

 ROSWELL PARK COMPREHENSIVE CANCER CENTER	Roswell Park Comprehensive Cancer Center Policy and Procedure	Date Issued: 7/1/2004	Number: 1204.1
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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, or reviewing research, or in the reporting of 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 is a significant departure from accepted practices of the relevant research community.
2. The misconduct is committed intentionally, knowingly, or recklessly.
3. The allegation be proven by a preponderance of the evidence (42 CFR Part 93.105) (Roswell Park's or union disciplinary procedures may establish a different standard of proof for disciplinary actions).

This policy only addresses 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, Roswell Park Cancer Research Corporation 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

misconduct 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 research misconduct findings associated with PHS funded research, will be reported to the federal Office of Research Integrity (ORI).

This Policy and associated procedures will be followed when allegations of possible research misconduct are made, unless particular circumstances in individual cases not involving PHS funded research, 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 the US Department of Health and Human Services (HHS) received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.1045(b).

C. ADMINISTRATION

This Policy and Procedure will be administered by the Ethics Officer, who acts as the Institute Official (IO) in conjunction with the General Counsel or designee and the Senior Vice President, Cancer Education and Training 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 allegation, inquiry, investigation, and determination and reporting of good faith allegations of research misconduct is summarized 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. **Allegation:** An allegation of research misconduct should be reported to the Ethics Officer, who serves as the Research Integrity Officer (RIO), and who will review the allegation with the Senior Vice President, Cancer Education and Training (if involving a trainee) or the appropriate SVP (if involving a faculty or staff member). An initial assessment will be made by the Ethics Officer 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 ORI will be notified by the Ethics Officer, as required.

- b. **Inquiry:** If the preliminary assessment identifies sufficient information to allow specific follow-up, the Inquiry process will be initiated an inquiry will consist 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 matter 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 culminating in an Investigation Report.
- d. **Determination and Reporting:** The President and CEO, or 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 will also 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, Roswell Park Cancer Research Corporation or HRI have a responsibility to report observed, suspected, or apparent research misconduct to the Ethics Officer. Individuals who are unsure whether a suspected incident falls within the definition of research misconduct should consult with the Ethics Officer, the General Counsel, 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. Persons who are the subject of allegations of research misconduct will be treated fairly and impartially; 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.

c. HHS, as required.

- 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 take all reasonable and practical efforts so 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 take all reasonable and practical efforts to 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.

The complainant may be interviewed during the Inquiry and the Investigation, be provided with a recording or transcript of the interview, if one is made, for correction, and the corrected transcript will be included in the Investigation record.

- iii. 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, Roswell Park shall provide the following notifications to all identified respondents:
 - a. Initiation of Inquiry - Prior to or at the beginning of the inquiry, the RIO shall provide the respondent(s) written notification of the inquiry. The Respondent(s) will be given a copy of the institutional policy and procedure for the handling of research misconduct allegations. 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. Comment on Inquiry Report - The respondent(s) shall be provided with an opportunity to comment on the Inquiry report in a timely fashion so that any comments can be attached to the report.

- c. Results of the Inquiry – The RIO shall notify the respondent(s) of the results of the Inquiry and provide a copy(ies) of the Inquiry Report for the respondent(s) review.
- d. Initiation of Investigation - Within a reasonable time after the determination that an Investigation is warranted, but not later than thirty (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 after determining to 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) will be notified that any comments must be submitted within 30 days of the date on which he/she received the draft report. The complainant, if any, shall also be provided with a copy of the draft investigation report or relevant portions of that report. The comments of the complainant, if any, must be submitted within thirty (30) days of the date on which the complainant received the draft investigation report or relevant portions of it. The comments from the respondent(s) and complainant will be included so as to be considered in the final Investigation Report.

e. Ensuring a Fair Research Misconduct Proceeding

- i. The Ethics Officer will take all reasonable steps to ensure an impartial and unbiased research misconduct proceeding to the maximum extent practicable, without compromising health and safety or the thorough execution of the Inquiry of Investigation. Roswell Park shall select those conducting the inquiry or investigation on the basis of scientific expertise that is pertinent to the matter and, prior to selection, shall screen them for any unresolved personal, professional, or financial conflicts of interest with the respondent, complainant, potential witnesses, or others involved in the matter. Any such conflict which a reasonable person would consider demonstrating potential bias shall disqualify the individual from selection.
- ii. 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 the respondent(s) interview(s) but **may not testify or comment.**

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. 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.

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. Maintenance and Custody of Research Records and Evidence of Misconduct

- i. Roswell Park shall take the following specific steps to obtain, secure, and maintain the research records and evidence pertinent to the research misconduct proceeding:
 - a. **Either before or at the time when Roswell Park notifies the respondent of the allegation, inquiry, investigation,** Roswell Park shall promptly take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding (including electronic devices), inventory those materials, and sequester them in a secure manner. When scientific instruments that are 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.
 - b. Where appropriate, Roswell Park will give the respondent copies of, or reasonable, supervised access to the research records.
 - c. Roswell Park will undertake all reasonable and practical efforts to take custody of additional research records and evidence discovered during the course of the research misconduct proceeding, including at the inquiry and investigation stages, or if new allegations arise, subject to the exception for scientific instruments in (a) above.
 - d. Roswell Park shall maintain all records of the research misconduct proceeding, as defined in 42 CFR Section 93.317(a) , for seven years after completion of the proceeding, or any ORI or HHS proceeding under Subparts D and E of 42 CFR Part 93 , whichever is later, unless Roswell Park has transferred custody of the records and evidence to HHS, or ORI has advised us that records no longer need to be retained.

i. Interim Protective Actions

At any time during a research misconduct proceeding, Roswell Park shall take appropriate interim actions to protect public health, federal funds and equipment, and the integrity of the PHS supported research process. The necessary actions will vary according to the circumstances of each case, but examples of actions that may be necessary include delaying the publication of research results, providing for closer supervision of one or more researchers, requiring approvals for actions relating to the research that did not previously require approval, auditing pertinent records, or taking steps to contact other institutions that may be affected by an allegation of research misconduct.

j. Notification of ORI of special circumstances that may require protective actions

- i. At any time during a research misconduct proceeding, Roswell Park shall notify ORI immediately if there is reason to believe that any of the following conditions exist:
 - a. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
 - b. HHS resources or interests are threatened.
 - c. Research activities should be suspended.
 - d. There is a reasonable indication of violations of civil or criminal law.
 - e. Federal action is required to protect the interests of those involved in the misconduct research proceeding.

- f. Roswell Park believes the research misconduct proceeding may be made public prematurely, so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
- g. Roswell Park believes the research community or public should be informed.

3. Procedures

a. Preliminary Assessment

- i. Upon receipt of an allegation of research misconduct, defined as a disclosure of possible research misconduct through any means of communication, the Ethics Officer will convene a meeting with the designee from the General Counsel's office, the Senior Vice President for Cancer Education and Training or SVP, and representative of the Department of Human Resources Management as soon as practical, to review the allegation and any information presented to determine if:
 - a. the allegation meets the definition of research misconduct in 42 CFR Section 93.103 (copy attached);
 - b. the allegation involves either the PHS supported research, applications for PHS research support, or research records specified in 42 CFR Section 93.102(b) (copy attached); and
 - c. the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

If the above criteria are met, the Ethics Officer will begin an inquiry to determine if there is sufficient evidence to warrant an Investigation.

- ii. Roswell Park will also conduct an assessment if the ORI, or any other Institution, forwards an allegation to Roswell Park alleging misconduct.
- iii. The preliminary assessment should be completed within five (5) calendar days of receipt of the allegation unless circumstances warrant more time.
- iv. If it is determined that there is not sufficient evidence to warrant an inquiry, the complainant(s) will be notified.

b. Committee for conducting an Inquiry and Investigation

- i. The Committee shall be appointed by the Ethics Officer and shall include:
 - a. the Ethics Officer,
 - b. the Senior Vice President for Cancer Education and Training (for cases involving trainees)
 - c. two (2) or 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 experts in the subject matter or scientific area,
 - e. a representative of Department of Human Resources Management,
 - 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, attorneys, or other qualified persons from inside or outside Roswell Park. The Ethics Officer notify the respondent(s) of the proposed Committee membership, when and if an Investigation is determined to be warranted. If the respondent(s) submits to the Ethics Officer a written objection to any appointed member of this Committee within three (3) calendar days, the Ethics Officer will determine whether to replace the challenged member or expert with another 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's preliminary assessment;
 - 4. States the factors that would warrant an investigation; and
 - 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) (copy attached).
- 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.

c. Inquiry

- i. If it is determined that an inquiry (i.e. an initial review of the evidence to determine if the criteria for conducting an investigation have been met) is warranted, the inquiry committee shall complete the inquiry, including preparation of the final inquiry report, within 60 calendar days of receipt of the allegation, unless the circumstances warrant a longer period. If this time frame is not possible in a particular case, the reasons for the delay are to be documented and the CEO so informed. The inquiry will function to determine if an investigation is warranted. 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).
- ii. The inquiry report shall be guided by:
 - a. Identification of any outside funding source(s) for the research that is the subject of the inquiry shall be identified.
 - b. Interviews of relevant individuals, including the complainant(s), if known.
 - c. Review of all research records and/or evidence collected by the Inquiry Committee. Those conducting the inquiry or investigation are to promptly 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.
 - d. Comments provided by the respondent or complainant. At the time of, or before the beginning of an inquiry, 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)").

Note: The documentation of the inquiry 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.

- iii. The final inquiry report shall include:
 - a. the name and position of the respondent(s);
 - b. a description of the allegations of research misconduct;
 - c. the PHS support involved, including for example, grant numbers, grant applications, contracts, and publications listing PHS support;
 - d. the basis for whether the alleged actions warrant an investigation or not; and
 - e. any comments on the report by the respondent or the complainant.

Note: The final report of the inquiry and a copy of the documentation are to be transmitted to the CEO and maintained by the Ethics Officer for seven years.

- iv. If the report of the Inquiry Committee recommends that a formal Investigation is warranted, the Ethics Officer shall:
 - a. Make a written determination of whether an investigation is warranted;
 - b. Notify the respondent(s);
 - c. Initiate a formal Investigation as provided in the procedures below; and
 - d. Where there is PHS funding, Roswell Park shall:
 - 1. Provide ORI with the written finding by the Inquiry committee and a copy of the inquiry report containing the information required by 42 CFR Section 93.309(a) on or before the date on which the investigation begins.
 - 2. Upon request, Roswell Park will provide: a copy of our institutional policies and procedures under which the inquiry was conducted; the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and the charges for the investigation to consider.
 - 3. 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.

d. Investigation

- i. If the inquiry leads to the conclusion that an investigation is warranted, the Ethics Officer shall begin the investigation within (30) calendar days of that determination and use its best efforts to complete the investigation and send the final report to the CEO within 90 days of the date on which it began. If an investigation cannot be completed within this time frame, the CEO should be notified as soon as possible.
- ii. Where there is PHS funding, the investigation must be completed within 120 calendar days of the date on which it began, including conducting the investigation, preparing the report of findings, providing the draft report for comment, and

sending the final report to ORI. If it becomes apparent that the investigation cannot be completed within that period, the Ethics Officer shall promptly request an extension in writing from ORI. This time period does not apply to separate termination hearings.

- iii. 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.
- iv. In conducting all investigations, the Investigation Committee shall:
 - a. 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 the allegations;
 - b. Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of investigation (any comments should be

- c. 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
- d. Otherwise comply with the requirements for conducting an investigation in 42 CFR Section 93.310.

- e. Investigation Report

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- b. Describe and document the PHS support, including, for example any grant numbers, grant applications, contracts, and publications listing PHS support;
- c. Describe the specific allegations of research misconduct considered in the investigation;
- d. Include the institutional policies and procedures under which the investigation was conducted, if not already provided to ORI;
- e. Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody, but not reviewed. **The report should also describe any relevant records and evidence not taken into custody and explain why.**
- f. Provide a finding as to whether research misconduct did or did not occur for each separate allegation of research misconduct identified during the investigation, and if misconduct was found,
 - 1. identify it as falsification, fabrication, or plagiarism and whether it was intentional, knowing, or in reckless disregard;
 - 2. summarize the facts and the analysis supporting the conclusion and consider the merits of any reasonable explanation by the respondent and any evidence that rebuts the respondent's explanations;
 - 3. identify the specific PHS support;
 - 4. identify any publications that 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(s) has pending with non-PHS Federal agencies; and
- g. Include and consider any comments made by the respondent(s) and complainant(s) (if applicable) on the draft investigation report.
- h. Include either the actual text or an accurate summary of the views of the respondent(s)
- i. Include a description of any proposed sanctions and recommended administrative actions.

Note: Roswell Park shall maintain and provide to ORI upon request all relevant research records and records of our research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.

Note: If sanctions may be warranted, the CEO shall refer the final report to 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 Ethics Officer shall be informed, and he or she should append that information to the final report.

- v. 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 designee, within a reasonable timeframe of receipt of the report. Such reply shall be incorporated as an appendix to the report of the Investigation Committee.
- vi. 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.

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 designee, the matter shall be closed and the concerned parties shall be informed.
 - ii. If the report of the Investigation Committee substantiates the allegations against the respondent(s), the President and CEO, or designee, will make the final determination whether to accept the Investigation report, its findings, and the recommended actions within thirty (30) business days of receipt of the final report. If this determination differs from that of the Committee, the President and CEO, or 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 designee, also may return the report to the Committee for further fact-finding or analysis.
 - iii. The determination of the President and CEO, or designee, together with the Committee's report, constitutes the final investigation report. Roswell Park will cooperate with and assist ORI and HHS, as needed, to carry out any administrative actions HHS may impose as a result of a final finding of research misconduct by HHS. Actions may range from suspension or termination of employment in 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 Ethics Officer will notify the respondent(s) and the complainant(s) in writing. In addition, the President & CEO, or 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. All aspects of the investigation, institutional review, and decision, including sending the final report to ORI where there is PHS funding, is to be completed within one-hundred twenty (120) days of beginning the investigation, unless the ORI grants an extension on the basis of Roswell Park 's written request.
 - vi. Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently.
- g. Restoring Reputations
Following the determination made by the CEO, efforts will be made to restore the reputations of those involved in the research misconduct proceeding.
- i. Respondents: Roswell Park shall undertake all reasonable, practical, and appropriate efforts to protect and restore the reputation of any person alleged to have engaged in research misconduct, but against whom no finding of research misconduct was made, if that person or his/her legal counsel or other authorized representative requests that Roswell Park does so.
 - ii. Complainants, Witnesses, and Committee Members: Roswell Park shall undertake all reasonable and practical efforts to protect and restore the position and reputation of any complainant, witness, or committee member and to counter potential or actual retaliation against those complainants, witnesses and committee members.

- h. 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 Ethics Officer 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. 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 thirty (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. Cooperation with ORI and Funding Agencies

- a. 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.
- b. In cases where allegations of research misconduct involve PHS funded research, Roswell Park shall cooperate fully and on a continuing basis with ORI during its oversight reviews of this institution and its research misconduct proceedings and during the process under which the respondent may contest ORI findings of research misconduct and proposed HHS

administrative actions. This includes providing, as necessary to develop a complete record of relevant evidence, all witnesses, research records, and other evidence under our control or custody, or in the possession of, or accessible to, all persons that are subject to our authority.

7. External Reporting Requirements

- a. In cases where allegations of research misconduct involve PHS funded research, Roswell Park will report to ORI any proposed settlements, admissions of research misconduct, or institutional findings of misconduct that arise at any stage of a misconduct proceeding, including the allegation and inquiry stages.
- b. 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 Ethics Officer to the extent feasible and appropriate in such cases. Absent such urgent need, Roswell Park will not make interim reports to outside agencies unless required by external regulation.
- c. In accordance with the requirements of federal funding agencies, in cases involving research funded by those agencies, the agency will be informed in the situations listed below. Except as specifically described at the end of this section, the following notifications to federal funding agencies will be made only by the Ethics Officer, acting on behalf of the CEO:
 - i. Outcome of an Inquiry
 - a. 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.
 - ii. Commencement of an Investigation
 - a. 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.
 - iii. Written Request for a Time Extension
 - a. Regulations generally permit one-hundred twenty calendar (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 Ethics Officer 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.

- iv. Interim Reports
 - a. 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.
- v. Early Termination
 - a. 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.
- vi. Final Outcome
 - a. 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.
 - b. 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.
- vii. Premature Closures to ORI
 - a. 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, 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

8. 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 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.