



## Policy and Procedures for Responding to Allegations of Research Misconduct

### General Policy

MSKCC is committed to the responsible conduct of research, and has policies and procedures in place for responding to allegations of misconduct in science. Allegations of research misconduct will be reviewed promptly, thoroughly, and objectively, with concern for the rights, reputations, and privacy of all those involved.

This document describes the MSKCC policies and procedures that guide the manner in which all allegations of misconduct in science are handled, regardless of the funding source. It is written to conform to federal regulations (see 42 CFR Part 93 “Public Health Service Policies on Research Misconduct” or [www.ori.dhhs.gov/documents/42\\_cfr\\_parts\\_50\\_and\\_93\\_2005.pdf](http://www.ori.dhhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf)), as is required for managing misconduct proceedings that involve research support from agencies of the U.S. Public Health Service (PHS), including the National Institutes of Health. If the source of funding for the work in question is not an agency of the U.S. Public Health Service, these policies and procedures will be followed, but reporting to the Office of Research Integrity (ORI), PHS, is not required.

### Definition of Research Misconduct

Misconduct in science is defined as fabrication, falsification, or plagiarism in proposing, performing, or 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.

Research misconduct does not include honest error, differences in opinion, or authorship or collaboration disputes.

### The Principals Responsible for Managing Misconduct Proceedings

Research at MSKCC is conducted under the auspices of either the Sloan-Kettering Institute (SKI) or Memorial Hospital (MH), or both, and is overseen by Program Chairs (in SKI) or Department Chairs (in Memorial Hospital) and by subordinate laboratory heads and service chiefs.

When allegations of misconduct arise, a number of individuals with oversight of research may become involved, but the person with primary responsibility is the Vice President, Research and Technology Management, who is the Research Integrity Officer (RIO). The RIO is responsible for assessing allegations of research misconduct, overseeing inquiries and investigations and other matters described in this policy.

The Director of SKI is the Deciding Official (DO) when allegations are primarily related to laboratory research, and the Physician-in-Chief is the DO when allegations are primarily related to clinical research (i.e., research involving human subjects). When the allegation pertains to both laboratory research and clinical research, the RIO will consult with both the Director of SKI and the Physician-in-Chief and together they will determine which of them will serve as the DO. The DO is the institutional official who makes final determinations on allegations of research misconduct and on

any institutional administrative action that may be taken as a result of the misconduct proceedings. Throughout this document, reference to DO will signify the appropriate DO to handle research misconduct allegations involving laboratory research, clinical research, or both.

## **Confidentiality**

Disclosure of the identity of those who are accused of research misconduct and those who raise allegations of misconduct is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective, and fair research misconduct proceeding. To the maximum extent possible, 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 misconduct proceedings.

## **The Steps in Handling Misconduct Proceedings**

### *(1) Allegations:*

Allegations may be raised by anyone who believes that research misconduct has been committed. The individual(s) who makes such allegations is termed the complainant(s). Allegations of research misconduct should be brought to the attention of the supervisor of the individual(s) whose actions are in question, to the relevant Program Chair or Department Chair, or directly to the RIO. Allegations may be conveyed either orally or in writing. An allegation including the following information is most useful: the name of the person(s) about whom the allegation is made (termed the respondent[s]), the name of the complainant(s), the names of potential witnesses, and a description of the alleged misconduct.

If the RIO is not the original recipient of the allegations, the individual who received the allegations shall immediately inform the RIO.

### Assessing Allegations:

The RIO is responsible for assessing allegations of misconduct. The assessment should be concluded within a week, if possible. This assessment shall include consideration as to whether the allegation(s) falls under the definition of research misconduct described earlier in this document and whether the allegation is sufficiently credible and specific enough so that potential evidence of research misconduct may be identified. If the RIO determines that these criteria are met, the RIO will immediately initiate the inquiry process.

If, during the initial assessment, the RIO and the DO agree that the likelihood of misconduct is sufficiently strong, it is possible to move directly to the investigation phase without an inquiry.

During the assessment, the RIO will also ascertain whether the research in question involves PHS funding jurisdiction.

### *(2) Inquiry:*

#### Initiating an Inquiry:

The inquiry should begin immediately after the RIO determines, based on the assessment, that an inquiry should be undertaken. The purpose of an inquiry is to make a preliminary evaluation of the available evidence and the testimony of the complainant(s), the respondent(s), and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation.

The scope of an inquiry does *not* normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct, or conducting exhaustive interviews and analyses.

### Notifying the Respondent(s) and Sequestering Records:

At the time of or before beginning an inquiry, the RIO shall notify the respondent(s) in writing, if the respondent(s) is known. The RIO shall take all practical and reasonable steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner.

### Selecting and Charging the Inquiry Committee:

The RIO, in consultation with the Deciding Official (DO), may convene an Inquiry Committee to conduct the inquiry. An Inquiry Committee is not always required, however, and the decision to convene such an Inquiry Committee should be made by the RIO and DO. Usually, but not necessarily, the Inquiry Committee will be composed of MSKCC staff members. The Inquiry Committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with the complainant(s) or the respondent(s) named in the inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegations.

At the Inquiry Committee's first meeting, the RIO will review the charge with the Committee, describe the allegations and any related issues, and discuss the appropriate procedures for conducting the inquiry.

### Performing an Inquiry:

The inquiry phase of a misconduct proceeding (including preparation of the final inquiry report and the determination of the DO as to whether an investigation is warranted) should be completed within 60 days of the decision to begin an inquiry, unless an extension is approved by the RIO. The RIO must document why an extension was granted.

The Inquiry Committee will normally interview the complainant(s), the respondent(s), and pertinent witnesses, as well as examine relevant research records and materials. The Inquiry Committee will then evaluate the evidence, recommend whether an investigation is warranted, and prepare a written report as described below. An investigation is warranted if there is a reasonable basis for concluding that 1) the allegation falls within the definition of research misconduct noted earlier in this policy and 2) the preliminary fact-finding from the inquiry indicates that the allegation may have substance.

### Providing Materials to the Respondent(s) and Complainant(s):

The RIO shall notify the respondent(s) as to whether the Inquiry Committee has found that an investigation is warranted, and will provide a copy of the draft report of the preliminary inquiry to the respondent(s) for comment. The respondent(s) should be given 10 days to reply. The RIO shall also give the respondent(s) a copy of 42 CFR Part 93 (if the misconduct proceedings involve PHS funding jurisdiction) and a copy of this Policy.

The complainant(s) must be given an opportunity to review any summaries of interviews with him/her and be given a chance to comment. If the RIO so chooses, the complainant(s) may also be notified as to whether the inquiry found an investigation to be warranted and may be provided with the draft report for comment.

A written confidentiality agreement must be a condition for access to the draft report on the part of the respondent(s) and/or the complainant(s).

### Preparing the Inquiry Report:

The final written inquiry report must include the following information: the name and position of the respondent(s); a description of the allegations; the PHS support (if any); the basis for recommending or not recommending that the allegations warrant an investigation; and any comments on the draft report by the respondent(s) and/or complainant(s). It should also include the names and titles of the members of the Inquiry Committee, a list of the research records reviewed, summaries of any interviews, and a statement as to whether any other actions should be taken if an investigation is not recommended.

### Determination by the Deciding Official:

The RIO will transmit the final inquiry report to the Deciding Official (DO). Based on the final inquiry report, including comments from the respondent(s) and/or complainant(s), if any, and, as an option, discussion with members of the Inquiry Committee, the DO will issue in writing a determination as to whether an investigation is warranted. The inquiry is completed when the DO issues this determination.

### Notifying the Office of Research Integrity (ORI) Following an Inquiry:

If the DO determines that an investigation is warranted and the research in question falls under PHS funding jurisdiction, the RIO will provide ORI with the DO's decision and a copy of the final inquiry report. This reporting must be done within 30 calendar days of the DO's decision.

If the DO decides that there is insufficient evidence of possible misconduct to warrant an investigation, ORI does not need to be notified. Also, if there is no PHS funding jurisdiction, regardless of the DO's final decision, ORI does not need to be notified.

If the respondent(s) admits to misconduct at the inquiry stage of the process and the DO decides that no further investigation is necessary, the DO must report this determination to ORI (provided PHS has funding jurisdiction) and state why the institution believes that no further investigation is necessary. If ORI consents, the case shall be closed.

If the DO decides that an investigation is not warranted, the RIO shall secure and maintain for seven years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted.

### *(3) Investigation:*

#### Initiating an Investigation:

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted.

The purpose of the investigation is to explore the allegations in detail, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation shall also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the allegations.

This is especially important in cases that involve clinical trials, or potential harm to human subjects or the general public.

#### Notifying the Respondent(s) and Sequestering Records:

On or before the date on which the investigation begins, the RIO must notify the respondent(s) in writing of the allegations to be investigated. The RIO must also give the respondent(s) written notice of any new allegations of research misconduct not addressed in the inquiry.

The RIO will take steps to obtain custody of and sequester all research records and evidence that were not previously sequestered during the inquiry.

#### Selecting and Charging the Investigation Committee:

The RIO, in consultation with the DO, will appoint an Investigation Committee as soon after the beginning of the investigation as practical.

The Investigation Committee should consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those named in the investigation, and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation. Individuals appointed to the Investigation Committee may have served on the Inquiry Committee. The members may come from institutions other than MSKCC. The RIO will define the subject matter of the investigation in a written charge to the Committee that:

- describes the allegations and related issues identified in the inquiry;
- identifies the respondent(s);
- defines research misconduct;
- informs the Committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
- informs the Committee that, in order to determine that the respondent(s) committed research misconduct, it must find that a preponderance of the evidence establishes that:
  - 1) research misconduct, as defined in this policy, occurred;
  - 2) the research misconduct is a significant departure from accepted practices of the relevant research community; and
  - 3) the respondent(s) committed the research misconduct intentionally, knowingly, or recklessly; and
- informs the Committee that it must prepare a written investigation report that meets the requirements of this policy.

#### Conducting the Investigation:

The RIO will convene the first meeting of the Investigation Committee to review the charge, the final inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality.

The Investigation Committee and the RIO must:

- use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;
- take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
- interview each respondent, complainant, and any other available witnesses, transcribe each interview, provide the transcript to each interviewee for correction, and include the transcript in the record of the investigation; and,
- pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct.

The investigation is to be completed within 120 days of its beginning. This 120-period includes conducting the investigation, preparing the report of findings, providing the draft report to the respondent(s) for comment, and sending the final report to ORI. If the RIO determines that the investigation will not be completed within this 120-day period, that time frame may be extended. If the investigation relates to research funded by PHS, the RIO must seek such an extension from ORI.

#### Preparing the Investigation Report:

The Investigation Committee and the RIO are responsible for preparing a written draft report of the investigation that:

- describes the nature of the allegations of misconduct, including identification of the respondent(s);
- describes and documents PHS support, if any;
- describes the specific allegations of research misconduct considered in the investigation;
- includes this MSKCC policy and procedures document;

- identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
- includes a statement of findings for each allegation of research misconduct identified during the investigation.

Each statement of findings must:

- 1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly;
- 2) summarize the facts and analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent(s), including any effort by the respondent(s) to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or difference of opinion;
- 3) identify the specific PHS support, if any;
- 4) identify whether any publications need to be corrected or retracted;
- 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.

#### Giving the Respondent(s) and Complainant(s) an Opportunity to Comment:

The RIO must give the respondent(s) a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to, the evidence on which the draft investigation report is based. The respondent(s) shall be allowed 30 days from the date he/she receives the draft report to submit comments to the RIO. If the RIO so chooses, the complainant(s) may be given a copy of the draft report or relevant portions of it for comment. Any comments from the respondent(s) or the complainant(s) must be included in the final report.

A written confidentiality agreement must be a condition for access to the draft investigation report on the part of the respondent(s) and/or the complainant(s).

#### Making Final Determinations:

The DO will, in writing, determine: 1) whether the institution accepts the investigation report and its findings and 2) the appropriate institutional actions in response to any accepted findings of research misconduct. If the decisions of the DO vary from the findings or recommendations of the Investigation Committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the conclusions of the Investigation Committee. Alternatively, the DO may return the report to the Investigation Committee with a request for further fact-finding or analysis before making a final determination.

Once a final decision on the case has been reached by the DO, the RIO will notify both the respondent(s) and the complainant(s) in writing. As part of this notification, if the case falls under the funding jurisdiction of PHS, the respondent(s) will be provided with a copy of 42 CFR Part 93, "Public Health Service Policies on Research Misconduct," for reference to actions that may be taken by PHS on the basis of research misconduct proceedings conducted at the institutional level.

#### Reporting to the Office of Research Integrity (ORI):

If the investigation involves research under PHS funding jurisdiction, the RIO must, within the 120-day period for the investigation, submit the following to ORI:

- 1) a copy of the final investigation report with all attachments;
- 2) a statement as to whether the institution accepts the findings of the investigation report;
- 3) a statement as to whether the institution found misconduct and, if so, who committed the misconduct; and
- 4) a description of any pending or completed administrative actions against the respondent(s).

### Appealing a Misconduct Determination:

The respondent(s) has 20 days after receiving the final determination on the case to appeal the decisions to the DO in writing. The DO will have 120 days to reach a decision on the appeal.

If there is an appeal in a case involving PHS funding jurisdiction, the report of the investigation and the report of the outcome of the appeal shall be submitted to ORI within 120 days after the appeal is made by the respondent, unless the institution requests and receives an extension from ORI.

### Notifying Relevant Parties and Maintaining Records:

After a final decision on the case is reached, the RIO is responsible for determining whether law enforcement agencies, professional societies, professional licensing boards, editors of involved journals, collaborators of the respondent(s), or other relevant parties should be notified of the outcome of the case.

The RIO is responsible for maintaining and providing to ORI upon request (if the matter involves PHS funding jurisdiction) all relevant research records and records of the institution's research misconduct proceedings, including the results of all interviews and the transcripts or recordings of those interviews. Such records must be maintained for seven years after the misconduct proceeding is concluded.

## **Other Considerations**

### Continuing the Proceeding if the Respondent(s) Leaves the Institution:

If the respondent(s) terminates institutional employment at any time during the research misconduct proceedings, either by resignation or otherwise, the proceedings shall continue. If the respondent(s) refuses to participate in the misconduct proceedings after terminating employment, the RIO and an Inquiry or Investigation Committee will continue to use their best efforts to reach a conclusion concerning the allegations.

### Notifying ORI of Special Circumstances:

The RIO shall immediately notify ORI if, at any time during the research misconduct proceeding, the RIO has reason to believe that any of the following conditions exist: the health or safety of the public is at risk, including an immediate need to protect human or animal subjects; PHS resources or interests are threatened; research activities should be suspended; there is indication of possible violations of civil or criminal law; federal action is required to protect the interests of those involved in the research misconduct proceeding; the research misconduct proceeding may be made public prematurely and PHS action may be necessary to safeguard evidence and protect the rights of those involved; or the research community or public should be informed.

### Protecting the Complainant(s), Respondent(s), Witnesses and Committee Members:

Following a final finding of no research misconduct, including (where the matter involves PHS funding jurisdiction) concurrence by ORI, the RIO must, at the request of the respondent(s), undertake all reasonable and practical efforts to restore the reputation of the respondent(s). This might include notifying those individuals aware of or involved in the investigation of the final outcome and expunging all reference to the research misconduct allegation from the personnel file of the respondent(s).

During the research misconduct proceeding, and upon its completion, regardless of whether the institution or ORI determines that research misconduct occurred, the RIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant(s) who made allegations of research misconduct and of any witnesses and committee members who cooperated with the research misconduct proceeding.