

The Lincoln University

RESPONSIBLE CONDUCT OF RESEARCH

&

RESPONSE TO

ALLEGATIONS OF RESEARCH MISCONDUCT

POLICY



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LINCOLN UNIVERSITY OF PENNSYLVANIA

POLICY FOR

RESPONSIBLE CONDUCT OF RESEARCH & RESPONSE TO ALLEGATIONS OF

RESEARCH MISCONDUCT

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**The LINCOLN UNIVERSITY
POLICY
FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT**

I. Introduction

A. General Policy

A university community has the obligation to conduct research and/or scholarly work and communicate results using the highest standards and ethical practices. Lincoln University of Pennsylvania (LUPA) is responsible for promoting academic practices that prevent misconduct and for developing policies and procedures for dealing with allegations of misconduct. All members of the LUPA community--students, staff, faculty, and administrators--share responsibility for developing and maintaining standards to ensure ethical conduct of research and detection and appropriate handling of abuse of these standards. This responsibility must be assumed while sustaining the openness and creativity that is vital to the enterprise research.

Federal agencies require that institutions receiving federal funds for the conduct of biomedical and behavioral research submit an assurance of compliance with federal guidelines on misconduct in science and engineering research, and an Annual Report on Possible Misconduct in Science. This LUPA policy is in response to federal requirements as listed in 42 Code of Federal Regulations Part 93.

The purpose of this policy is to provide the members of this academic community a framework for reporting suspected incidents of misconduct, as well as investigating and adjudicating cases of misconduct in a fair and consistent manner. It is also intended that any such action be in accordance with applicable federal and state law as well as the Collective Bargaining Agreement (CBA).

It is generally recognized in academia that an accusation of misconduct in scholarship and/or research is among the most serious charge that can be leveled against a scholar/researcher.

Consequently, it is highly advised that any individual contemplating such an accusation fully consider the gravity of the accusation and its consequences, and make every reasonable effort to avoid lodging charges that lack a substantial element of truth. Frivolous or false accusations may constitute grounds for disciplinary action against the accuser consistent with this policy and any applicable collective bargaining agreement.

B. Scope

This policy is intended to carry out LUPA's responsibilities for all research including, but not limited to, federal, state, local and private grant opportunities. This policy

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 this institution; and
- Biomedical or behavioral research, research training, or activities related to that research or research training, such as the (1) operation of tissue and data banks and the dissemination of research information, (2) applications or proposals for 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 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 funds resulted in a grant, contract, cooperative agreement, or other form of support.

This policy and the associated procedures do not apply to authorship or collaboration disputes and apply only to allegations of research misconduct.

II. Operational Definitions

- Allegation* means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institutional or grantor official.
- Collective Bargaining Agreement* means the agreement between Lincoln University of the Commonwealth System of Higher Education and the Lincoln University Chapter of the American Association of University Professors.
- Complainant* means a person who in good faith makes an allegation of research misconduct.
- Deciding Official (DO)* means the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. At LUPA, the DO will be Dr. Kenoye Eke, Sr., Provost & Vice President for Academic Affairs. At no times will this be the Research Integrity Officer.
- 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.
- 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 it is 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 purpose of helping an institution meet its responsibilities under any federal or state law or contractual obligation. 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.

- G. *Grantor* means the person or entity that is supplying funds, goods or services in support of the research conducted pursuant to this policy. This could include, but not be limited to, the United States Department of Health and Human Services, the National Science Foundation or any other Federal, State, Local or private entity/person that directly provides support to the research conducted pursuant to this policy.
- H. *HHS* means the United States Department of Health and Human Services.
- I. *Inquiry* means preliminary information-gathering and preliminary fact-finding as to whether an allegation of apparent instance of violation of responsible conduct of research warrants an investigation. When applicable, it shall meet the criteria and follow the procedures of 42 CFR §§ 93.307-93.309.
- J. *Institutional Counsel* means the University Legal Counsel who represents the institution during the violations of responsible conduct of research inquiry and investigation, and who is responsible for advising the Research Integrity Officer, the inquiry and investigation committees, and the Deciding Official on relevant legal issues. The institutional counsel does not represent the respondent, an informant or any other person participating during the inquiry, investigation or any follow-up action, except the institutional officials responsible for managing or conducting the institutional violations of responsible conduct of research process as part of their official duties.
- K. *Institutional member* means a person who is employed by, is an agent of, or is affiliated by contract or agreement with LUPA. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.
- L. *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. All such investigations, to the extent that it does not conflict with federal or state law, shall be consistent with the CBA.

- M. *Office of Research Integrity or ORI* means the office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities.
- N. *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.
- O. *Public Health Service or PHS* means the unit within HHS that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.
- P. *PHS support* means PHS funding, or applications or proposals therefor, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: PHS grants, cooperative agreements, or contracts or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contract.
- Q. *Records of research misconduct proceedings* means: (1) the research records and evidence secured for the research misconduct proceeding pursuant to this policy and 42 CFR §§ 93.305, 93.307(b) and 93.310(d), if applicable except to the extent the Research Integrity Officer determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that have been retained; (2) the documentation of the determination of irrelevant or duplicate records; (3) the inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate, as required by 42 CFR §93.309(c) if applicable, (4) the investigation report and all records (other than drafts of the report) in support of the report, including the recordings or transcripts of each interview conducted; and (5) the complete record of any appeal within the institution from the finding of research misconduct.
- R. *Research Integrity Officer (RIO)* means the LUPA official responsible for: (1) assessing allegations of research misconduct, in collaboration with appropriate Academic Deans and Departmental Chairs, to determine if they fall within the definition of research misconduct, 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; and (2) overseeing inquiries and investigations; and (3) the other responsibilities described in this policy. At LUPA, the RIO will be Dr. Michael Ehi Ayewoh, Chief Research & Sponsored Programs Officer (CRSPO)/Assistant Vice President for Research & Sponsored Programs (AVP).

- S. *Research misconduct* means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- T. *Research misconduct proceeding* means any actions related to alleged research misconduct that is within 42 CFR Part 93 if applicable including, but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings and administrative appeals.
- U. *Research record* means the record of data or results that embodies the facts resulting from scientific inquiry including, but not limited to, data, document, computer file, computer CD or diskette or any other written or non-written account of object that reasonably may be expected to provide evidence or information regarding the proposed, conducted or reported research that constitutes the subject of an allegation or violations or responsible conduct of research. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports that are internal or external; journal articles; laboratory notebooks; notes; correspondence; videos; photographs; theses; oral presentations; X-ray films, slides, biological materials; computer files and printouts; manuscripts and publications, index cards; equipment use logs; laboratory procurement records, animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.
- V. *Respondent* means the person against whom an allegation of research misconduct is directed or who is the subject of research misconduct proceeding. There can be more than one respondent in any inquiry or investigation.
- W. *Retaliation* means an adverse action that affects the employment or other status of an individual because the individual has, in good faith, made an allegation of violations of scientific misconduct or of an inadequate institutional response thereto, or has cooperated in good faith with an investigation of such allegation including, but not limited to, being a witness or committee member.

III. Examples of Best Practices to Deter Academic Misconduct

LUPA recognizes that efforts to avoid academic misconduct may also effectively impede scholarship and research pursuits. However, it believes that scholars, researchers and administrators can take active measures to create a climate of openness in research which may discourage academic misconduct. The following measures should be viewed as examples of best practice which may deter academic misconduct if regularly practiced:

- A. Maintain and store raw data upon which research conclusions are based in a safe environment. The raw data is best protection against claims of fabricated or falsified research. Researchers are encouraged to consider backup systems for raw data.
- B. Preview research proposals and manuscripts with colleagues of equal or greater experience. This may serve to improve the technical/scientific quality of the proposal or manuscript, while also providing for corroboration of research ideas and timing.
- C. Present research findings at departmental or other faculty meetings. This also provides for more open discourse among colleagues for the mutual protection of individual researchers leading to an enhanced climate of integrity and objectivity.
- D. Adhere to established standards of ethics regarding authorship of publications. All authors named on a collaborative study accept full responsibility for the work published or at least for that portion of the research for which they are responsible. Researchers should be familiar with established guidelines and should also adhere to requirements set by individual publishers.
- E. Hold staff meetings for the purposes of previewing research proposals and presenting research findings. Such forums may be useful in enlisting the department's assistance in solving administrative and other problems involving research projects. Department chairs might consider requesting a file copy of each research manuscript submitted for publication.
- F. Encourage the incorporation of formal course work in ethics into the curriculum, making this subject an integral part of the research and educational experience.

IV. Rights and Responsibilities

A. Research Integrity Officer

The Chief Research & Sponsored Programs Officer (CRSPO)/Assistant Vice President (AVP) of the Office of Research and Sponsored Programs (ORSP) will be the Research Integrity Officer (RIO) at Lincoln University of Pennsylvania (LUPA). He will have primary responsibility for implementation of the institution's policies and procedures on research misconduct. The RIO will be well qualified to administer the procedures and is sensitive to the varied demands made on those who conduct research, those who are accused of research misconduct, those who make good faith allegations of research misconduct, and those who may serve on inquiry and investigation committees.

A detailed listing of the responsibilities of the RIO is set forth in Appendix A on pages 24 to 31 of this policy. 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 VI.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 or other required individuals and/or entities, internal and external, of special circumstances, in accordance with Section VI.F. of this policy;
- Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with Section VI.C. and VIII.B. 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, if 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 VI.C. and IX. B. of this policy;
- Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- In consultation with appropriate Academic Deans, Departmental Chairpersons, Director of Human Resources, and the Provost, 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 refusal, 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, if applicable or other Grantor if required by law or contract;
- 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;
- Maintain records of the research misconduct proceeding and make them available to ORI or other Grantor if required by law or contract, in accordance with Section IX. F. of this policy;
- Conduct all of the actions above in accordance with federal and state laws and in the absence of such, in conformity with the CBA.

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 a summary of the interview for correction, addition or deletion. The complainant must be interviewed during an investigation, and be given the summary of the interview for correction.

C. Respondent

The respondent will be informed of the allegations when an inquiry is open. The respondent will also be notified in writing of the final determination and resulting actions as required by the CBA. The respondent will also be permitted a union representative as outlined within the CBA.

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation.

In the event of a conflict between this policy and federal and state law, federal and state law shall control. In the event that there is a conflict between these policies and an applicable CBA, the CBA will take precedence.

Institutional employees accused of violations of academic misconduct may consult with a Union Representative to seek advice and may bring a Union Representative to interviews or meetings pertaining to the investigation.

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 when the inquiry is open;
- 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, if applicable, and a copy of the institution's policies and procedures on research misconduct;
- The Respondent is entitled to be informed of the allegations when an inquiry is opened 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 interview summary, and have the corrected summary included in the record of the investigation;
- 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 summary of testimony provided to the witness for correction, and have the corrected summary 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 twenty (20) business 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. With the advice of the RIO and institutional legal counsel, 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 or other Grantor.

D. Deciding Official

The Provost/Vice President of Academic Affairs, DR. Kenoye Eke, Sr., will be the DO. He will receive the inquiry report and after consulting with Dr. Ayewoh, the RIO, decide whether an investigation is warranted under the criteria in 42 CFR §§ 93.307(d) if applicable. Any finding that an investigation is warranted must be made in writing by the DO and Grantor or must be provided to the University President, DR. Robert Jennings, University Legal Counsel and ORI; together with a copy of the

inquiry report meeting the requirements of 42 CFR §93.309, if applicable, within forty (40) business 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 or any other Grantor may assess the reasons why the institution decided not to conduct an investigation.

The DO will receive the investigation report and, after consulting with the RIO, University President, University Legal Counsel, and other appropriate officials, decide the extent to which LUPA accepts the findings of the investigation. If research misconduct is found, the DO will decide what, if any, institutional administrative actions are appropriate. The DO shall ensure that the final investigation report, the findings of the RIO, the inquiry and investigative committees, and a description of any pending or completed administrative action are provided to ORI, as required by 42 CFR §93.315, if applicable, or other Grantor if required by law or contract.

V. General Policies and Principles

A. Responsibility to Report Misconduct

All institutional members will report observed, suspected, or apparent research misconduct to the RIO. The Institution's RIO is Dr. Michael E. Ayewoh, Chief Research & Sponsored Programs Officer/Assistant Vice President for Research and Sponsored Programs in Wright Hall 116. He can also be reached at (484) 365-7693 or by e-mail at mayewoh@lincoln.edu.

Any university official who receives an allegation of research misconduct must report it immediately to the 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 within LUPA with responsibility for resolving the problem.

At any time, an institutional member 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. 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 42 CFR § 93.108, and shall in regards to all other grants (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 and confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

D. Protecting Complainants, Witnesses, and Committee Members

Institutional members will 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. Disciplinary action will be taken for retaliation.

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 proceedings, the RIO is responsible for ensuring that respondents receive all the notices and opportunities and the applicable policies and procedures of the institution.

If the Inquiry and Investigation committees find the charge of misconduct to be unfounded, the report and supporting evidence shall be forwarded to the RIO shall be kept in a secure location for three years following the conclusion of the Investigation. Both the appropriate Deans and the RIO will undertake diligent efforts to restore the respondent's reputation with regard to the unsupported allegations. All individuals related to the review process, the Provost/Vice President for Academic Affairs, the President, Academic Dean(s), and Chairperson(s) of the researcher's department will be notified that the charge of misconduct in research was unfounded. The positions and reputations of persons who make allegations in good faith shall also be protected.

E. Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal, state or private funds and equipment, or the integrity of the supported research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and Grantor

pursuant to legal or contractual requirements, take appropriate interim action to protect against any such threat consistent with applicable laws or the CBA. Interim action might include but not be limited to 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 or the Grantor if required to do so by law or contract, 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;
- Grantor 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 action by the Grantor may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

VI. 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) if applicable, and whether the allegation falls within the definition of research misconduct in this policy and 42 CFR § 93.103, if applicable. 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. Both formal and informal approaches will provide the RIO with the flexibility to assess the merits of the allegations. The RIO shall, on or before the date

on which the respondent is notified of the allegation, obtain research records and evidence needed to conduct the research misconduct proceeding.

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. The purpose of the inquiry is not to reach a final conclusion about whether misconduct occurred or who was responsible but to make a recommendation to the Deciding Official of whether misconduct occurred. The Deciding Official reserves the right to make a final decision and/or any appropriate discipline.

C. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the RIO shall 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. The RIO may consult with University Legal Counsel or on the advice of ORI Counsel or other Grantor for advice and assistance in this regard.

D. Appointment of the Inquiry Committee (IQC)

The RIO, in consultation with appropriate Academic Deans, Departmental Chairpersons or other appropriate institutional officials, will appoint an Inquiry Committee (IQC) and Committee Chair within ten (10) business days of the initiation of the inquiry or as soon thereafter as practical. The IQC shall 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 and/or subject-specific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. The IQC should consist of no less than three (3) individuals and those three (3) can include one or more experts from outside of Lincoln University of Pennsylvania if necessary.

E. Charge to the Inquiry Committee (IQC) and First Meeting

The RIO shall prepare a charge for the IQC that includes the following:

- 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, but 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) if applicable; 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 if applicable 42 CFR § 93.309(a).
- At the IQC's first meeting, the RIO will review the charge with the membership, 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, as well as University Legal Counsel, will be present or available throughout the inquiry to advise the committee as needed.

F. Inquiry Process

The IQC, after five (5) business days, will normally interview the complainant, the respondent, and key witnesses as well as examining relevant research records and materials. Then, the IQC 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 42 CFR § 93.307(d) if applicable. 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.

G. The Inquiry Report

1) *Elements of the Inquiry Report*

A written inquiry report shall be prepared that includes the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) the PHS or alternative grantor support including, for example, grant numbers, grant applications, contracts and publications listing PHS or other grantor support; (4) the basis for recommending or not recommending that the allegations warrant an investigation; (5) any comments on the draft report by the respondent or complainant. The inquiry report shall include: the names and titles of the committee members and experts who conducted the inquiry; a summary of the inquiry process used; a list of the research records reviewed and summaries of any interviews including dates of meetings.

Institutional counsel should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the inquiry committee.

2) *Notification to the Respondent and 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 five (5) business days of completion by the Committee, and include a copy of or refer to 42 CFR Part 93 if applicable and the institution's policies and procedures on research misconduct. A confidentiality agreement shall be a condition for access to the report.

Any comments that are submitted 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.

3) *Institutional Decision and Notification*

i. Decision by Deciding Official

The RIO will transmit the final inquiry report and any comments to the DO, who will determine in writing whether an investigation is warranted. The inquiry is completed when the DO makes this determination.

ii. Notification to ORI

Within five (5) business days of the DO's decision that an investigation is warranted, the RIO will provide ORI, or other grantor if required by law or contract, with the DO's written decision and a copy of the inquiry report. The

RIO will also notify those institutional officials who need to know of the DO's decision. The RIO shall provide the following information to ORI or a grantor if required by law or contract 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.

iii. Documentation of Decision Not to Investigate

If the DO decides that an investigation is not warranted, the RIO shall secure and maintain for seven (7) years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI or a grantor of the reasons why an investigation was not conducted. These documents shall be provided to ORI or other authorized HHS personnel upon request or to a grantor if required by law or contract.

H. Timeline and Final Inquiry Report

The inquiry, including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted, shall be completed within twenty (20) business days of initiation of the inquiry, unless the 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 twenty (20)-day period. The respondent will be notified of the extension.

VII. Conducting the Investigation

A. Initiation and Purpose

Absent unusual circumstances, the investigation must begin within twenty (20) business days after the determination by the DO 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. 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 will 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 RIO shall: (1) notify the ORI Director or Grantor, if required by law or contract, of the decision to begin the investigation and provide ORI or Grantor a copy of the inquiry report; and (2) 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.

Prior to notifying respondent of the allegations, the RIO will 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. 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.

C. Appointment of the Investigation Committee

The RIO, in consultation with appropriate Academic Deans, Departmental Chairpersons, and other institutional officials as appropriate, will appoint an investigation committee (or IVC) and the committee chair within five (5) business days of the beginning of the investigation or as soon thereafter as practical. The IVC 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 and/or technical expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant, and conduct the investigation. Individuals appointed to the IVC may also have served on the inquiry committee or IQC. When necessary to secure the necessary expertise or to avoid conflicts of interest, the RIO may select appropriate committee members from outside LUPA.

D. Charge to the Committee and the First Meeting

1. *Charge to the IVC*

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;

- Identifies the respondent;
- Informs the committee that it must conduct the investigation as prescribed in item E of paragraph VII, page 18, of this policy;
- 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; beyond reasonable doubt, 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 42 CFR § 93.313, if applicable.

2. First Meeting

The RIO shall convene the first meeting of the Investigative Committee (IVC) 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 IVC will be provided with a copy of this policy and 42 CFR Part 93, if applicable. The RIO and University Legal Counsel will be present or available throughout the investigation to advise the committee as needed.

E. Investigation Process

The investigation committee or IVC and the Research Integrity Officer or 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 recommendation 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 a written summary to the interviewee for correction, and include the written summary 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 sixty (60) business 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, if applicable or other Grantor if required by law or contract. However, if the RIO determines that the investigation will not be completed within this sixty (60)-day period, he/she will submit to ORI if applicable, or other Grantor if required by law of contract, 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 applicable or other Grantor, if ORI or Grantor grants the request for an extension and directs the filing of such reports.

VIII. The Investigation Report

A. Elements of the Investigation Report

The IVC 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;
- Describes and documents the Public Health Service (PHS), as described on page 4 of this policy, or other Grantor support including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support;
- Describes the specific allegations of research misconduct considered in the investigation;

- Includes 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; and
- Includes a statement of findings for each allegation of research misconduct identified during the investigation. 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/Grantor 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.

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 ten (10) business 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. *Confidentiality*

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. Decision by Deciding Official

The RIO will assist the Investigation Committee (IVC) 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 DO, who will determine in writing and report to the University President: (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 IVC, 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 IVC. Alternatively, the DO may return the report to the IVC 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. The complainant will only be entitled to know whether or not the allegation of misconduct was founded. After informing ORI, if applicable or other Grantor if required by law or contract, 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. Disciplinary Measures for Founded Misconduct

When research misconduct has been recommended by the Committee, potential disciplinary action will be taken in accordance with the applicable CBA.

E. Notice to ORI of Institutional Findings and Actions

Unless an extension has been granted, the RIO must, within the sixty (60) business day period for completing the investigation, submit the following to the Federal Office of Research Integrity (ORI), if applicable or to another Grantor is required to by law or contract: (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.

F. Maintaining Records for Review by ORI

The RIO shall maintain and provide to ORI upon request “records of research misconduct proceedings” as that term is defined by 42 CFR § 93.317. This standard will be used for all grants received by the University. 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 shall be maintained in a secure manner for seven (7) years after completion of the proceeding or the completion of any PHS 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.

VIII. 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, or another grantor if required to by law or contract, 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, or another grantor if required to by law or contract, as prescribed in this policy and 42 CFR § 93.315, if applicable.

X. 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 applicable.

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. Protection of the Complainant, Witnesses, and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the institution or ORI, or the Grantor, determines that research misconduct occurred, the RIO will 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 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.

C. 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 there was an absence of good faith, he will determine whether any administrative action should be taken against the person who failed to act in good faith. Discipline for this action will be in accordance with applicable CBA or policy.

Approved:

Robert R. Jennings, Ed.D., President

Date

APPENDIX A

Responsibilities of Research Integrity Officer

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, when applicable;
- Complies with its written policies and procedures and the requirements of 42 CFR Part 93, when applicable;
- 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.
- This criteria applies to all Federal and non-Federal grants as well.

II. Notice and Reporting to ORI and Cooperation with ORI or alternative Grantor, if applicable

The RIO has lead responsibility for ensuring that the institution:

- Files an annual report with ORI containing the information prescribed by ORI or as required by any grantor;
- 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, if applicable, or fulfill any reporting requirements outlined by any Grantor;
- Notifies ORI, or other Grantor, 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 or other Grantor's 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, or other Grantor if required by law or contract, with the written finding by the responsible institutional official that an investigation is warranted and a copy of the inquiry report, within five (5) business days of the date on which the DO's finding is made;
- Notifies ORI, or other Grantor if required by law or contract of the decision to begin an investigation on or before the date the investigation begins;
- Within sixty (60) business days of beginning an investigation, or such additional days as may be granted by ORI or other Grantor if required by law or contract, provides ORI or other Grantor 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, or other Grantor approval if required by law or contract, 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, or other Grantor if required by law or contract, during its oversight review and any subsequent administrative hearings, 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, if applicable, 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 refusal, to ensure that no person with such a conflict is involved in the research misconduct proceeding;
- Keeping the Deciding Official (DO), University President, University Legal Counsel 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 seven (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. This shall apply to all grants received by the Institution;
- 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), if applicable, 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), if applicable;

- Determining whether circumstances clearly warrant a period longer than twenty (20) business 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 twenty (20) business day period in the record of the research misconduct proceeding;
- Assisting the inquiry committee (IQC) 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 IQC 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 five (5) business 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, if applicable and the institution's research misconduct policies and procedures;
- Providing to ORI, upon request or other Grantor if required by law or contract, 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 charges to be considered in the investigation;
- If the DO decides that an investigation is not warranted, securing and maintaining for seven (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 ten (10) business days after the determination by the DO that an investigation is warranted;

- On or before the date on which the investigation begins: (1) notifying ORI of the decision to begin the investigation or other Grantor if required by law or contract and providing ORI a copy of the inquiry report or other Grantor if required by law or contract; and (2) notifying 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 (IVC) and committee chair as soon after the initiation of the investigation as is practical;
- Preparing a charge for the IVC in accordance with the institution's policies and procedures;
- Convening the first meeting of the IVC 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, if applicable;
- Providing the IVC 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 sixty (60) business days of its initiation (including providing the draft report for comment and sending the final report with any comments to ORI or other Grantor if required by law or contract), submitting a request to ORI for an extension of the sixty (60) business day period that includes a statement of the reasons for the extension or other Grantor if required by law or contract. If the extension is granted, the RIO will file periodic progress reports with ORI or other Grantor if required by law or contract;
- Assisting the investigation committee in preparing a draft investigation report that meets the requirements of 42 CFR Part 93, if applicable, 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 ten (10) business 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 IVC 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, or other Grantor if required by law or contract, 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;
- 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.