Harvard Pilgrim Health Care, Inc.
Harvard Pilgrim Health Care Institute

Office of Sponsored Programs

Policy and Procedure

TITLE: RESEARCH MISCONDUCT

PERSONS AFFECTED:
This policy and procedure (P&P) applies to all Harvard Pilgrim Health Care, Inc. ("HPHC") and Harvard Pilgrim Health Care Institute, LLC ("HPHCI"), (collectively, "HPHC/I") personnel, including, but not limited to any person paid by, under the control of, or affiliated with HPHC/I such as investigators, faculty, project managers, data analysts, staff members, who are engaged in or support research activities, research training, or research-related grants or cooperative agreements with or supported by the Public Health Service (PHS) (collectively herein "research activities") at HPHC/I.

PURPOSE
To describe the process to be followed at HPHC/I to report, respond to, and investigate any allegations of research misconduct. Any variation from this P&P must ensure fair treatment to the subject of the Inquiry or Investigation and should be approved in advance by the HPHCI Research Integrity & Compliance Officer who is also referred to in this P&P as the Research Integrity Officer.

POLICY
The integrity of the research and teaching programs of HPHC/I requires that all HPHC/I personnel who are engaged in or support research activities follow the regulations set forth in 42 CFR 50 and 93 regarding responding to allegations of research misconduct and:

- give careful attention to any allegations of misconduct in research and carefully and equitably resolve any such allegations while providing maximum support to good faith whistleblowers; and

- be conscious of the following considerations:
  - the responsibility of HPHC/I to HPHC members, HPHC/I employees, affiliated institutions and to the community;
  - HPHC/I responsibilities to the person making the allegations in good faith (Complainant) and the person who may be charged with research misconduct (Respondent);
  - obligations of HPHC/I to research sponsors and to the Office of Research Integrity (ORI); and

- the importance of resolving allegations or suspicions of misconduct fairly, in a timely fashion, and with respect for all parties involved.

DEFINITIONS: Terms not listed below have the same meaning as given them in the *Public Health Service Policies on Research Misconduct; Final Rule* at 42 CFR 50 and 93.

- *Allegation* – a disclosure of possible research misconduct through any means of communication including written or oral statement to a HPHC/I leader or U.S. Department of Health and Human Services official.

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

- *Good faith* –

  - as applied to a Complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the Complainant's or witness's position could have based on the information known to the Complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony.
  - as applied to a Research Integrity Committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping HPHC/I meet it responsibilities under the P&P. A Research Integrity Committee member does not act in good faith if his/her acts or omissions on the Research Integrity Committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

- *Inquiry* – preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of 42 CFR 93.307 – 93.309.

- *Investigation* – the formal development of a factual record and the examination of the 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.

- *Notice* – a written communication served in person, sent by mail or its equivalent to the last known street address, facsimile number or email address of the addressee.

- *Research misconduct* – fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
  - *Fabrication* – making up data or results and recording or reporting them.
  - *Falsification* – manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

- *Plagiarism* – the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- *Research misconduct does not include honest error or differences of opinion*.

PROCEDURE:

I. Rights and Responsibilities

A. Research Integrity Officer

The HPHCI Research Integrity & Compliance Officer serves as the Research Integrity Officer (RIO) with primary responsibility for implementing and managing the procedures outlined in this P&P, as well as reporting to and communicating with the Office of Research Integrity (ORI) regarding developments during the course of the Inquiry and Investigation. A detailed description of the responsibilities of the RIO is set forth in Appendix A and described throughout this P&P.

B. Complainant

The Complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the Inquiry and Investigation. As a matter of good practice, the Complainant should be interviewed at the Inquiry stage and given the transcript or recording of the interview for correction. The Complainant must be interviewed during an Investigation and be given the transcript or recording of the interview for correction.

C. Respondent

The Respondent is responsible for maintaining confidentiality and cooperating with the conduct of an Inquiry and Investigation. The Respondent is entitled to:

1. a good faith effort from the RIO to notify the Respondent in writing at the time of or before beginning an Inquiry;
2. an opportunity to comment on the Inquiry Report and have his/her comments attached to the report;
3. ae 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 93 and HPHC/I's P&Ps on research misconduct;
4. be notified in writing of the allegations to be investigated within a reasonable time after the determination that an Investigation is warranted, but before the Investigation begins (within 30 days after HPHC/I decides to begin an Investigation), and be notified in writing of any new allegations, not addressed in the Inquiry or in the initial notice of Investigation, within a reasonable time after the determination to pursue those allegations;
5. be interviewed during the Investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the Investigation;

6. have interviewed during the Investigation any witness who has been reasonably identified by the Respondent as having information on relevant aspects of the Investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of Investigation; and
receive a copy of the draft Investigation Report and, concurrently, a copy of or supervised access to the evidence on which the Report is based and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by HPHC/I 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/or other HPHC/I leaders, the Deciding Official may terminate HPHC/I's review of an allegation that has been admitted, if HPHC/I's acceptance of the admission and any proposed settlement is approved by ORI.

D. Deciding Official

The HPHC Chief Medical Officer, or the individual he/she designates in writing, will act as the Deciding Official (DO). The DO will receive the Inquiry Report and after consulting with the RIO and/or other HPHC/I leaders, decide whether an Investigation is warranted under the criteria in 42 CFR 93.307(d). Any finding that an Investigation is warranted must be made in writing by the DO and must be provided to ORI, together with a copy of the Inquiry Report meeting the requirements of 42 CFR 93.309, within 30 days of the Finding. If it is found that an Investigation is not warranted, the DO and the RIO will ensure that detailed documentation of the Inquiry is retained for at least 7 years after termination of the Inquiry, so that ORI may assess the reasons why HPHC/I decided not to conduct an Investigation.

The DO will receive the Investigation Report and, after consulting with the Research Integrity Committee and the RIO and/or other HPHC/I leaders, decide the extent to which HPHC/I accepts the findings of the Investigation and, if research misconduct is found, decide what, if any, HPHC/I administrative actions are appropriate. The DO shall ensure that the final Investigation Report, the Findings of the DO and a description of any pending or completed administrative actions are provided to ORI, as required by 42 CFR 93.315.

E. The Research Integrity Committee

The Research Integrity Committee (RIC) is responsible for reviewing allegations that the HPHC RIO determines to be appropriate for its review. The RIC will be comprised of the HPHC Vice President of Compliance (or designee), a member of the HPHC Legal Department, and the Chair of the HPHC Ethics Committee (or designee). The RIO shall be responsible for marshalling HPHCI resources as necessary, including logistical support, outside expert advice, and clerical support (including scheduling interviews with witnesses and recording and/or transcribing those interviews). The RIC process will begin as outlined in III. E.

II. General Policies and Principles

A. Responsibility to Report Misconduct

All HPHC/I personnel will report observed, suspected, or apparent research misconduct to the RIO at Research_Admin@HPHC.org. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he/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 leaders with responsibility for resolving the concern.

B. Cooperation with Research Misconduct Proceedings

HPHC/I personnel will cooperate with the RIO and other HPHC/I leaders in the review of allegations and the conduct of Inquiries and Investigations. HPHC/I personnel, including Respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other HPHC/I leaders.

C. Confidentiality

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

D. Protecting Complainants, Witnesses, and Committee Members

HPHC/I personnel may not retaliate in any way against Complainants, witnesses, or RIC members. HPHC/I personnel should immediately report any alleged or apparent retaliation against Complainants, witnesses or RIC members to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

E. Protecting the Respondent

As requested and as appropriate, the RIO and other HPHC/I leaders shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made. During the research misconduct proceeding, the RIO is responsible for ensuring that Respondents receive all the notices and opportunities provided for in 42 CFR 93 and the P&Ps of HPHC/I. Respondents

may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the matter) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the matter.

F. Interim Administrative Actions and 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 funds and equipment, or the integrity of the PHS supported research process. In the event of such a threat, the RIO will, in consultation with the HPHC RIC and other HPHC/I leaders and ORI, take appropriate interim action to protect against any such threat. Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results, or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:

1. health or safety of the public is at risk, including an immediate need to protect human subjects;

2. PHS resources or interests are threatened;

3. research activities should be suspended;

4. there is a reasonable indication of possible violations of civil or criminal law;

5. federal action is required to protect the interests of those involved in the research misconduct proceeding;

6. the research misconduct proceeding may be made public prematurely and PHS action may be necessary to safeguard evidence and protect the rights of those involved; or

7. the research community or public should be informed.

III. Conducting the Assessment and Inquiry

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether it is within the jurisdictional criteria of 42 CFR 93.102(b), and whether the allegation falls within the definition of research misconduct in 42 CFR 93.103. An Inquiry must be conducted if these criteria are met.

The assessment period should be brief, preferably concluded within a week. In conducting the assessment, the RIO need not interview the Complainant, Respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The RIO shall, on or before the date on which the Respondent is notified of the allegation, obtain custody of, inventory, and sequester all research

records and evidence needed to conduct the research misconduct proceeding, as provided in paragraph C. of this section.

B. Initiation and Purpose of the Inquiry

If the RIO determines that the criteria for an Inquiry are met, he/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.

C. Notice to Respondent and Sequestration of Research Records

At the time of or before beginning an Inquiry, the RIO must make a good faith effort to notify the Respondent in writing, if the Respondent is known. If the Inquiry subsequently identifies additional Respondents, they must be notified in writing. Respondent will be notified of the RIC membership and may submit an objection based upon personal, professional, or financial conflicts of interest within 10 calendar days. 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 ORI for advice and assistance in this regard.

D. Charge to the Committee and First Meeting

The RIO will prepare a charge for the RIC that:

1. sets forth the time for completion of the Inquiry;
2. describes the allegations and any related issues identified during the allegation assessment;
3. states that the purpose of the Inquiry is to conduct an initial review of the evidence, including the testimony of the Respondent, Complainant and key witnesses, to determine whether an Investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
4. states that an Investigation is warranted if the RIC determines: there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR 93.102(b) and the allegation may have substance, based on the RIC's review during the Inquiry; and
5. informs the RIC that they are responsible for preparing or directing the preparation of a written Inquiry Report that meets the requirements of this P&P and 42 CFR 93.309(a).

At the RIC's first meeting, the RIO will review the charge with the RIC, discuss the allegations, any related issues, and the appropriate procedures for conducting the Inquiry, assist the RIC with

organizing plans for the Inquiry, and answer any questions asked by the RIC. The RIO will be present or available throughout the Inquiry to advise the RIC as needed.

E. Inquiry Process

The RIC will normally interview the Complainant, the Respondent, and key witnesses as well as examining relevant Research Records and materials. Then the RIC will evaluate the evidence, including the testimony obtained during the Inquiry. After consultation with the RIO, the RIC will decide whether an Investigation is warranted based on the criteria in this P&P and 42 CFR 93.307(d). The scope of the Inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the Respondent, misconduct may be determined at the Inquiry stage if all relevant issues are resolved. In that matter, the RIO shall promptly consult with ORI to determine the next steps that should be taken. See Section VII.

F. Time for Completion

The Inquiry, including preparation of the final Inquiry Report and the decision of the DO on whether an Investigation is warranted, must be completed within 60 calendar 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 60-day period.

IV. The Inquiry Report

A. Elements of the Inquiry Report

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

1. the name and position of the Respondent;
2. the names and titles of the RIC members;
3. a description of the allegation of misconduct;
4. PHS and other sponsor support (i.e., grant numbers, contracts, grant applications, etc.);
5. a summary of the Inquiry Process;
6. a list of research records reviewed, and summaries of interviews conducted;
7. the basis for recommending that alleged actions warrant an Investigation;
8. any recommendations on what other actions should be pursued if an Investigation is not warranted; and
9. any comments on the report by the Complainant or Respondent.

HPHC/I counsel should review the Inquiry Report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the RIC. The Inquiry Report should also include the names and titles of the RIC and experts who conducted the Inquiry.

B. Notification to the Respondent and Opportunity to Comment

The two possible outcomes of the Inquiry phase are: (1) insufficient evidence that the allegation is considered research misconduct; and (2) evidence indicates that an Investigation into research misconduct is warranted. The RIO shall notify the Respondent whether the Inquiry found an Investigation to be warranted, include a copy of the draft Inquiry Report for comment within 10 days, and include a copy of or refer to 42 CFR 93 and this P&P on research misconduct. Any comments that are submitted by the Respondent or Complainant will be attached to the final Inquiry Report. Based on the comments, the RIC may revise the draft report as appropriate and prepare it in final form. The RIC will deliver the final report to the RIO to transmit to the Deciding Official.

C. HPHC/I Decision and Notification

1. Decision by Deciding Official

The RIC 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.

2. Notification to ORI

Within 30 calendar days of the DO's decision that an Investigation is warranted, the RIO will provide ORI with the DO's written decision and a copy of the Inquiry Report. The RIO will also notify those HPHC/I leaders who need to know of the DO's decision. The RIO must provide the following information to ORI upon request: (1) the HPHC/I P&Ps under which the Inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the Investigation.

3. Documentation of Decision Not to Investigate

If the DO decides that an Investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the Inquiry sufficiently detailed documentation of the Inquiry to permit a later assessment by ORI of the reasons why an Investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request.

V. Conducting the Investigation

A. Initiation and Purpose

The Investigation must begin within 30 calendar days after the determination by the DO that an Investigation is warranted.[24] 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. Under 42 CFR 93.313 the findings of the Investigation must be set forth in an Investigation Report.

B. Notifying Respondent and Sequestration of Research Records

On or before the date on which the Investigation begins, the RIO must 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.

The RIO will, prior to notifying Respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the Inquiry. The need for additional sequestration of records for the Investigation may occur for any number of reasons, including HPHC/I'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.

If PHS funding is involved, the RIO must notify the ORI Director of the decision to begin the Investigation and provide ORI a copy of the Inquiry Report.

C. Appointment of the Investigation Committee

The RIC will serve as the Investigation Committee, appointing additional members as needed.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The RIO will define the subject matter of the Investigation in a written charge to the RIC that:

a. Describes the allegations and related issues identified during the Inquiry;
b. Identifies the Respondent;
c. Informs the RIC that it must conduct the Investigation as prescribed in paragraph E of this section;
d. Defines research misconduct;
e. Informs the RIC 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;
f. Informs the RIC that in order to determine that the Respondent committed research misconduct, it must find that a preponderance of evidence establishes that: (1) research misconduct, as defined in this policy, occurred (Respondent has the

burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the Respondent committed the research misconduct intentionally, knowingly, or recklessly; and

g. Informs the RIC that it must prepare or direct the preparation of a written Investigation Report that meets the requirements of this P&P and 42 CFR 93.313.

2. First Meeting

The RIO will convene the first meeting of the Investigation RIC to review the charge, the Inquiry Report, and the prescribed procedures and standards for the conduct of the Investigation, including the necessity for confidentiality and for developing a specific Investigation plan. The Investigation RIC will be provided with a copy of this statement of policy and procedures and 42 CFR 93. The RIO will be present or available throughout the Investigation to advise the RIC as needed.

E. Investigation Process

The RIC and the RIO must:

1. Use diligent efforts to ensure that the Investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;
2. Take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical;
3. Interview each Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation, including witnesses identified by the Respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the Investigation; and
4. 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 120 days of beginning it, including conducting the Investigation, preparing the report of findings, and providing the draft report for comment. In matters where PHS funding is involved a final report will be submitted to ORI. If the Investigation will not be completed within this 120-day period, the RIO will notify the DO setting forth the reasons for the delay. In the matter involving PHS funding, the RIO will submit a request for an extension to ORI. The RIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.

VI. The Investigation Report

A. Elements of the Investigation Report

The RIC and the RIO are responsible for preparing a written draft report of the Investigation with the following content:

1. Description of the allegations.
2. Description of PHS and other funder support (i.e., grant numbers, contracts, grant applications, etc.).
3. The HPHC/I P&Ps under which the Investigation was conducted.
4. Identification and summary of the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
5. A statement of findings for each allegation of research misconduct identified during the Investigation. Each statement of findings must identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly.
6. Summary of 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/she did not engage in research misconduct because of honest error or a difference of opinion.
7. Identify any specific current or known applications or proposals that the Respondent has pending with any non-federal agencies.
8. Identify whether any publications need correction or retraction.
9. Identify the person(s) responsible for the misconduct.

B. Comments on the Draft Report and Access to Evidence

1. Respondent

The RIO must give the Respondent a copy of the draft Investigation Report for comment and, concurrently, a copy of or supervised access to the evidence on which the report is based. The Respondent will be allowed 30 days from the date he/she received the draft report to submit comments to the RIO. The Respondent's comments must be included and considered in the final report.

2. Confidentiality

In distributing the draft report, or portions thereof, to the Respondent, the RIO will inform the Respondent 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 Respondent sign a confidentiality agreement.

C. Decision by Deciding Official

The RIO will assist the RIC 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: (1) whether HPHC/I accepts the Investigation Report, its findings, and the recommended HPHC/I actions; and (2) the appropriate HPHC/I

actions in response to the accepted findings of research misconduct. If this determination varies from the findings of the RIC, 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 RIC. Alternatively, the DO may return the report to the RIC with a request for further fact-finding or analysis.

When a final decision on the matter has been reached, the RIO will notify both the Respondent and the Complainant in writing. The RIO will inform ORI as applicable and 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 matter. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Notice to ORI of HPHC/I Findings and Actions

Unless an extension has been granted, the RIO must, within the 120-day period for completing the Investigation, submit the following to ORI: (1) a copy of the final Investigation Report with all attachments; (2) a statement of whether HPHC/I accepts the findings of the Investigation Report; (3) a statement of whether HPHC/I found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the Respondent.

E. Maintaining Records for Review by ORI

The RIO must maintain and provide to ORI upon request "records of research misconduct proceedings" as that term is defined by 42 CFR 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation. 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 HPHC/I's handling of such an allegation.

VII. Completion of Cases and Reporting Premature Closures to ORI

Generally, all Inquiries and Investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify ORI in advance if there are plans to close a matter 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 matter at the Inquiry stage on the basis that an Investigation is not warranted; or (2) a finding of no misconduct at the Investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR 93.315.

VIII. HPHC/I Administrative Actions

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

A. withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
B. removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
C. restitution of funds to the grantor agency as appropriate; and
D. other action appropriate to the research misconduct.

IX. Other Considerations

A. Termination or Resignation Prior to Completion

The termination of the Respondent's HPHC/I 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 HPHC/I's responsibilities under 42 CFR 93. If the Respondent, without admitting to the misconduct, elects to resign his/her position after HPHC/I 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 the RIC will use their best efforts to reach a conclusion concerning the allegations, noting in the report the Respondent's failure to cooperate and its effect on the evidence.

B. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI concurrence where required by 42 CFR 93, HPHC/I must, at the request of the Respondent, undertake all reasonable and practical efforts to restore the Respondent's reputation. Depending on the particular circumstances and the views of the Respondent, HPHC/I should consider notifying those individuals aware of or involved in the Investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the Respondent's personnel file. Any HPHC/I action to restore the Respondent's reputation should first be approved by the DO and RIC.

C. Protection of the Complainant, Witnesses and RIC

During the research misconduct proceeding and upon its completion, regardless of whether HPHC/I or ORI determines that research misconduct occurred, HPHC/I must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any Complainant who made allegations of research misconduct in good faith and of any witnesses and RIC members who cooperate in good faith with the research misconduct proceeding. The DO will determine, after consulting with the RIO,

and with the Complainant, witnesses, or RIC, 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.

D. 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 RIC member acted in good faith. If the DO determines that there was an absence of good faith, he/she will determine whether any administrative action should be taken against the person who failed to act in good faith.

APPENDIX A: RESEARCH INTEGRITY OFFICER RESPONSIBILITIES

I. General

The Research Integrity Officer (RIO) has lead responsibility for ensuring that HPHC/I:

- 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 P&Ps for responding to allegations of research misconduct and reporting information about that response to ORI, as required by 42 CFR 93.
- Complies with its written P&Ps and the requirements of 42 CFR 93.
- Informs its HPHC/I personnel who are subject to 42 CFR 93 about its research misconduct P&Ps and its commitment to compliance with those P&Ps.
- Takes appropriate interim action during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the PHS supported research process.

II. Notice and Reporting to ORI and Cooperation with ORI

The RIO has lead responsibility for ensuring that HPHC/I:

- Files an annual report with ORI containing the information prescribed by ORI.
- Sends to ORI with the annual report such other aggregated information as ORI may prescribe on HPHC/I's research misconduct proceedings and HPHC/I's compliance with 42 CFR 93.
- Notifies ORI immediately if, at any time during the research misconduct proceeding, it has reason to believe that health or safety of the public is at risk, HHS resources or interests are threatened, research activities should be suspended, there is reasonable indication of possible violations of civil or criminal law, federal action is required to protect the interests of those involved in the research misconduct proceeding, HPHC/I believes that the research misconduct proceeding may be made public prematurely, or the research community or the public should be informed.
- Provides ORI with the written finding by the responsible HPHC/I leader that an Investigation is warranted and a copy of the Inquiry Report, within 30 days of the date on which the finding is made.
- Notifies ORI of the decision to begin an Investigation on or before the date the Investigation begins.
- In matters involving PHS funding, provide ORI with the Investigation Report, a statement of whether HPHC/I accepts the Investigation's findings, a statement of whether HPHC/I found research misconduct and, if so, who committed it, and a description of any pending or completed administrative actions against the Respondent within 120 days of beginning an Investigation, or such additional days as may be granted by ORI.

• Seeks advance ORI approval if HPHC/I plans to close a matter 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 matter at the Inquiry stage on the basis that an Investigation is not warranted or a finding of no misconduct at the Investigation stage.

• Cooperates fully with ORI during its oversight review and any subsequent administrative hearings or appeals, including providing all research records and evidence under HPHC/I'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 HPHC/I personnel with research misconduct proceedings, including, but not limited to their providing information, research records and evidence.

• Providing confidentiality to those involved in the research misconduct proceeding as required by 42 CFR 93.108, other applicable law, and HPHC/I policy.

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

• Keeping the Deciding Official (DO) and others who need to know apprised of the progress of the review of the allegation of research misconduct.

• In cooperation with other HPHC/I leaders, taking all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and RIC members and to counter potential or actual retaliation against them by respondents or other HPHC/I personnel.

• 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 RIC member determined by the DO not to have acted in good faith.

• Maintaining records of the research misconduct proceeding, as defined in 42 CFR 93.317, in a secure manner for 7 years after completion of the proceeding, or the completion of any ORI proceeding involving the allegation of research misconduct, whichever is later, unless

custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained.

- Ensuring that administrative actions taken by HPHC/I 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:

1. Consulting confidentially with persons uncertain about whether to submit an allegation of research misconduct.
2. Receiving allegations of research misconduct.
3. Assessing each allegation of research misconduct to determine if an Inquiry is warranted because the allegation falls within the definition of research misconduct, is within the jurisdictional criteria of 42 CFR 93.102(b) and is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

C. Inquiry

The RIO is responsible for:

1. Initiating the Inquiry process if it is determined that an Inquiry is warranted.
2. 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.
3. 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.

- Preparing an Inquiry charge for the RIC in accordance with HPHC/I's P&Ps.
- Convening the first Inquiry meeting of the RIC and at that meeting briefing the RIC on the allegations, the charge to the RIC, and the appropriate procedures for conducting the Inquiry, including the need for confidentiality and for developing a plan for the Inquiry, and assisting the RIC with organizational and other issues that may arise.
- Being available or present throughout the Inquiry to advise the RIC as needed and consulting with the RIC prior to its decision on whether to recommend that an Investigation is warranted on the basis of the criteria in HPHC/I's P&Ps and 42 CFR 93.307(d).
- Determining whether circumstances clearly warrant a period longer than 60 days to complete the Inquiry (including preparation of the final Inquiry Report and the decision of the DO on whether an Investigation is warranted) and documenting the reasons for exceeding the 60-day period in the record of the research misconduct proceeding.

- Assisting the Inquiry RIC in preparing a draft Inquiry Report, sending the Respondent and the Complainant a copy of the draft report for comment 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, and ensuring that the comments are attached to the final Inquiry Report.
- Receiving the final Inquiry Report from the Inquiry RIC and forwarding it, together with any comments the RIO may wish to make, to the DO who will determine in writing whether an Investigation is warranted.
- Within 30 days of a DO decision that an Investigation is warranted, providing ORI with the written finding and a copy of the Inquiry Report and notifying those HPHC/I leaders who need to know of the decision.
- Notifying the Respondent whether the Inquiry found an Investigation to be warranted and including in the notice copies of or a reference to 42 CFR 93 and HPHC/I's research misconduct P&Ps.
- Providing to ORI, upon request, the HPHC/I P&Ps under which the Inquiry was conducted, the research records and evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents, and the allegations to be considered in the Investigation.
- If the DO decides that an Investigation is not warranted, securing and maintaining for 7 years after the termination of the Inquiry sufficiently detailed documentation of the Inquiry to permit a later assessment by ORI of the reasons why an Investigation was not conducted.

D. Investigation

The RIO is responsible for:

1. Initiating the Investigation within 30 calendar days after the determination by the DO that an Investigation is warranted.
2. On or before the date on which the Investigation begins: (a) notifying ORI of the decision to begin the Investigation and providing ORI a copy of the Inquiry Report; and (b) notifying the Respondent in writing of the allegations to be investigated.
3. 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.
4. Preparing a charge for the Investigation RIC in accordance with HPHC/I's P&Ps.
5. Convening the first meeting of the Investigation RIC and at that meeting: (a) briefing the RIC 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 (b) providing RIC members a copy of HPHC/I's P&Ps and 42 CFR 93.
6. Being available or present throughout the Investigation to advise the RIC as needed.
7. On behalf of HPHC/I, the RIO is responsible for each of the following steps and for ensuring that the Investigation RIC: (a) 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; (b) takes reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical; (c) 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 (d) 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.

8. In matters involving PHS funding, notify ORI upon determining that the Investigation cannot be completed within 120 days of its initiation (including providing the draft report for comment and sending the final report with any comments to ORI). Submit a request to ORI for an extension of the 120-day period that includes a statement of the reasons for the extension. If the extension is granted, the RIO will file periodic progress reports with ORI.
9. Assisting the Investigation RIC in preparing a draft Investigation Report that meets the requirements of 42 CFR 93 and HPHC/I's P&Ps, sending the Respondent (and Complainant at HPHC/I's option) a copy of the draft report for his/her comment within 30 days of receipt, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the Respondent (and Complainant at HPHC/I's option) and ensuring that the comments are included and considered in the final Investigation Report.
10. Transmitting the draft Investigation Report to (HPHC/I or external) counsel for a review of its legal sufficiency.
11. Assisting the Investigation RIC in finalizing the draft Investigation Report and receiving the final report from the RIC.
12. Transmitting the final Investigation Report to the DO and: (a) if the DO determines that further fact-finding or analysis is needed, receiving the report back from the DO for that purpose; (b) if the DO determines whether or not to accept the report, its findings and the recommended HPHC/I actions, transmitting to ORI within the time period for completing the Investigation, a copy of the final Investigation Report with all attachments, a statement of whether HPHC/I accepts the findings of the report, a statement of whether HPHC/I found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the Respondent.
13. When a final decision on the matter is reached, the RIO will 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 matter.
14. Maintaining and providing to ORI upon request all relevant research records and records of HPHC/I's research misconduct proceeding, including the results of all interviews and the transcripts or recordings of those interviews.

REVISION HISTORY:

Department: OSP – Research Integrity & Compliance	**Title**: Research Misconduct Allegations
Effective Date: 03/21/23	**Owner:** Research Integrity & Compliance Officer
Replaces P/P Dated: 01/30/08, 3/1/19	
Related Documents:	
References: 42 CFR 50 & 93	