

 ROSWELL PARK <small>COMPREHENSIVE CANCER CENTER</small>	Roswell Park Comprehensive Cancer Center Policy and Procedure	Date Issued: 7/1/2004	Number: 1204.1
Title: Research Misconduct	Revision: 6	Effective Date: 3/5/2018	
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A. GENERAL STATEMENT OF POLICY

Roswell Park Comprehensive Cancer Center (Roswell Park) 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;
2. The misconduct be committed intentionally, knowingly, or recklessly;
3. The allegation be proven by a preponderance of the evidence (42 CFR Part 93.104) (RP's or union disciplinary procedures may establish a different standard of proof for disciplinary actions)

This policy addresses only research misconduct. Roswell Park's policy has been interpreted to include such other misdeeds as reckless disregard for accuracy, failure to supervise adequately, and other lapses from professional conduct or neglect of academic duties. Findings (pursuant to this research misconduct procedure) of serious academic deficiencies in proposing, conducting or reporting research - but not constituting research misconduct - are to be addressed by initiating the relevant disciplinary process, as appropriate.

B. SCOPE

This Policy and associated procedures apply to any person paid by, under the control of, or affiliated with Roswell Park 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; research proposed, conducted or reported elsewhere by such Roswell Park-related individuals as part of their Roswell Park-related duties or activities; and at the discretion of Roswell Park, to research proposed, conducted or reported where such research is claimed, cited or implied to have been done at Roswell Park, or where a Roswell Park appointment or official affiliation is claimed, cited or implied in connection with the research.

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, who acts as the Institute Official (IO) 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, or if the respondent admits to the misconduct, 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 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. An inquiry consists of preliminary information-gathering and preliminary fact-finding to determine whether an allegation or an apparent instance of misconduct has substance. The outcome of an inquiry is a determination as to whether or not an investigation is to be conducted.

When there is sufficient evidence already at hand, for example, as a result of an audit of a clinical trial, or where the misconduct has been admitted, the Center may move directly to the Investigation stage without an Inquiry.

- c. **Investigation:** An investigation is a formal examination and evaluation of relevant facts to determine whether or not misconduct has taken place.
- 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, Roswell Park 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, Roswell Park shall maintain the identity of respondents and complainants securely and confidentially, and shall not disclose any identifying information, except to:
 - a. those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and
 - b. 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. Roswell Park 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 Roswell Park or HRI.
 - ii. Roswell Park 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, Roswell Park 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.
- e. Respondent(s)
- i. During the research misconduct proceeding, Roswell Park shall provide the following notifications to all identified respondents:
 - a. 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 Roswell Park 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.
 - b. 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.
 - c. 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.
- d. **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.
 - e. **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.
 - f. **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.
- f. **Cooperation with Inquiries and Investigations**
Employees will cooperate with responsible Roswell Park and/or outside officials in reviewing allegations and conducting inquiries and investigations, and are required to provide relevant evidence.
 - g. **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.
 - h. **Research Records and Evidence of Misconduct**
 - i. Either before or at the time when Roswell Park notifies the respondent of the allegation, inquiry or investigation, Roswell Park 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. Preliminary Assessment

- 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 any information presented to determine whether it constitutes alleged misconduct as defined by this policy and whether the allegation is sufficiently credible and specific so that potential evidence of misconduct can be identified. If both these criteria are met, the VP of Corporate Ethics will begin an inquiry to determine if there is sufficient evidence to warrant an Inquiry.
- ii. Roswell Park will also conduct an assessment if the ORI, or any other Institution, forwards an allegation to Roswell Park 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. Committee for conducting an Inquiry or Investigation

- i. The Committee shall be appointed by the VP, Corporate Ethics and shall include:
 - a. the Vice President for Corporate Ethics,
 - b. the CAO (for cases involving trainees)
 - c. to three (3) faculty representatives (at least one statistician and one faculty member with expertise specific to the research topic);
 - d. two representatives from outside the unit or department of the complainant(s) who are expert in the subject matter or scientific area,
 - e. a representative of Department of Human Resources,
 - f. a Roswell Park attorney, and
 - g. any other members deemed appropriate.
- ii. Members selected are to 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 Inquiry and/or Investigation. Members may be scientists, administrators, subject matter experts, lawyers, or other qualified persons from inside or outside Roswell Park. The Vice President for Corporate Ethics will notify

the respondent(s) of the proposed Committee membership, when and if an Investigation is warranted. 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.

- iii. Charge to the Inquiry Committee;
 - a. The RIO will prepare a charge for the inquiry committee that:
 - 1. Sets forth the time for completion of the inquiry;
 - 2. States the purpose of the inquiry
 - 3. Describes the allegations and any related issues identified during the allegation assessment;
 - 4. States the factors that would warrant an investigation
 - 5. 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).
- iv. 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 throughout the inquiry to advise the committee as needed
- v. Charge to the Investigative Committee:
 - a. The RIO will define the subject matter of the investigation in a written charge to the committee that:
 - 1. Describes the allegations and related issues identified during the inquiry;
 - 2. Identifies the respondent;
 - 3. Informs the committee that it must conduct the investigation as described in paragraph 3 (c) of this section;
 - 4. Defines research misconduct;
 - 5. 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;
 - 6. 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
 - 7. 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
 - 8. 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.

c. Inquiry

- i. An inquiry is to determine whether a formal investigation is warranted, and will be guided by the following:
 - a. Any outside funding source(s) for the research that is the subject of the inquiry shall be identified.
 - b. Those conducting the inquiry or investigation are promptly to take all reasonable and practical steps to obtain custody of the research records and/or evidence needed to conduct the misconduct proceeding, inventory the records and evidence, and sequester them in an appropriate manner.
 - c. At the time of, or before the beginning of an inquiry, the accused individual (hereafter "the respondent") shall be informed of the allegations, and be invited to comment on them. The respondent shall also be provided with a copy of the draft report of the inquiry, and be given an opportunity to comment on the findings for the consideration of those conducting the inquiry. In so doing, best efforts shall be made (where feasible) to protect the confidence of the individual(s) who brought forward the complaint (hereafter "the complainant(s)").
 - d. Relevant individuals, including the complainant(s), if known, should be interviewed.
 - e. The final report, including a recommendation as to whether or not a full investigation is warranted, is to be submitted by the Inquiry group to the CEO within 60 days of receipt of the allegation. (If this time frame is not possible in a particular case, the reasons are to be documented and the CEO so informed.) The final report shall include any comments provided by the respondent in response to the draft report.
 - f. The documentation should include sufficient detail to permit a later assessment of the determination of whether or not a full investigation was warranted. It should describe the information reviewed, include a summary of the interviews conducted, state conclusions reached, and indicate whether or not the Inquiry group believes an investigation is warranted.
 - g. The final report of the inquiry and a copy of the documentation are to be transmitted to the CEO and maintained by the VP for Corporate Ethics for seven years.
- ii. An investigation is warranted if the following determinations are made:
 - a. There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and;
 - b. Preliminary information gathering and fact finding from the inquiry indicates that the allegation may have substance (merit).
 - c. 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.
- iii. 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:
 - a. the name and position of the respondent

- b. a description of the allegations of research misconduct and a description of the PHS/financial support, if any. This shall include grant numbers, applications, contracts and publications
 - c. the basis for recommending or not recommending that an investigation is warranted
 - d. any comments the respondent has made on the report after being afforded an opportunity to do so; and
- iv. If the report of the Inquiry Committee recommends that a formal Investigation is warranted, the VP for Corporate Ethics shall:
- a. Notify the respondent(s);
 - b. Initiate a formal Investigation as provided in the procedures below;
 - c. 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, Roswell Park 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.
 - d. 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.
 - e. At any stage of the Inquiry or Investigation, the Center shall notify the ORI immediately if it ascertains that any of the following special circumstances exist:
 1. The health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
 2. HHS resources or interests are threatened;
 3. Research activities should be suspended;
 4. Federal Action is required to protect the interests of those involved in the research misconduct proceeding.
 5. It is probable that the alleged incident is going to be prematurely reported publicly;
 6. There is a reasonable indication of possible criminal violation.
 7. The research community or public should be informed.

d. Investigation:

- i. If the inquiry leads to the conclusion that an investigation is warranted, it will be guided by the following considerations:
 - a. The formal investigation should begin within 30 days of the completion of the inquiry and after written notice to the respondent. The investigation is to be completed and the final report sent to the CEO within 90 days (from the start of an investigation). If an investigation cannot be completed within this time frame, the CEO should be notified as soon as possible. In such cases, it may be necessary for the VP Corporate Ethics to request an extension of time from federal funding agencies.
 - b. An investigation should normally include an examination of the relevant documentation, including but not limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls.
 - c. Complainants, respondents, and witnesses who may have information related to the matter should be interviewed. Complete written summaries of

each interview should be provided to the individual being questioned, and any comments should be appended to the summary, or reflected in a revised summary if the interviewer agrees. The summaries must be retained by the VP Corporate Ethics.

- d. All significant issues should be pursued until the investigative committee is reasonably certain that they have amassed all necessary and appropriate information.
- e. A draft written report of findings shall be made available to the respondent with the opportunity to provide comments for the consideration of those conducting the investigation. Where identified and appropriate, complainants should also receive the portions of the draft report which concern the role or opinions they had in the investigation. Any comments on the draft from the respondent (and from the complainants, if applicable) shall be appended to the final report. NOTE: If there is more than one respondent, and their involvements are found not to be identical, separate draft reports should be prepared if practical, in order to preserve confidentiality. Comments should be returned to the investigative committee within 10 days.
- f. In addition to the interview summaries and comments by the respondent and complainant(s) (if applicable) on the draft report, the final written report should include:
 - 1. how and from whom relevant information was obtained
 - 2. the findings and basis for them.
 - 3. the recommended actions needed and sanctions warranted
- g. If sanctions may be warranted, the CEO shall refer the final report to the Human Resources who will assist the CEO in making the determination. The report should be sufficient to determine whether disciplinary action is called for. If any sanctions result, the VP Corporate Ethics shall be informed, and he or she should append that information to the final report.
- h. comply with any other the requirements for conducting an investigation in 42 CFR Section 93.310.

e. Investigation Report

- i. 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.
- ii. Findings of the Investigation and the respondent's comments, if any, 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.
- iii. Elements of the Investigation Report
 - a. The investigation committee and the RIO are responsible for preparing a written draft report of the investigation that:
 - 1. 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.]
 - 2. 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;
 - 3. Describes the specific allegations of research misconduct considered in the investigation;

4. If the report is going to the ORI: the institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously;
 5. Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
 6. 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
- b. The report will include either 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.
 - c. 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.
 - d. 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.
 - e. 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 Roswell Park 's written request.
 - f. 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.
- f. 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 Roswell Park 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 Human Resources and internal disciplinary policies and 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. Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently.

g. 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, Roswell Park 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.

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.)

7. **External Reporting Requirements**

Roswell Park will comply with the applicable requirements and regulations of its funding agencies, and will cooperate with those agencies in the agencies' own procedures in regard to research misconduct.

Under circumstances not involving federal funding agencies, the CEO will make the decision whether information about the charges and their disposition will be disclosed publicly or to specific parties, including the research sponsor. This decision will normally be made upon the conclusion of the final report. However, if required by urgent circumstances, such a disclosure may be made at any time. The CEO may consult with the VP Corporate Ethics to the extent feasible and appropriate in such cases. Absent such urgent need, RP will not make interim reports to outside agencies unless required by external regulation.

8. In accord with the requirements of federal funding agencies, in cases involving research funded by those agencies, the agency will be informed in the following situations. Except as specifically described at the end of this section, the following notifications to federal funding agencies will be made only by the VP Corporate Ethics, acting on behalf of the CEO:

- a. Outcome of an Inquiry

- i. Federal funding agencies, e.g. ORI will be notified of the outcome of an inquiry involving funds from their agency only if that outcome includes the recommendation to conduct a full investigation.

- b. Commencement of an Investigation

- i. Written notification will be provided to federal funding agencies upon determination that an investigation will be conducted. This notice is to be provided on or before the commencement of the investigation, and must include all information required by the agency. Generally, this notice must include at least the following: name(s) and position(s) of the respondent(s); general nature of the allegation(s); the agency support including any proposal or award numbers; the

basis for the recommendation of an investigation; any comments by the respondent. This information will be held in confidence to the extent permitted by law.

- c. Written Request for a Time Extension
 - i. Regulations generally permit 120 days for completion of the investigation and submission of the final report. If the investigation and determination of discipline are likely to take more time than specified by the relevant funding agency's regulations to complete, the VP Corporate Ethics will so notify the federal funding agency, including reasons for the delay, interim progress reports, the estimated date of completion of the report, and any other necessary information. If an extension is granted, the agency may (if so provided by its regulations) require the submission of periodic interim reports, or the agency may undertake its own investigation prior to Roswell Park's completion of its investigation.
- d. Interim Reports
 - i. Federal funding agencies must be apprised during an investigation of facts that may affect current or potential funding of the individual(s) under investigation, or that may need to be disclosed in order to ensure proper use of federal funds or protection of the public interest.
- e. Early Termination
 - i. Federal funding agencies must be notified of any decision to terminate an inquiry or investigation prior to the completion of all relevant requirements. This notice must include the reasons for such action. Some agencies have retained the right to investigate the matter further on their own.
- f. Final Outcome
 - i. Federal funding agencies will be notified of the final outcome of an investigation involving their funded project(s), and provided with a complete copy of the final report.
 - ii. The report to ORI shall include all the above information provided to the CEO, and in addition:
 - 1. Completion of Cases; Reporting Whether Roswell Park accepts the findings of the investigation
 - 2. A description of any pending or completed administrative actions against the respondent.
- g. 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

E. DISTRIBUTION

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