

**FRED HUTCHINSON CANCER RESEARCH CENTER
RESEARCH MISCONDUCT POLICY AND PROCEDURES**

RESTATED 3/14/07

POLICY STATEMENT

In all of its research activities, Fred Hutchinson Cancer Research Center (the "Center") expects the highest standards of professional conduct. The enterprise of scientific research relies upon the trust and confidence of both the scientific community and the public at large. Unethical behavior undermines confidence in the reliability of science and the integrity of the Center. For these reasons, the Center considers misconduct in science a betrayal of fundamental scientific principles and shall deal with all instances of possible research misconduct firmly in accordance with the Center's Research Misconduct Policy and Procedures ("Policy"). Situations that do not constitute research misconduct may be reviewed under the Center's other policies, including but not limited to the Center's Research Integrity Policy and Procedures. In some cases, the alleged conduct under review may be subject to both this Policy and the Center's Research Integrity Policy.

BACKGROUND

This Policy is developed to prevent, detect and deal with possible research misconduct in the Center's research programs. It is designed to balance the need to deal firmly and effectively with allegations of possible research misconduct with the need for openness and creativity in the scientific enterprise. In responding to allegations of research misconduct, the Center also must comply with all applicable laws and regulatory requirements of federal agencies supporting the research in question, as well as Center policies and procedures. In cases involving research funded by the U.S. Department of Health and Human Services ("HHS"), the Office of Research Integrity ("ORI") oversees the Center's compliance with HHS research misconduct regulations (See Exhibit "A"). In cases involving research funded by the National Science Foundation ("NSF") (See Exhibit "B") and other federal agencies, the Office of the Inspector General ("OIG") generally carries out enforcement of research misconduct regulations. This Policy will refer throughout simply to ORI except in those instances in which the procedures mandated by NSF regulations differ from those imposed by HHS.

The Center's President and Director ("Director") has the final authority and responsibility for defining the ethical standards for the Center.

This Policy replaces in its entirety the Center's prior policy dated September 24, 2003.

PREVENTION

The Center expects intellectual honesty in all of its endeavors. All employees should maintain open communication, submit work for peer review, disclose and cooperate in the management of conflicts of interest, commit to self-regulation, and comply with Center processes for the disclosure and management of conflicts of interest. (See: http://www.fhcrc.org/intranet/general_counsel/conflict_interest_2002.pdf)

The Center shall educate and inform all employees regarding its ethical standards, its guidelines for conducting and reporting research, its philosophy and policy of dealing with and reporting possible research misconduct and the importance of complying with the relevant policies and procedures.

As a regular element of its policy of maintaining the highest possible standard of scientific productivity, the Center will continue to maintain a regular and rigorous system of review of the quality of the scientific programs of its investigators.

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The Center's Director shall appoint a Research Integrity Officer to (i) assist with the education of all staff and employees regarding the Center policies and procedures relating to research misconduct; (ii) provide clarification and information to individuals with concerns regarding potential incidents of misconduct; (iii) assist individuals in understanding the Center's policies and procedures in this area; (iv) assist with the administration of this Policy including inquiries and investigations conducted pursuant to this Policy; and (v) provide mediation services where indicated.

The Center shall periodically evaluate its policy and procedures for educating its staff about the proper conduct of research and assess whether additional efforts are necessary.

DEFINITION OF RESEARCH MISCONDUCT

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

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

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

Research misconduct does not include honest error or honest differences in interpretations or judgments of data.

A finding of research misconduct requires that (i) there is a significant departure from accepted practices of the relevant research community; (ii) the misconduct is committed intentionally, knowingly, or recklessly; and (iii) the allegation of research misconduct is proven by a preponderance of the evidence. There may be a different standard of proof for misconduct under other Center policies.

PROCEDURES

The procedures described in this Policy represent the general approach to be employed by the Center in instances of possible research misconduct, since no policy and procedures can anticipate every possible issue that might arise in the course of an inquiry or investigation. The Center's Director is responsible for implementing these procedures and modifying them as necessary to ensure adherence to the Policy.

I. CONFIDENTIALITY

To the extent allowed by law, the Center shall maintain the identity of the individual(s) against whom the allegation of research misconduct is made ("respondents") and the individual(s) bringing forward the allegation ("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.

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.

The Center prohibits retaliation of any kind against a person who, acting in good faith, reports or provides information about suspected misconduct.

II. RESEARCH MISCONDUCT PROCEEDINGS—CRITERIA, REPORTS, AND TIME LIMITATIONS¹

A. Preliminary Assessment

Disclosures of possible research misconduct received by the Center through any means of communication (“Allegation”) shall be promptly referred to the director of the division in which the alleged research misconduct occurred (“Division Director”). The Division Director shall assess the Allegation to determine if:

1. it meets the definition of research misconduct²;
2. it involves Public Health Service (“PHS”) supported research, applications for PHS research support, or research records³;
3. it is sufficiently credible and specific so that potential evidence of research misconduct may be identified; and
4. it is timely.⁴

If the Division Director determines that these criteria have not been met, then the matter will not proceed to inquiry and may be reviewed under the Center’s other policies, including but not limited to the Center’s Research Integrity Policy and Procedures. If the Center’s Division Director determines that these criteria have been met, then the matter will proceed to inquiry.

B. Inquiry⁵

An inquiry is an initial review of the evidence to determine if the criteria for conducting an investigation have been met. The criteria for determining whether or not an investigation may be required include a finding that:

1. There is a reasonable basis for concluding that the Allegation falls within this Policy’s definition of research misconduct; and
2. The preliminary review of the facts indicates that the Allegation has substance.

The Center shall complete the inquiry, including preparation of the inquiry report and giving the respondent a reasonable opportunity to comment on it, within sixty (60) calendar days of its initiation, unless the circumstances warrant a longer period. If the inquiry takes longer than sixty (60) days to complete, the Center shall include documentation of the reasons for the delay in the inquiry record.

The inquiry report shall contain the following information:

1. The name and position of the respondent;
2. A description of the Allegation of research misconduct;
3. The PHS support involved, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support;
4. The basis for recommending that the alleged actions warrant an investigation; and
5. Any comments on the report by the respondent or the complainant.

The Center’s Director will make a written determination of whether an investigation is warranted. If the Center’s Director determines that an investigation is not warranted, then the matter may be reviewed

¹ NSF proceeding requirements can be found in 45 CFR Section 689.4 and Section 689.6 (See Exhibit B). In absence of any specific requirements, the Center may follow the HHS requirements.

² The definition of research misconduct can be found above and in 42 CFR Section 93.103 (See Exhibit A) and/or in 45 CFR Section 689.1 (See Exhibit B).

³ HHS describes research in 42 CFR Section 93.102(b) (See Exhibit A). NSF describes research in 45 CFR Section 689.1 (See Exhibit B).

⁴ In cases involving PHS supported research, the time limitations can be found in 42 CFR Section 93.103 (See Exhibit A).

⁵ NSF time limitations and extensions for an inquiry can be found in 45 CFR Section 689.4 (See Exhibit B).

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under the Center's other policies, including but not limited to the Center's Research Integrity Policy and Procedures, if warranted in the sole discretion of the Center's Director.

C. Investigation⁶

If the Center's Director determines that an investigation is warranted, then the Center shall begin the investigation within thirty (30) calendar days of that determination and, on or before the date on which the investigation begins, send the inquiry report and the written determination to ORI. The Center shall use its best efforts to complete the investigation within one hundred and twenty (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 Center cannot complete the investigation within that period, the Center shall promptly request an extension in writing from ORI.

In conducting all investigations, the Center shall:

1. Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the Allegation;
2. 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;
3. 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
4. Otherwise comply with the requirements for conducting an investigation⁷.

The Center shall prepare the draft and final institutional investigation reports in writing and provide the draft report for comment as provided elsewhere in these policies and procedures and as required by law⁸. The final investigation report shall:

1. Describe the nature of the Allegation of research misconduct;
2. Describe and document the PHS support, including, for example any grant numbers, grant applications, contracts, and publications listing PHS support;
3. Describe the specific Allegation of research misconduct considered in the investigation;
4. Include the Center's policies and procedures under which the investigation was conducted, if not already provided to ORI;
5. 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.
6. 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:
 - a. identify it as falsification, fabrication, or plagiarism and whether it was intentional, knowing, or in reckless disregard;
 - b. 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;
 - c. identify the specific PHS support;

⁶ NSF requirements for an inquiry can be found in 45 CFR Section 689.4 (See Exhibit B).

⁷ HHS requirements for conducting an investigation can be found in 42 CFR Section 93.310 (See Exhibit A).

NSF requirements for conducting an investigation can be found in 45 CFR Section 689.6 (See Exhibit B).

⁸ HHS requirements for investigation reports can be found in 42 CFR Section 93.312 (See Exhibit A). NSF requirements for investigation reports can be found in 45 CFR Section 689.6 (See Exhibit B).

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- d. identify any publications that need correction or retraction;
 - e. identify the person(s) responsible for the misconduct, and
 - f. list any current support or known applications or proposals for support that the respondent has pending with non-PHS Federal agencies.
7. Include and consider any comments made by the respondent and complainant on the draft investigation report.

The Center shall maintain and provide to ORI upon request all relevant research records and records of the Center's research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.

III. ENSURING A FAIR RESEARCH MISCONDUCT PROCEEDING

The Center shall take all reasonable steps to ensure an impartial research misconduct proceeding to the maximum extent practicable. The Center shall select those conducting the inquiry or investigation on the basis of scientific expertise that is pertinent to the matter and, prior to selection, the Center 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 to demonstrate potential bias shall disqualify the individual from selection.

A. Notice to Respondent and Complainant⁹.

During the research misconduct proceeding, the Center shall provide the following notifications to all identified respondents¹⁰:

B. Initiation of Inquiry.

Prior to or at the beginning of the inquiry, the Center shall provide the respondent written notification of the inquiry and contemporaneously sequester all research 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.

C. Comment on Inquiry Report.

The Center shall provide the respondent, and may provide complainant at the Center's discretion, an opportunity to comment on the inquiry report in a timely fashion so that any comments can be attached to the report. If there is more than one respondent, then the Center may prepare separate reports to preserve confidentiality.

D. Results of the Inquiry.

The Center shall notify the respondent, and may notify the complainant at the Center's discretion, of the results of the inquiry and attach to the notification copies of the inquiry report and the Center's policies and procedures for the handling of research misconduct Allegations.

E. Initiation of Investigation.

Within a reasonable time after the Center's determination that an investigation is warranted, but not later than thirty (30) calendar days after that determination, the Center shall notify the respondent, and may notify the complainant at the Center's discretion, in writing of the Allegation to be investigated.

The Center shall give respondent written notice of any new Allegation within a reasonable time after determining to pursue any Allegation not addressed in the inquiry or in the initial notice of the investigation.

⁹ NSF notification requirements can be found in 45 CFR Section 689 (See Exhibit B).

¹⁰ ORI notification requirements can be found in 42 CFR Section 93.309(a) (See Exhibit A). NSF notification requirements can be found in 45 CFR Section 689 (See Exhibit B).

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F. Scheduling of Interview.

The Center will notify the respondent sufficiently in advance of the scheduling of his/her interview in the investigation so that the respondent may prepare for the interview and arrange for the attendance of legal counsel at his/her own expense, if the respondent wishes.

G. Comment on Draft Investigation Report.

The Center shall give the respondent, and may provide the complainant at the Center's discretion, a copy of the draft investigation report, and concurrently, a copy of, or supervised access to, the evidence on which the report is based and notify the respondent and complainant that any comments must be submitted within thirty (30) days of the date on which he/she received the draft report. If there is more than one respondent, then the Center may prepare separate reports to preserve confidentiality. The Center shall ensure that these comments are included and considered in the final investigation report.

IV. NOTIFYING ORI OF THE DECISION TO OPEN AN INVESTIGATION AND OF INSTITUTIONAL FINDINGS AND ACTIONS FOLLOWING THE INVESTIGATION

On or before the date on which the investigation begins (the investigation must begin within thirty (30) calendar days of the Center's finding that an investigation is warranted), the Center shall provide ORI with the written finding by the Center's Director and a copy of the inquiry report containing the information required by law¹¹. Upon a request from ORI, the Center shall promptly send to ORI:

1. a copy of the Center's policies and procedures under which the inquiry was conducted;
2. the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and
3. the charges for the investigation to consider.

The Center shall promptly provide to ORI after the investigation:

1. a copy of the investigation report and all attachments;
2. a statement of whether the Center found research misconduct and, if so, who committed it;
3. a statement of whether the Center accepts the findings in the investigation report; and
4. a description of any pending or completed administrative actions against the respondent.

V. MAINTENANCE AND CUSTODY OF RESEARCH RECORDS AND EVIDENCE¹²

The Center 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 when the Center notifies the respondent of the Allegation, the Center shall promptly take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory those materials, and sequester them in a secure manner. As an exception, in those cases where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

B. Where appropriate, the Center shall give the respondent copies of, or reasonable, supervised access to the research records.

C. The Center shall 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.

¹¹ See 42 CFR Section 93.309(a) (See Exhibit A) and/or 45 CFR Section 689.4 (See Exhibit B).

¹² NSF requirements for records and evidence can be found in 45 CFR Section 689 (See Exhibit B).

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D. The Center shall maintain all records of the research misconduct proceeding¹³, for seven (7) years after completion of the proceeding, or any ORI or HHS proceeding¹⁴, whichever is later, unless the Center has transferred custody of the records and evidence to HHS, or ORI has advised the Center that it no longer need to retain the records.

VI. INTERIM PROTECTIVE ACTIONS

At any time during a research misconduct proceeding, the Center 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.

VII. NOTIFYING ORI OF SPECIAL CIRCUMSTANCES THAT MAY REQUIRE PROTECTIVE ACTIONS¹⁵

At any time during a research misconduct proceeding, the Center shall notify ORI immediately if the Center has 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 research misconduct proceeding.
- F. The Center 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. The Center believes the research community or public should be informed.

VIII. INSTITUTIONAL ACTIONS IN RESPONSE TO FINAL FINDINGS OF RESEARCH MISCONDUCT

The Center will cooperate with and assist ORI and HHS as needed, to carry out any administrative actions those agencies may impose as a result of a final finding of research misconduct.

Violations of this Research Misconduct Policy and Procedures may result in discipline up to and including termination of employment.

Situations that do not constitute research misconduct may be reviewed under the Center's other policies, including but not limited to the Center's Research Integrity Policy and Procedures.

IX. RESTORING REPUTATIONS

- A. Respondents. The Center shall undertake all reasonable 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 the Center do so.
- B. Complainants, Witnesses, and Committee Members. The Center shall undertake all reasonable efforts to protect and restore the position and reputation of any complainant, witness, or committee

¹³ The HHS definition for records is defined in 42 CFR Section 93.317(a) (See Exhibit A).

¹⁴ The HHS description of proceedings can be found in Subparts D and E of 42 CFR Part 93 (See Exhibit A).

¹⁵ NSF notification requirements can be found in 45 CFR Section 689 (See Exhibit B).

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member and to counter potential or actual retaliation against those complainants, witnesses and committee members.

X. COOPERATION WITH ORI¹⁶

The Center 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 the Center's control or custody, or in the possession of, or accessible to, all persons that are subject to the Center's authority.

Reporting to ORI The Center will report to ORI any proposed settlements, admissions of research misconduct, or the Center's findings of misconduct as required by law.

Exhibit A: 42 CFR Part 93 (See: http://ori.dhhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf)

Exhibit B: 45 CFR Section 689 (See: <http://www.nsf.gov/oig/resmisreg.pdf>)

¹⁶ The Center will cooperate with NSF as required under 45 CFR Section 689 (See Exhibit B).