Procedure No. - 01-

Responding to Allegations of Research Misconduct

Commonwealth University of Pennsylvania Responsible Office:

Research and Sponsored Programs

Approved: Date of Approval

To confidentially report an allegation of research misconduct, please contact CU's Research Integrity Officer (RIO) using the contact information found under Section 4 of this document.

1. Procedure Purpose

Commonwealth University of Pennsylvania prohibits research misconduct as defined in Policy XX-XXX and ensures that good-faith efforts to report suspected research misconduct will be supported and allegations of research misconduct will be promptly and thoroughly addressed. Procedure XX-XXX supports Policy XX-XXX by detailing the steps CU will follow when responding to allegations of research misconduct.

2. Procedure

- **2.1 Assessment**: The assessment determines whether an allegation warrants an inquiry and is intended to be a review of readily accessible information relevant to the allegation. Upon receiving an allegation of research misconduct, the RIO will promptly determine whether the allegation (a) falls within the definition of research misconduct, (b) is within the applicability criteria of 42 CFR Part 93 § 93.102, and (c) is credible and specific enough to identify and sequester potential evidence.
- **2.1.1**: If the RIO determines that the allegation <u>meets</u> these three criteria, they will promptly (a) document the assessment and (b) initiate an inquiry and sequester all research records and other evidence. The RIO must retain the assessment documentation securely for seven years after completion of the misconduct proceedings.
- **2.1.2**: If the RIO determines that the alleged misconduct <u>does not meet</u> the criteria to proceed to an inquiry, they will write sufficiently detailed documentation to permit a later review by ORI of why CU did not proceed to an inquiry and securely retain this documentation for seven years.
- **2.2 Inquiry**: An inquiry is warranted if the allegation (a) falls within the definition of research misconduct under 42 CFR Part 93, (b) is within the applicability criteria of § 93.102, and (c) is sufficiently credible and specific so that potential evidence of research misconduct may be identified. An inquiry's purpose is to conduct an initial review of the evidence to determine whether an allegation warrants an investigation. An inquiry does not require a full review of all related evidence. CU will complete the inquiry within 90 days of initiation. If circumstances warrant a longer period, CU will sufficiently document the reasons for exceeding the 90-day time limit in the inquiry report.
- **2.2.1** Sequestering Evidence and Notifying the Respondent: Before or at the time of notifying the respondent, CU will obtain the original (or substantially equivalent) copies of all research records and other evidence pertinent to the proceeding. CU will inventory these materials, sequester them in a secure manner, and retain them for seven years. CU's duty to obtain, inventory, and securely sequester evidence extends to additional items that become known or relevant to the inquiry or investigation.

Before or at the time of inquiry, CU will make a good-faith effort to notify the presumed respondent, in writing, that an allegation of research misconduct has been raised against them, that the relevant research records have been sequestered, and that an inquiry will be conducted to determine whether to proceed with an investigation. If additional allegations are raised, CU will notify the respondent in writing. When appropriate, CU will give the respondent copies of, or reasonable supervised access to, the sequestered materials.

If additional respondents are identified, CU will provide written notification to the new respondents. All additional respondents will be given the same rights and opportunities as the initial respondent. Only allegations specific to a particular respondent will be included in the notification to that respondent.

- **2.2.2 Convening the Committee and Ensuring Neutrality**: CU will ensure that all inquiry committee members understand their responsibilities, maintain the confidentiality of respondents, complainants, and witnesses, and conduct the research misconduct proceedings in compliance with the PHS regulation. In lieu of a committee, the RIO may conduct the inquiry, provided they utilize subject matter experts as needed to assist in the inquiry.
- **2.2.3 Determining Whether an Investigation Is Warranted**: The inquiry committee or RIO will conduct a preliminary review of the evidence. During the fact-finding process, the respondent and witnesses may be interviewed. The inquiry committee or RIO may find that an investigation is warranted if (a) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct under 42 CFR Part 93 and that it is within the applicability criteria in § 93.102 and (b) the inquiry's preliminary information-gathering and fact-finding indicates that the allegation may have substance.

The inquiry committee or RIO will not determine if research misconduct occurred, nor assess whether the alleged misconduct was intentional, knowing, or reckless. These determinations are not made until the case proceeds to an investigation.

- **2.2.4 Documenting the Inquiry**: At the inquiry's conclusion, regardless of whether an investigation is warranted, the inquiry committee or RIO will prepare a written inquiry report. A complete inquiry report will include:
 - a) The names, professional aliases, and positions of the respondent and complainant(s).
 - b) A description of the allegation(s) of research misconduct.
 - c) Details about any PHS funding, including grant numbers, grant applications, contracts, and publications listing PHS support.
 - d) The composition of the inquiry committee, if used, including name(s), position(s), and subject matter expertise.
 - e) An inventory of sequestered research records and other evidence, and a description of how sequestration was conducted.
 - f) Transcripts of interviews, if transcribed.
 - g) Inquiry timeline and procedural history.
 - h) Any scientific or forensic analyses that were conducted.

- i) The basis for recommending that the allegation(s) warrant an investigation.
- j) The basis on which any allegation(s) do not merit further investigation.
- k) Any comments on the inquiry report by the respondent or the complainant(s).
- I) Any institutional actions implemented, including internal communications or external communications with journals or funding agencies.
- m) Documentation of potential evidence of honest error or difference of opinion.
- **2.2.5 Completing the Inquiry**: CU will give the respondent a copy of the draft inquiry report for review and comment. CU may, but is not required to, provide relevant portions of the report to the complainant for comment. CU will notify the respondent of the inquiry's final outcome and provide the respondent with copies of the final inquiry report, the PHS regulation, and these policies and procedures.

CU may, but is not required to, notify the complainant whether the inquiry found that an investigation is warranted. If CU provides notice to one complainant in a case, it must provide notice, to the extent possible, to all complainants in the case.

- **2.2.6 If an Investigation is Not Warranted**: If the inquiry committee or RIO determines that an investigation is not warranted, CU will keep sufficiently detailed documentation to permit a later review by ORI of why the institution did not proceed to an investigation, securely store these records for at least seven years after the termination of the inquiry, and provide them to ORI upon request.
- **2.2.7 If an Investigation is Warranted**: If the inquiry committee or RIO determines that an investigation is warranted, CU must (a) provide written notice to the respondent of the decision to investigate of the alleged misconduct, including any allegations of research misconduct not addressed during the inquiry and (b) provide ORI with a copy of the inquiry report within 30 days of determining that an investigation is warranted.

On a case-by-case basis, CU may choose to notify the complainant that an investigation of the alleged misconduct will be conducted. However, CU is required to take the same notification action for all complainants in cases where there is more than one complainant.

- **2.3 Investigation**: An investigation formally develops a factual record, pursues leads, examines the record, and recommends findings to the IDO. The IDO will make the final decision, based on a preponderance of evidence, on each allegation and any institutional actions. CU will diligently pursue all significant issues and relevant leads, including any evidence of additional instances of possible research misconduct, and continue the investigation to its completion. Within 30 days after deciding that an investigation is warranted, CU will notify ORI of its decision to investigate and initiate the investigation.
- **2.3.1** Notifying the Respondent and Sequestering Evidence: CU will notify the respondent of the allegation(s) within 30 days of determining that an investigation is warranted and before the investigation begins. If any additional respondents are identified during the investigation, CU will notify them of the allegation(s) and provide them an opportunity to respond consistent with the PHS regulation. If additional respondents are identified during the investigation, CU may choose to either conduct a separate inquiry or add the new respondent(s) to the ongoing investigation. CU will obtain the original (or substantially equivalent) copies of all research records and other evidence, inventory these materials, securely sequester them, and retain them for seven years after its proceeding or any HHS proceeding, whichever is later.
- 2.3.2 Convening an Investigation Committee: After vetting investigation committee members for conflicts of

interest and appropriate scientific expertise, CU will convene the committee and ensure that the members understand their responsibility to conduct the research misconduct proceedings in compliance with the PHS regulation. The investigation committee will conduct interviews, pursue leads, and examine all relevant research records and other evidence to reach a decision on the merits of the allegation(s). CU will be diligent in ensuring that the investigation is thorough, sufficiently documented, impartial, and unbiased to the maximum extent possible. CU will notify the respondent in writing of any additional allegations raised against them during the investigation.

- **2.3.3 Conducting Interviews**: CU will interview each respondent, complainant, and any other person reasonably identified as having information relevant to the investigation, including witnesses identified by the respondent. CU will number all relevant exhibits and refer to any exhibits shown to the interviewee during the interview by that number. CU will record and transcribe interviews during the investigation and make the transcripts available to the interviewee for correction. CU will include the transcripts with any corrections and exhibits in the institutional record of the investigation. The respondent will not be present during the witnesses' interviews; however, CU will provide the respondent with a transcript of each interview, with appropriate redactions to maintain confidentiality.
- **2.3.4 Documenting the Investigation**: CU will complete all aspects of the investigation within 180 days, including (a) conducting the investigation, (b) preparing the draft investigation report for each respondent, and (c) providing the opportunity for respondents to comment. CU will document the IDO's final decision and transmit the institutional record (including the final investigation report and IDO's decision) to ORI. If the investigation takes more than 180 days to complete, CU will ask ORI, in writing, for an extension and document the reasons for exceeding the 180-day period in the investigation report.

The investigation report for each respondent will include:

- a) Description of the nature of the research misconduct allegation(s), including any additional allegation(s) addressed during the research misconduct proceeding.
- b) Description and documentation of any PHS support, including grant numbers, grant applications, contracts, and publications listing PHS support, as well as documentation of known applications or proposals for support that the respondent has pending with PHS and non-PHS federal agencies.
- c) Description of the specific research misconduct allegation(s) for consideration in the investigation of the respondent.
- d) Composition of the investigation committee, including name(s), position(s), and subject matter expertise.
- e) Inventory of sequestered research records and other evidence, except records that the institution did not consider or rely on, including manuscripts and funding proposals that were considered or relied on during the investigation, as well as a description of how any sequestration was conducted during the investigation.
- f) Transcripts of all interviews conducted.
- g) Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS funding applications, progress reports, presentations, posters, or other research records that contain the allegedly falsified, fabricated, or plagiarized material.
- h) Any scientific or forensic analyses that were conducted.

- i) A copy of these policies and procedures.
- j) Any comments made by the respondent and complainant on the draft investigation report and the investigation committee's consideration of those comments.
- k) A statement for each separate allegation of whether the investigation committee recommends a finding of research misconduct.
- **2.3.5 Finding of Research Misconduct Recommended**: If the investigation committee recommends a finding of research misconduct for an allegation, the investigation report will present a finding for each allegation. These findings will (a) identify the individual(s) who committed the research misconduct, (b) indicate whether the misconduct was falsification, fabrication, and/or plagiarism, (c) indicate whether the misconduct was committed intentionally, knowingly, or recklessly, (d) indicate that the allegation was proven by a preponderance of the evidence, (e) identify any significant departure from the accepted practices of the relevant research community, (f) summarize the facts and analysis that support the investigation committee's conclusion and consider the merits of any explanation given by the respondent, (g) identify any specific PHS support, and (h) state whether any publications need correction or retraction.
- **2.3.6 Finding of Research Misconduct Not Recommended**: If the investigation committee does not recommend a finding of research misconduct for an allegation, the investigation report will provide a detailed rationale for this conclusion. The investigation committee should also include a list of any current support or known applications for support that the respondent has pending with PHS and non-PHS federal agencies in the report.
- **2.3.7 Completing the Investigation**: CU will provide the respondent with a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the research records and other evidence that the investigation committee considered or relied upon. The respondent will submit any comments on the draft investigation report to the institution within 30 days of receiving the draft investigation report.

If CU chooses to share a copy of the draft investigation report or relevant portions of it with the complainant(s) for comment, the complainant's comments will be submitted within 30 days of the date on which they received the report, and CU will add any comments received to the investigation report.

- **2.3.8 IDO Review of the Investigation Report**: The IDO will review the investigation report and make a final written determination of whether CU found research misconduct and, if so, who committed the misconduct. The IDO will include a description of relevant institutional actions taken or to be taken in this written determination.
- **2.3.9 Creating and Transmitting the Institutional Record**: After the IDO has made a final determination of research misconduct findings, CU will add the IDO's written decision to the investigation report and organize the institutional record in a logical manner.

The institutional record consists of the records that were compiled or generated during the research misconduct proceeding, except for those records that the institution did not rely on. The institutional record should include documentation of the assessment, a single index listing all research records and evidence, the inquiry report and investigation report, and all records considered or relied on during the investigation. The institutional record also includes the IDO's final decision and any information the respondent provided to the institution. The institutional record must also include a general description of the records that were sequestered but not considered or relied on.

After the IDO has made a final written determination, CU must transmit the institutional record to ORI.

If the respondent files an appeal, the complete record of any appeal also becomes part of the institutional record. CU will wait until the appeal is concluded to transmit the institutional record to ORI.

2.4 Other Procedures and Special Circumstances

- **2.4.1 Multiple Respondents**: If the alleged research misconduct involves multiple respondents, CU may either conduct a separate inquiry for each new respondent or add them to ongoing proceedings. CU must give additional respondent(s) notice of and an opportunity to respond to the allegations.
- **2.4.2 Multiple Institutions**: If the alleged research misconduct involves multiple institutions, CU may work closely with the other affected institutions to determine whether a joint research misconduct proceeding will be conducted. If so, the cooperating institutions will choose one institution to serve as the lead institution. In a joint research misconduct proceeding, the lead institution will obtain research records and other evidence pertinent to the proceeding, including witness testimony, from the other institutions. By mutual agreement, the joint research misconduct proceeding may include committee members from all of the institutions involved. The determination of whether further inquiry and/or investigation is warranted, whether research misconduct occurred, and the institutional actions to be taken may be made by the institutions jointly or tasked to the lead institution.
- **2.4.3 Respondent Admissions**: CU will promptly notify ORI in advance if, at any point during the proceedings (including the assessment, inquiry, investigation, or appeal stage), it plans to close a research misconduct case because the respondent has either (a) admitted to committing research misconduct or (b) a settlement with the respondent has been reached. If the respondent admits to research misconduct, the institution will not close the case until it provides ORI with the respondent's signed, written admission. The admission must state the specific fabrication, falsification, or plagiarism that occurred, which research records were affected, and that it constituted a significant departure from accepted practices of the relevant research community. CU cannot close the case until it gives ORI a written statement confirming the respondent's culpability and explaining how the institution determined that the respondent's admission fully addresses the scope of the misconduct.
- **2.4.4 Other Special Circumstances**: At any time during the misconduct proceedings, CU will immediately notify ORI if any of the following circumstances arise:
 - a) The health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
 - b) HHS resources or interests are threatened.
 - c) Research activities should be suspended.
 - d) There is reasonable indication of possible violations of civil or criminal law.
 - e) Federal action is required to protect the interests of those involved in the research misconduct proceeding.
 - f) HHS may need to take appropriate steps to safeguard evidence and protect the rights of those involved.
- 2.5 Records Retention: CU will maintain the institutional record and all sequestered evidence, including

physical objects (regardless of whether the evidence is part of the institutional record), in a secure manner for seven years after the completion of the proceeding or the completion of any HHS proceeding, whichever is later, unless custody has been transferred to HHS.

3. Related Information

3.1. Related Policies: Policy XX-XXX

3.2. Other Related Information: PHS Policies on Research Misconduct (42 CFR Part 93, "the PHS regulation")

4. Responsible Office and Contact

4.1. **Responsible Office:** Research and Sponsored Programs

4.2. **Procedure Approved by:**

4.3. **Contact Information:** Dr. Heather Feldhaus, Academic Integrity Officer

4.4. **Email:** hfeldhau@commonwealthu.edu

4.5. **Telephone:** 570-389-4214

5. Procedure History

5.1. **Procedure History:** Issued as a new procedure from information derived from former Bloomsburg University PRP 6820--Research Misconduct (May 2008)