ROSWELL PARK CANCER INSTITUTE	**Roswell Park Cancer Institute** Policy and Procedure	**Date Issued:** 7/1/2004	**Number:** 1204.1
Title: Research Misconduct		**Revision:** 5	**Effective Date:** 4/25/16
Prepared by: VP Corporate Ethics		**Approved by:** Michael B. Sexton, General Counsel	**Page:** 1 of 13

A. GENERAL STATEMENT OF POLICY

Roswell Park Cancer Institute (RPCI) requires the highest standards of ethical practice and integrity in the conduct of its research. The staff is expected to maintain these standards and to conduct research in a manner that is above reproach and suspicion. All employees are required to report actual or suspected instances of research misconduct.

For purposes hereof, "misconduct" means fabrication, falsification, or plagiarism in proposing, performing, reviewing research or in reporting research results.

Fabrication is making up data or results and recording or reporting them.

Falsification is manipulating research materials, equipment or processes or changing or omitting data or results such that the research is not accurately represented in the research record.

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

A finding of misconduct requires that:

1. There be a significant departure from accepted practices of the relevant research community; and
2. The misconduct be committed intentionally, knowingly, or recklessly; and
3. The allegation be proven by a preponderance of the evidence (42 CFR Part 93.104)

B. SCOPE

This Policy and associated procedures apply to any person paid by, under the control of, or affiliated with RPCI or Health Research Inc., Roswell Park Division (HRI), such as clinicians, scientists, trainees, volunteers, technicians and other staff members, students, fellows, guest researchers, or collaborators. It will also apply to allegations of research by a person who was affiliated by contract or agreement with this institution.

Procedures set forth in this Policy are in accordance with those promulgated by the Public Health Service (PHS) and the National Science Foundation (NSF). PHS regulation at 42 C.F.R. Part 93 applies to any biomedical or behavioral research, research-training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination

of research information, applications or proposals for support for biomedical or behavioral research, research training or activities related to that research or research training, or plagiarism of research records produced in the course of any supported research, research training or activities related to that research. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for funds resulted in a grant, contract, cooperative agreement, or other form of support. This policy is to be followed regardless of funding source, except that PHS funded research misconduct findings need to be reported to the federal Office of Research Integrity.

This Policy and associated procedures will be followed when allegations of possible research misconduct are made, unless particular circumstances, in individual cases, dictate some variation.

This statement of policy and procedures does not apply to authorship or collaboration disputes and applies only to allegations of research misconduct that occurred within six years of the date the institution or HHS received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

C. ADMINISTRATION

This Policy and Procedure will be administered by the Vice President for Corporate Ethics, in conjunction with the Compliance Officer or Counsel for Corporate Compliance, and the Chief Academic Officer (hereinafter "the CAO") for allegations involving trainees, or the appropriate Senior Vice President (hereinafter "the SVP") for Basic Science, Clinical Research, Population Science, or Translational Research for allegations involving faculty or staff under their area of responsibility.

D. POLICY / PROCEDURE

1. **Summary**

The procedure to be employed for the reporting and investigation of good faith allegations of research misconduct is presented below. When there is sufficient evidence already at hand, the process may move directly to the investigation stage. The process may be terminated at any point along the continuum if the allegation is determined to be without merit.

a. **Report:** An allegation of research misconduct should be reported to the Vice President for Corporate Ethics, who serves as the Research Integrity Officer (RIO) , and who will review the allegation with the CAO (if involving a trainee) or the appropriate SVP (if involving a faculty or staff member). An initial assessment will be made and if the allegation is determined to meet the criteria in 42 CFR Part 93.103 (it involves PHS supported research, falls under the PHS definition of research misconduct and the allegation is specific so that potential evidence of research misconduct can be identified) an Inquiry will be initiated. If the matter involves PHS funding, the Federal Office of Research integrity (ORI) will be notified by the Vice President for Corporate Ethics as required.

b. **Inquiry:** If the preliminary assessment identifies sufficient information to allow specific follow-up and the incident falls under the PHS definition of research misconduct, the Inquiry process will be initiated. The purpose of the Inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent(s), complainant(s), and any key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an Investigation. In general, absent full admissions, the Inquiry should not be used to make findings on whether research misconduct in fact occurred. The findings of the Inquiry and any recommendation(s) are to be set forth in an Inquiry report, to be forwarded to the President & CEO or designee, for a determination as to what further actions, if any, are necessary.

When there is sufficient evidence already at hand, for example as a result of an audit of a clinical trial, the Institute may move directly to the Investigation stage without an Inquiry.

c. **Investigation:** The purpose of the Investigation is to explore the allegation(s) in detail, to examine the evidence in depth, and to determine specifically whether research misconduct has been committed, by whom, and to what extent. The Investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegation(s). The findings of the Investigation are to be set forth in an Investigation Report that is submitted to the President and CEO and, where applicable to the Federal Office of Research Integrity (ORI) for oversight review. A finding of research misconduct requires that:

   i. there be a significant departure from accepted practices of the relevant research community;
   ii. the research misconduct be committed intentionally, knowingly, or recklessly; and
   iii. the allegation be proven by a preponderance of evidence.

d. **Determination and Reporting**

The President and CEO, or his designee, will make the final determination whether to accept the Investigation Report, its findings, and its recommended actions. When a final decision has been reached, the respondent(s) and the complainant(s) will be notified in writing. This information also will be transmitted to the (ORI) by the RIO, the applicable sponsor and/or other agencies, as required.

2. **General Policies and Principles**

a. Responsibility to Report Misconduct

   i. All employees of, or individuals associated with RPCI or HRI have a responsibility to report observed, suspected, or apparent research misconduct to the Vice President for Corporate Ethics. Individuals who are unsure whether a suspected incident falls within the definition of research misconduct should consult with the Vice President for Corporate Ethics, Counsel for Corporate Compliance, or any Senior Vice President. Through such consultation, the individual is afforded the expertise of individuals who are familiar with the process, and can assist the individual in determining whether the matter should be reported as this policy requires.

   ii. All personnel involved must be diligent in protecting the privacy, position, reputation and safety of any person who, in good faith, reports apparent research misconduct. Retaliation of any kind, direct or indirect, will be considered a serious deviation from acceptable employee conduct standards, and will result in disciplinary measures up to and including termination, in accordance with the collective bargaining agreements, if applicable. Allegations of research misconduct will be treated fairly and impartially; always respecting, to the extent possible, the confidentiality of all parties.

b. Confidentiality

   i. To the extent allowed by law, RPCI shall maintain the identity of respondents and complainants securely and confidentially, and shall not disclose any identifying information, except to:

- those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and
- ORI as it conducts its review of the research misconduct proceeding and any subsequent proceedings, as applicable.

ii. To the extent allowed by law, any information obtained during the research misconduct proceeding that might identify the subjects of research shall be maintained securely and confidentially and shall not be disclosed, except to those who need to know in order to carry out the research misconduct proceeding.

iii. All parties, complainant, respondent, committee members are responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and/or investigation.

c. Complainant(s)

i. RPCI will assure that the complainant(s) and those who cooperate in Inquiries or Investigations are not retaliated against in the terms and conditions of their employment or other status at RPCI or HRI.

ii. RPCI and HRI will protect the positions, reputations and privacy rights of those who report research misconduct in good faith, to the extent possible. For example, if the complainant(s) requests anonymity, RPCI will make an effort to honor the request during the allegation assessment, Inquiry and Investigation, within applicable policies and regulations and state and federal laws. The complainant(s) will be advised that if the matter is referred for a formal Investigation and/or if the complainant's testimony is required, anonymity may no longer be possible.

iii. The complainant may be interviewed during the Investigation, be provided with a recording or transcript of the interview if taken, for correction, and that interview transcript will be included in the record of Investigation.

iv. The complainant may receive a copy of the draft Investigation Report for comment, to be returned to the President & CEO within 30 days of receipt.

v. False allegations of research misconduct can do irreversible damage to the reputation of an accused individual, even if the person is later exonerated. Therefore, an employee who is found to have intentionally or recklessly made a false allegation may be subject to progressive counseling and/or disciplinary action up to and including termination, in accordance with the collective bargaining agreements, if applicable.

d. Respondent(s)

i. During the research misconduct proceeding, RPCI shall provide the following notifications to all identified respondents:

- Initiation of Inquiry - As soon as applicable, the RIO will make a good faith effort to notify the respondent(s) in writing of the Inquiry and RPCI will contemporaneously sequester all research records, including electronic records, and other evidence needed to conduct the research misconduct proceeding. If the Inquiry subsequently identifies additional respondents, they shall be promptly notified in writing.
- Results of the Inquiry - The respondent(s) will be notified of the results of the Inquiry, and given a copy (ies) of the Inquiry Report and the

institutional policies and procedures for the handling of research misconduct allegations.

- Comment on Inquiry Report - The respondent(s) will be provided with an opportunity to comment on the Inquiry report in a timely fashion (ten (10) business days, unless more time is warranted) so that any comments can be attached to the report.
- Initiation of Investigation - Within a reasonable time after the determination that an Investigation is warranted, but not later than 30 calendar days after that determination, the respondent(s) will be notified in writing of the allegation to be investigated. The respondent(s) shall be given written notice of any new allegations within a reasonable time if during the course of the Investigation it has been determined that the committee will pursue allegations not addressed in the Inquiry or in the initial Notice of the Investigation.
- Scheduling of Interview - The respondent(s) will be notified sufficiently in advance of the scheduling of his/her interview so that the respondent(s) may prepare for the interview and arrange for the attendance of a union representative or legal counsel, if the respondent(s) so wishes.
- Comment on Draft Investigation Report - The respondent(s) will be given a copy of the draft Investigation Report and concurrently, a copy of, or supervised access to, the evidence on which the report is based. The respondent(s) must submit any comments within 30 days of the date on which he/she received the draft report. These comments will be included and considered in the final Investigation Report.

ii. Inquiries and investigations will be conducted so as to ensure fair treatment to the respondent(s) and confidentiality, to the extent possible, without compromising public health and safety or the thorough execution of the Inquiry or Investigation.

iii. An employee accused of research misconduct may consult with a union representative, legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case). The union representative, counsel or personal adviser may attend interviews or meetings on the case, **but may not testify or comment**.

iv. Whether or not the respondent can continue with the research after the allegation of misconduct has been made will be determined on a case-by-case basis.

e. Cooperation with Inquiries and Investigations

Employees will cooperate with responsible RPCI and/or outside officials in reviewing allegations and conducting inquiries and investigations, and are required to provide relevant evidence.

f. Evidentiary Standards

The burden of proof for making a finding of research misconduct must be met. A finding of research misconduct will be established by a preponderance of the evidence. Preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

g. Research Records and Evidence of Misconduct

i. Either before or at the time when RPCI notifies the respondent of the allegation, inquiry or investigation, RPCI will take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the proceeding, inventory the records and evidence and sequester them in a secure manner, except that where scientific instruments shared by a number of users are involved, custody may be limited to copies of the data or evidence from such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

ii. Custody will be taken of additional records or evidence discovered to be needed during the course of the proceeding.

iii. The respondent will be given copies of, or reasonable, supervised access to the research records, where appropriate.

iv. All records, evidence, or other instruments of the research misconduct proceeding will be maintained in a secure manner for seven years after completion of the proceeding or any federal ORI proceeding whichever is later, unless custody has been transferred to the ORI or the ORI has notified the institution that it no longer needs to maintain the records.

3. **Procedures**

a. Report

i. Upon receipt of an allegation of research misconduct, the Vice President for Corporate Ethics will convene a meeting with the Counsel for Corporate Compliance , the CAO or SVP, and/or Corporate Counsel, as soon as practical, to review the allegation and determine if there is sufficient evidence to warrant an Inquiry. Any inquiry will be conducted if:

- the allegation is within the definition of research misconduct;
- the ORI rule applies; and
- the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

ii. RPCI will also conduct this three-prong assessment if the ORI, or any other Institution, forwards an allegation to RPCI for that purpose.

iii. Deliberations should be completed within five (5) working days of receipt of the allegation, unless circumstances warrant more time. If it is determined that there is not sufficient evidence to warrant an inquiry, the complainant(s) will be notified. If, however, there is deemed to be sufficient evidence, the matter will proceed to an Inquiry.

b. Inquiry

i. The purpose of the Inquiry is to evaluate the available evidence and testimony of the respondent(s), complainant(s), and key witnesses, and examine relevant research records and materials, to determine whether there is sufficient evidence of possible research misconduct to warrant an Investigation. The Inquiry is not intended to reach a final conclusion about whether research misconduct definitely occurred or who was responsible.

ii. An investigation is warranted if the following determinations are made:

- There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and;
- Preliminary information gathering and fact finding from the inquiry indicates that the allegation may have substance (merit).

iii. The Inquiry will be conducted by a Committee appointed by the Vice President for Corporate Ethics. The Committee shall consist of the Vice President for Corporate Ethics, the CAO (for cases involving trainees) or SVP (for cases involving faculty or staff) and up to four (4) faculty representatives (at least one statistician and one faculty member with expertise specific to the research topic); and an Institute attorney.

iv. Charge to the Committee;

- The RIO will prepare a charge for the inquiry committee that:
- Sets forth the time for completion of the inquiry;
- Describes the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
- States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within 10 the definition of research misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b); and, (2) the allegation may have substance, based on the committee's review during the inquiry.
- Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and 42 CFR § 93.309(a).

v. At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The RIO will be present or throughout the inquiry to advise the committee as needed

vi. The Committee will complete the Inquiry within 60 business days of initiation of the inquiry, unless circumstances warrant a longer period, or there is sufficient evidence, will proceed directly to investigation.

vii. Documentation of the reasons for exceeding the 60-day period must be included in the report. The findings of the Inquiry must be set forth in a report to the President & CEO, or his designee. The report of the Inquiry Committee must include:

- the name and position of the respondent
- a description of the allegations of research misconduct and a description of the PHS support, if any.
- the basis for recommending or not recommending that an investigation is warranted
- any comments the respondent has made on the report after being afforded an opportunity to do so; and

- a finding of sufficient or insufficient evidence of research misconduct to proceed to an Investigation.

vi. If the report of the Inquiry Committee recommends that a formal Investigation is warranted, the President & CEO, or his designee, shall:
- Notify the respondent(s);
- Initiate a formal Investigation as provided in the procedures below;
- Where there is PHS funding, notify the Director, ORI, in writing, within 30-days of finding an investigation is warranted, including a written finding by responsible IO (IO - the Vice President for Corporate Ethics); and a copy of the inquiry report. Upon request, RPCI will provide: Institutional Policies and Procedures for conducting the inquiry, the research records and evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents, and the charges for the investigation to consider.
- Notify the ORI within 24 hours of obtaining any reasonable indication of possible criminal violations, so that the ORI may then immediately notify the Department's Office of Inspector General (OIG) as per its policy.
- At any stage of the Inquiry or Investigation, the Institute shall notify the ORI immediately if it ascertains that any of the following special circumstances exist:
  - The health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
  - HHS resources or interests are threatened;
  - Research activities should be suspended;
  - Federal Action is required to protect the interests of those involved in the research misconduct proceeding.
  - It is probable that the alleged incident is going to be prematurely reported publicly;
  - There is a reasonable indication of possible criminal violation.
  - The research community or public should be informed.

vii. The Inquiry report will include the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) the PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support; (4) the basis for recommending or not recommending that the allegations warrant an investigation; (5) any comments on the draft report by the respondent or complainant

c. <u>Investigation</u>

i. In conducting all investigations, the investigation committee shall:

- Use diligent efforts to ensure that the investigation is thoroughly and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations;
- Interview each respondent, complainant, and any other available persons who have been 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 investigation;
- Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of

additional instances of possible research misconduct, and continue the investigation to completion; and
- Otherwise comply with the requirements for conducting an investigation in 42 CFR Section 93.310.

ii. The findings of the investigations will be set forth in a report to the President & CEO, or his designee. The report will include a presentation of the evidence and any testimony. It also will put forward any proposed sanctions and administrative actions that should be taken by RPCI.

iii. Investigation Procedure:

- Within 30 days after determining that an investigation is warranted, the Investigation will be initiated. The purpose of the Investigation is to explore the allegations in detail, to examine the evidence in depth, and to determine specifically whether research misconduct has been committed, by whom, and to what extent. The Investigation also will determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important when the alleged misconduct involves clinical trials, 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.

    - Findings of the Investigation are to be set forth in an Investigation report to the President & CEO, or his designee. This report should ordinarily be completed within 60 days of the initiation of the Investigation, unless further time is warranted.
    - The respondent(s) shall be given a copy of the draft report, and concurrently, a copy of, or supervised access to, the evidence on which the report is based. The respondent shall have an opportunity to comment on the report, and these comments should be submitted within 10 days of receiving the report. Comments will be made part of the record.

- The Investigation Committee appointed by the VP, Corporate Ethics shall include:

    - at least two members of the Inquiry Committee,
    - two representatives from outside the unit or department of the complainant(s) who are expert in the subject matter or scientific area,
    - a representative of Department of Human Resources,
    - an institute attorney, and
    - any other members deemed appropriate.

- Members selected will have no real or apparent conflicts of interest in the case, be unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the Investigation. Members may be scientists, administrators, subject matter experts, lawyers, or other qualified persons from inside or outside RPCI. The Vice President for Corporate Ethics will notify the respondent(s) of the proposed Committee membership. If the respondent(s) submits to the Vice President for Corporate Ethics a written objection to any appointed member of this Committee within three (3) business days, the Vice President for

Corporate Ethics will determine whether to replace the challenged member or expert with a qualified substitute.

- Charge to the Investigation Committee
  - The RIO will define the subject matter of the investigation in a written charge to the committee that:
    - Describes the allegations and related issues identified during the inquiry;
    - Identifies the respondent;
    - Informs the committee that it must conduct the investigation as described in paragraph 3 (c) of this section;
    - Defines research misconduct;
    - Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
    - Informs the committee that in order to determine that the respondent committed research misconduct it must find that a preponderance of the evidence establishes that: (1) research misconduct, as defined in this policy, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the respondent committed the research misconduct intentionally, knowingly, or recklessly; and
    - Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and 42 CFR § 93.313

- The Investigation usually will involve examination of all documentation including, but not limited to: relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. When possible, the Committee should interview the complainant(s), the respondents(s), and other individuals who might have information relevant to the allegations. Interviews of the respondent(s) should be tape recorded or transcribed. All other interviews should be transcribed, tape recorded, or summarized. Summaries or transcripts should be prepared and provided to the interviewed party for comment or revision, and included as part of the Investigation record.

- The final report must contain:

  - Elements of the Investigation Report The investigation committee and the RIO are responsible for preparing a written draft report of the investigation that:
    - Describes the nature of the allegation of research misconduct, including identification of the respondent; [Option: The respondent's c.v. or resume may be included as part of the identification.]
    - Describes and documents the PHS support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support;
    - Describes the specific allegations of research misconduct considered in the investigation;

- Includes the institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
- Includes a statement of findings for each allegation of research misconduct identified during the investigation. Each statement of findings must: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion; (3) identify the specific PHS support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies

- The report will include the actual text or an accurate summary of the views of the respondent(s), as well as a description of any proposed sanctions and recommended administrative actions.

- The report of the Investigation will be forwarded to the President and CEO, or his designee, for final action. The respondent(s) should receive the full report of the Investigation. When there is more than one respondent, each shall receive those parts that are pertinent to his or her role. The respondent(s) shall be permitted to make a written reply to the President and CEO, or his designee, within 10 business days of receipt of the report. Such reply shall be incorporated as an appendix to the report of the Investigation Committee.

- All aspects of the investigation, including sending the final report to ORI where there is PHS funding, is to be completed within 120 days of beginning it, unless the ORI grants an extension on the basis of RPCI's written request.

- Upon request, ORI will be supplied with copies of all relevant research records and evidence, including results of all interviews and transcripts or recordings of such interviews.

d. Institutional Review and Decision

i. If the report of the Investigation Committee finds the charges to be unfounded and this is accepted by the President and CEO, or his designee, the matter shall be closed and the concerned parties shall be informed. Reasonable efforts will be made by RPCI to mitigate any damage done to the reputation of the respondent(s).

ii. If the report of the Investigation Committee substantiates the allegations against the respondent(s), the President and CEO, or his designee, will make the final determination whether to accept the Investigation report, its findings, and the

recommended actions within 30 business days of receipt of the final report. If this determination differs from that of the Committee, the President and CEO, or his designee, will explain, in detail, the basis for rendering a decision different from that of the Committee to both the Committee and in any report to any applicable federal agencies such as ORI and any other agencies as required by law. The President and CEO, or his designee, also may return the report to the Committee for further fact-finding or analysis.

iii. The determination of the President and CEO, or his designee, together with the Committee's report, constitutes the final investigation report. Actions may range from suspension or termination of employment the case of serious offenses, to removal from a particular project, a letter of reprimand, special monitoring of future work, probation, reduction of salary, or reduction in rank. Such actions will be taken in accordance with the collective bargaining agreements, if applicable.

iv. When a final decision on the case has been reached, the Vice President for Corporate Ethics will notify the respondent(s) and the complainant(s) in writing. In addition, the President & CEO, or his designee, will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case.

v. The report to ORI shall include all the above information provided to the CEO, and in addition:
- Whether RPCI accepts the findings of the investigation
- A description of any pending or completed administrative actions against the respondent.

vi. Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. ORI will be notified in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR Part 93.315.

e. Termination or Resignation Prior to Completing Inquiry or Investigation

i. The termination of the respondent's employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the institution's responsibilities under 42 CFR Part 93.

ii. If the respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation, RPCI and any inquiry or investigation committee will use 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.

4. **Record Retention**

After completion of any case, the Vice President for Corporate Ethics will prepare a complete file, including the records of any Inquiry or Investigation and copies of all documents and other materials furnished to the Inquiry and Investigation committees. The file will be kept for seven years after the completion of the case to permit later assessment of the case. ORI or other authorized DHHS personnel will, upon request, be given access to those records that they are authorized to review.

Completion of Cases; Reporting Premature Closures to ORI Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify ORI in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315

5. **Appeals**

   a. There is no appeals process at the internal level, except as outlined in the collective bargaining agreements, where applicable. At the federal level, the Assistant Secretary for Health (ASH) makes the final PHS/HHS decision on the imposition of administrative actions after reviewing the recommendations made by ORI, except when the administrative actions include debarment or suspension. The ASH may accept, modify, or reject the administrative actions recommended by ORI. If the ASH accepts the recommendations, ORI sends the respondent a copy of the final ORI report and a notification letter that describes the proposed administrative actions to be taken against the respondent. ORI also provides notice of the respondent's opportunity to request a hearing before an Administrative Law Judge of the HHS Department Appeals Board on the misconduct finding and the administrative actions. The respondent has 30 days from receipt of the notification to file a request for a hearing.

   b. If a hearing is not requested, the research misconduct finding and administrative actions become final and are published in the Federal Register, the NIH Guide for Grants and Contracts, the ORI Newsletter, and the ORI Annual Report. In addition, HHS findings and administrative actions are posted on the PHS Administrative Actions Bulletin Board and the ORI website. Debarments are also published in the General Services Administration's Excluded Parties List System.

6. **ORI Jurisdiction**

   ORI does not have jurisdiction to review a research misconduct investigation or compliance or a retaliation issue related to non-PHS funded research. ORI jurisdiction only extends to projects for which PHS funds are requested or provided; the existence of an assurance does not give ORI authority over non-PHS matters (42 U.S.C. Part 289b (b), 42 C.F.R. Part 93.102.)

E. DISTRIBUTION

This policy and procedure will be distributed to all Managers via the RPCI internal web page and to holders of backup hard copies of the manual. Managers are responsible for communicating policy content to pertinent staff.