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

Office of Sponsored Programs and Office of Research Integrity & Compliance

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 in addressing 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 93 regarding addressing 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 against whom an allegation of research misconduct is made (respondent);
  - obligations of HPHC/I to research sponsors and to the federal 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.

- This policy and procedure applies only to research misconduct occurring within six years of the date the U.S. Department of Health and Human Services (HHS) or HPHCI receives an allegation of research misconduct, subject to the following exceptions:
    - The six-year time limitation does not apply if the respondent continues or renews any incident of alleged research misconduct that occurred before the six-year period through the use of, republication of, or citation to the portion(s) of the research record alleged to have been fabricated, falsified, or plagiarized, for the potential benefit of the respondent ("subsequent use exception"). For alleged research misconduct that appears subject to this subsequent use exception, but HPHCI determines is not subject to the exception, the institution will document its determination that the subsequent use exception does not apply and will retain this documentation for the later of seven years after completion of the institutional proceeding or the completion of any HHS proceeding.
    - The six-year time limitation also does not apply if ORI or HPHCI, following consultation with ORI, determines that the alleged research misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

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 93.

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

- *Allegation* – a disclosure of possible research misconduct through any means of communication and brought directly to the attention of an HPHC/I or HHS official.

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

- *Complainant* – an individual who in good faith makes an allegation of research misconduct.

- *Evidence* –anything offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact. Evidence includes documents, whether in hard copy or electronic form, information, tangible items, and testimony.

- *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.

- *Good faith* –

    - (a) as applied to a complainant or witness, means having a reasonable belief in the truth of one's allegation or testimony 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 knowledge of or reckless disregard for information that would negate the allegation or testimony.
    - (b) as applied to an institutional or Research Integrity Committee member means cooperating with the research misconduct proceeding by impartially carrying out the duties assigned for the purpose of helping HPHC/I meet it responsibilities under federal law. An institutional or Research Integrity Committee member does not act in good faith if their acts or omissions during the research misconduct proceedings 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 § 93.307through § 93.309.

- *Institutional Certifying Official* - HPHC/I official responsible for assuring on behalf of HPHC/I that HPHC/I has written policies and procedures for addressing allegations of research misconduct, in compliance with federal law; and complies with its own policies and procedures and the requirements of federal law. The Institutional Certifying Official is responsible for certifying the content of HPHC/I's annual report, which contains information specified by ORI on HPHC/I's compliance with federal law, and ensuring the report is submitted to ORI, as required.

- *Institutional Deciding Official* - HPHC/I official who makes final determinations on allegations of research misconduct and any institutional actions. The same individual cannot serve as the Institutional Deciding Official and the Research Integrity Officer.

- *Institutional record* - The institutional record comprises:

  (a) The records that HPHC/I compiled or generated during the research misconduct proceeding, except records HPHC/I did not consider or rely on. These records include, but are not limited to:
  (1) Documentation of the assessment as required by 42 CFR § 93.306(c).
  (2) If an inquiry is conducted, the inquiry report and all records (other than drafts of the report) considered or relied on during the inquiry, including, but not limited to, research records and the transcripts of any transcribed interviews conducted during the inquiry,

information the respondent provided to HPHC/I, and the documentation of any decision not to investigate as required by 42 CFR § 93.309(c).
(3) If an investigation is conducted, the investigation report and all records (other than drafts of the report) considered or relied on during the investigation, including, but not limited to, research records, the transcripts of each interview conducted pursuant to 42 CFR § 93.310(g), and information the respondent provided to HPHC/I.
(4) Decision(s) by the Institutional Deciding Official, such as the written decision from the Institutional Deciding Official under 42 CFR § 93.314.
(5) The complete record of any institutional appeal consistent with 42 CFR § 93.315.
(b) A single index listing all the research records and evidence that HPHC/I compiled during the research misconduct proceeding, except records HPHC/I did not consider or rely on.
(c) A general description of the records that were sequestered but not considered or relied on.

- *Intentionally* - to act with the aim of carrying out the act.

- *Investigation* – the formal development of a factual record and the examination of that record that meets the criteria and follows the procedures of 42 CFR §§ 93.310 through 93.317.

- *Knowingly* – to act with awareness of the act.

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

- *Plagiarism* - the appropriation of another person's ideas, processes, results, or words, without giving appropriate credit.

  (a) Plagiarism includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contributions of the author. It does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology.
  (b) Plagiarism does not include self-plagiarism or authorship or credit disputes, including disputes among former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct.

- *Preponderance of the evidence* - proof by evidence that, compared with evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not.

- *Recklessly* – to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism.

- *Research Integrity Officer or RIO* – HPHC/I official responsible for administering HPHC/I's written policies and procedures for addressing allegations of research misconducts in compliance with federal law.

- *Research misconduct* – fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

- *Research record* – the record of data or results that embody the facts resulting from scientific inquiry. Data or results may be in physical or electronic form. Examples of items, materials, or information that may be considered part of the research record include, but are not limited to, research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meeting reports, and journal articles.

- *Respondent* – the individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

- *Retaliation* – an adverse action taken against a complainant, witness, or Research Integrity Committee member by HPHC/I or one of its members in response to: (a) A good faith allegation of research misconduct; or (b) Good faith cooperation with a research misconduct proceeding.

I. Roles, Rights, and Responsibilities

A. Research Integrity Officer

The HPHCI Director, 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. Detailed responsibilities of the RIO are described throughout this P&P.

B. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the conduct of an 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 review and, if needed, correction. The complainant must be interviewed during an Investigation and be given the transcript or recording of the interview for review and, if needed, 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 their comments attached to the report;
3. 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 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 (within 30 days after HPHC/I decides to begin an Investigation), but before the Investigation begins, 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 review and, if needed, 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 review and, if needed, correction, and have the corrected recording or transcript included in the record of Investigation; and
7. 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 they 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 Point32Health Chief Medical Officer, or the individual they designate 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(f). 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 § 93.316.

E. The Research Integrity Committee

The Research Integrity Committee (RIC) is responsible for reviewing allegations that the RIO determines to be appropriate for its review. The RIC will be comprised of the Point32Health Chief Compliance Officer (or designee), a member of the Point32Health Legal Department, and the Point32Health Privacy Officer (or designee). The RIO shall be responsible for marshalling HPHC/I 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 Section III. E below.

F. Certifying Official

The Point32Health Chief Compliance Officer (or designee) is responsible for assuring that HPHC/I has written policies and procedures for addressing allegations of research misconduct, and HPHC/I complies with its policies and procedures and the requirements of 42 CFR 93. The Point32Health Chief Compliance Officer (or designee) is also responsible for certifying the content of HPHC/I's annual report, which contains information specified by ORI on HPHC/I's compliance and ensuring the report is submitted to ORI as required.

II. General Policies and Principles

A. Responsibility to Report Misconduct

All HPHC/I personnel must report observed, suspected, or apparent research misconduct to the RIO at Research_Admin@hphci.harvard.edu. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, they 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 and/or the allegation to other HPHC/I leaders who can address 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

HPHC/I personnel involved in addressing allegations of research misconduct shall, as required by 42 CFR § 93.106, limit disclosure of the identity of respondents, complainants, and witnesses while conducting the research misconduct proceedings to those who need to know, as determined by HPHC/I, consistent with a thorough, competent, objective, and fair research misconduct proceeding, and as allowed by law. Those who need to know may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions. The limitation on disclosure of the identity of respondents, complainants, and witnesses no longer applies once HPHC/I has made a final determination of research misconduct findings. HPHC/I must disclose the identity of respondents, complainants, or other relevant persons to ORI pursuant to an ORI review of research misconduct proceedings under this federal law. Except as may otherwise be prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research subjects might be identified. Confidentiality requirements do not prohibit HPHC/I from managing published data or acknowledging that data may be unreliable.

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 must 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 they have 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; or

6. PHS may need to take appropriate steps to safeguard evidence and protect the rights of those involved.

PROCEDURE:

III. Conducting the Assessment and Inquiry

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will promptly assess the allegation to determine whether the allegation: (1) falls within the definition of research misconduct (42 CFR § 93.234); (2) is within the applicability criteria of 42 CFR § 93.102; and (3) is sufficiently credible and specific so that potential evidence of research misconduct may be identified. . An Inquiry must be conducted if the allegation meets the three assessment criteria.

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. If the allegation involves an HPHCI faculty member of Harvard Medical School (HMS), the RIO will also contact HMS's Office for Academic and Research Integrity. If the RIO determines that the requirements for an inquiry are met, they will (1) document the assessment; (2) promptly sequester all research records and other evidence consistent with 42 CFR § 93.305(a); and (3) promptly initiate the inquiry. If the RIO determines the requirements for an inquiry are not met, sufficiently detailed documentation of the assessment will be kept in order to permit a later review by ORI of the reasons why an inquiry was not conducted. Such documentation must be retained in accordance with 42 CFR § 93.318.

B. Initiation and Purpose of the Inquiry

If the RIO determines that the criteria for an Inquiry are met, they will immediately initiate the Inquiry process. The purpose of the Inquiry 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 the evidence related to the allegation.

C. Notice to Respondent and Sequestration of Research Records

Notice to respondent

At the time of or before beginning an Inquiry, the RIO must make a good faith effort to notify the presumed respondent, if any. If the Inquiry subsequently identifies additional respondents, they must be notified in writing. The 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. Only allegations specific to a particular respondent are to be included in the notification to that respondent. If additional allegations are raised, the respondent(s) must be notified in writing of the additional allegations raised against them.

Sequestration of records

The RIO will take steps to obtain all research records and other evidence needed to conduct the research misconduct proceeding consistent with 42 CFR § 93.305(a). The RIO may consult with ORI for advice and assistance in this regard. When original records cannot be obtained, copies of records that are "substantially equivalent in evidentiary value" will fulfill the sequestration requirement.

Multiple institutions and Multiple Respondents

If the alleged research misconduct involves multiple institutions, HPHCI 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 an institution to serve as the lead institution. In a joint research misconduct proceeding, the lead institution will obtain research records and other evidence pertinent to the proceeding, including witness testimony, from the other relevant institutions. By mutual agreement, the joint research misconduct proceeding may include committee members from 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.

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

D. Charge to the RIC 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 determine whether an investigation is warranted. The RIC may interview witnesses or respondents that would provide additional information for the review.
4. states that an Investigation is warranted if the RIC determines: (i) 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; and (ii) preliminary information gathering and fact-finding from the inquiry indicates that the allegation may have substance.;
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; and
6. informs the RIC that findings of research misconduct, including the determination of whether the alleged misconduct is intentional, knowing, or reckless, cannot be made at the Inquiry stage.

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(f). The scope of the Inquiry does not 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 90 calendar days of initiation of the Inquiry, unless the RIO determines that circumstances warrant a longer period. If the RIO approves an extension, the Inquiry report must include documentation of the reasons for exceeding the 90-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 and complainant;
2. the composition of the RIC members; including name(s), position(s), and subject matter expertise
3. a description of the allegation of misconduct;
4. details about the PHS funding and other sponsor support (e.g., grant numbers, contracts, grant applications, etc.);
5. a summary of the Inquiry process;
6. a description of any scientific or forensic analyses conducted;
7. transcripts of any interviews that were transcribed;
8. inquiry timeline and procedural history;
9. an inventory of sequestered research records and description of how sequestration was conducted
10. any institutional actions implemented, including communications with journals or funding agencies;
11. the basis for recommending that the allegation(s) warrant an Investigation;
12. potential evidence of honest error or difference of opinion, if applicable;
13. the basis on which any allegation(s) do not merit an Investigation; and
14. any comments on the report by the complainant or respondent.

Point32Health 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 experts who conducted the Inquiry.

B. Notification to the Respondent and Complainant 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. HPHC/I is not required to notify the complainant of the outcome of the Inquiry. HPHC/I may, at its discretion, provide relevant portions of the Inquiry Report to the complainant for comment. 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 (when PHS funding is involved)

Within 30 calendar days of the DO determining that an Investigation is warranted, the RIO will provide ORI with 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 whenever requested: (1) the HPHC/I P&Ps under which the Inquiry was conducted; and (2) the research records and other evidence reviewed, and copies of all relevant documents.

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 DO decides 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. 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

Within a reasonable amount of time after determining that an Investigation is warranted, but before the date on which the Investigation begins, the RIO must notify the respondent in writing of the allegation(s). The respondent must be given written notice of any allegation(s) of research

misconduct not addressed during the Inquiry or in the initial notice of Investigation within a reasonable amount of time of deciding to pursue such allegation(s). If additional respondents are identified during the Investigation, a separate inquiry for each new respondent may be conducted. If additional respondent(s) are identified during the Investigation, they each must be notified of the allegation(s) and be provided with an opportunity to respond consistent with this P&P. While an investigation into multiple respondents can convene with the same RIC, separate Investigation Reports and research misconduct determinations are required for each respondent.

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 other evidence needed to conduct the research misconduct investigation 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 ORI 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. Interviews during the Investigation must be recorded and transcribed. Any exhibits shown to the interviewee during the interview must be numbered and referred to by that number in the interview. The transcript of the interview must be made available to the relevant interviewee for correction. The transcript(s) with any corrections and numbered exhibits must be included in the institutional record of the investigation. The respondent must not be present during the witnesses' interviews but must be provided a transcript of the interview. A research misconduct proceeding involving multiple institutions must be conducted consistent with 42 CFR § 93.305(e); 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. If additional allegations are raised, the respondent(s) must be notified in writing of the additional allegations raised against them.

F. Time for Completion

The Investigation is to be completed within 180 calendar days of beginning it, including conducting the Investigation, preparing the draft investigation report for each respondent, and providing the draft report to each respondent for comment. In matters where PHS funding is involved, the institutional record, including the final investigation report and decision by the DO, will be transmitted to ORI. If the Investigation will not be completed within this 180-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 in writing that includes the circumstances or issues warranting additional time. 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. If the investigation takes longer than 180 days to complete, the investigation report must include the reasons for exceeding the 180-day period.

VI. The Investigation Report

A. Elements of the Investigation Report

The RIC and the RIO are responsible for preparing a written Investigation report for each respondent- with the following content to be present in the final investigation report:

1. Description of the nature of the allegation(s) of research misconduct, including any additional allegation(s) addressed during the research misconduct proceeding.
2. Description and documentation of the PHS and other funder support (e.g., grant numbers, contracts, grant applications, etc.).
3. Description of the specific allegation(s) of research misconduct for consideration in the investigation of the respondent.
4. Composition of investigation committee, including name(s), position(s), and subject matter expertise.
5. Inventory of sequestered research records and other evidence, except records the institution did not consider or rely on; and a description of how any sequestration was conducted during the investigation. This inventory must include manuscripts and funding proposals that were considered or relied on during the investigation.
6. Transcripts of all interviews conducted, as described in 42 CFR § 93.301(g)
7. 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 allegedly contained the falsified, fabricated, or plagiarized material.
8. Any scientific or forensic analyses conducted.
9. If not already provided, the HPHC/I policy and procedures under which the investigation was conducted.
10. Any comments made by the respondent and complainant on the draft investigation report and the investigation committee's consideration of those comments.
11. A statement for each separate allegation whether the investigation committee recommends a finding of research misconduct.

a) If the RIC recommends a finding of research misconduct for an allegation, the investigation report must, for that allegation:

(i) identify the individual(s) who committed the research misconduct.

(ii) indicate whether the research misconduct was falsification, fabrication, and/or plagiarism.

(iii) indicate whether the research misconduct was committed intentionally, knowingly, or recklessly.

(iv) state whether the other requirements for a finding of research misconduct, as described in 42 CFR § 93.103, have been met

(v) Summarize the facts and the analysis that support the conclusion and consider the merits of any explanation by the respondent.

(vi) identify the specific PHS support.

(vii) identify whether any publications need correction or retraction.

b) If the RIC does not recommend a finding of research misconduct for an allegation, the investigation report must provide a detailed rationale.

c) List of any current or known applications or proposals for support that the respondent has pending with PHS- and any 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 research records and other evidence that the RIC considered or relied on. The respondent must submit any comments on the draft report to the RIO within 30 calendar days of receiving the draft investigation report. The respondent's comments must be included and considered in the final report. If HPHCI 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. Any comments received will be added to the Investigation 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.

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. The DO is responsible for making the final determination of research misconduct findings. This determination must be provided in a written decision that includes: (1) whether HPHC/I found research misconduct and, if so, who committed the misconduct; and (2) a description of relevant institutional actions taken or to be taken. If this determination varies from the findings of the RIC, the DO will, as part of their 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 the respondent 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. Institutional Appeals

If a respondent appeals HPHC/I's finding(s) of research misconduct or institutional actions, the RIO will promptly notify ORI if PHS funding is involved. If HPHC/I has not transmitted the institutional record to ORI as required under 42 CFR § 93.316 prior to the appeal, the RIO must wait until the appeal is concluded to transmit the institutional record. The RIO will ensure that the complete record of the appeal is included in the institutional record consistent with 42 CFR § 93.220(a)(5). If HPHC/I has transmitted the institutional record to ORI in accordance with 42 CFR § 93.316 prior to the appeal, the RIO must provide ORI a complete record of the appeal once the appeal is concluded.

E. Transmittal of the institutional record to ORI (when PHS funding is involved)

Unless an extension has been granted, the RIO must, within the 180-day period for completing the Investigation, transmit the institutional record to ORI. The institutional record must be consistent with 42 CFR § 93.220 and logically organized including: documentation of the Assessment; the Inquiry Report and all records considered or relied on during the Inquiry; the Investigation Report and all records considered or relied on during the Investigation; all transcripts; decisions by the DO; records of any appeals; an index listing all the research records and evidence that HPHC/I compiled during the research misconduct proceeding; and a general description of the records that were sequestered but not considered or relied on.

F. Retention and Custody of the Institutional Record and all Sequestered Evidence

The RIO must 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 7 years after completion of the proceeding or the completion of any HHS proceeding involving the research misconduct allegation unless custody has been transferred to HHS or ORI advises otherwise in writing. On request, HPHC/I must transfer custody, or provide copies, to HHS of the institutional record or any component of the institutional record and any sequestered evidence (regardless of whether the evidence is included in the institutional record) for ORI to conduct its oversight review.

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 and credible allegations of research misconduct will be pursued diligently. The RIO must notify ORI (when PHS funding is involved) in advance if there are plans to close a research misconduct proceeding at the Assessment, Inquiry, Investigation, or Appeal Stage on

the basis that the respondent has admitted to committing research misconduct or a settlement with the respondent has been reached.

A respondent's admission of research misconduct must be made in writing and signed by the respondent. An admission must specify the falsification, fabrication, and/or plagiarism that occurred and which research records were affected. The admission statement must meet all elements required for a research misconduct finding under 42 CFR § 93.103 and must be provided to ORI before HPHC/I closes its research misconduct proceeding. HPHC/I must also provide a statement to ORI describing how it determined that the scope of the misconduct was fully addressed by the admission and confirmed the respondent's culpability.

VIII. HPHC/I Administrative Actions

If the DO determines that research misconduct is substantiated by the findings, they 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 their 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, they will determine whether any administrative action should be taken against the person who failed to act in good faith.

REVISION HISTORY:

Department: Office of Research Integrity & Compliance	**Title**: Research Misconduct Allegations
Effective Date: 01/01/26	**Owner:** Director, Research Integrity & Compliance Officer
Replaces P/P Dated: 01/30/08, 03/01/19, 03/21/23	
Related Documents: RIO Procedure Checklist for Research Misconduct Proceedings	
References: 42 CFR 50 & 93	