An institution's decision to initiate an investigation must be reported in writing to the Director, federal Office of Research Integrity, on or before the date the investigation begins. At minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of research misconduct, and the PHS applications or grant number(s) involved. ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report. Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.

B. If an institution plans to terminate an inquiry for any reason other than that an investigation is not warranted or an investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.

C. If the institution determines that it will not be able to complete the investigation in one hundred twenty (120) days, the Research Integrity Officer will submit to ORI a written request for extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Research Integrity Officer will file periodic progress reports as requested by the ORI.

D. When PHS funding or applications for funding are involved and an admission of research misconduct is made, the Research Integrity Officer will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, the institution cannot accept an admission of research misconduct as a basis for closing a case or not undertaking and investigation without prior approval from ORI.

E. The Research Integrity Officer will notify ORI at any stage of the inquiry or investigation if:

(1) There is an immediate health or safety hazard involved, including the immediate need to protect human or animal subjects; or

(2) There is an immediate need to protect Federal funds or equipment; or

(3) There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any; or

(4) It is probable that the alleged incident is going to be reported publicly; or

(5) The research activities should be suspended; or

(6) There is reasonable indication of possible violation of civil or criminal law. In this instance, the institution must inform ORI immediately after obtaining that information.

X. 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. 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 and 42 CFR § 93.315. (42 CFR 93.3169(a)).

XI. Institutional Administrative Actions

Liberty University will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated. If the RIO determines that the alleged misconduct is substantiated by the findings, he or she will consult with the Deciding Official and other institutional parties as needed, on the appropriate actions to be taken. 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.

XII. Other Considerations

A. 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 42 CFR Part 93.

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.

B. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI concurrence where required by 42 CFR Part 93, the RIO must, at the request of the Respondent, undertake all reasonable and practical efforts to restore the Respondent's reputation (42 CFR § 93.304(k)). 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.

C. Protection of the Complainant, Witnesses and Committee Members

Regardless of whether the institution determines that research misconduct occurred, the RIO will make reasonable efforts to protect Complainants who made allegations of research misconduct in good faith and any individuals who cooperate in good faith with inquiries and investigations of such allegations (42 CFR § 93.304(l)). Upon completion of an investigation, the RIO will determine, after consulting with the Complainant as needed, what steps, if any, are needed to restore the position or reputation of the Complainant(s) and any individuals who cooperated in good faith with inquiries and investigations of such allegations (i.e., witnesses, committee members, et. al). The RIO is responsible for implementing

any such steps. The RIO will also make reasonable efforts during the inquiry and investigation to prevent any retaliation against the Complainant(s) and any other individuals who were involved in the inquiry and/or investigation of allegations of research misconduct.

D. Allegations Not Made in Good Faith

If relevant, the RIO will determine whether the Complainant's allegations of research misconduct were made in good faith. If a determination is made that an allegation was not made in good faith, the RIO will consult with the DO to determine whether any administrative action should be taken against the Complainant, as well as the most appropriate institutional office/official to administer any such actions.

E. Interim Administrative Actions

Institutional officials will take interim administrative actions, as appropriate, to protect external sponsors' funds and, if Federal funds are involved, ensure that the purposes of the Federal financial assistance are carried out.

XIII. Record Retention

After completion of a case and all ensuing related actions, the RIO will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the RIO or committees. The RIO will keep the file for seven (7) years beyond completion of the case. ORI or other authorized DHHS personnel will be given access to the records upon request.