## Guidelines and Procedures for Responding to Allegations of Research Misconduct<sup>1</sup>

February 11, 2009

<sup>&</sup>lt;sup>1</sup> Formerly, <u>Operating Rules and Procedures of the Standing Committee on Research Misconduct</u>

## **Table of Contents**

I. Introduction	4
A. General Policy	4
B. Scope	
II. Definitions	
A. Research	
B. Research Misconduct	
C. Public Health Service Office of Research Integrity (PHS/ORI)	
III. Roles and Responsibilities	
A. Research Integrity Officer	
B. Standing Committee on Research Misconduct	
C. Deciding Official	
D. Complainant	
E. Respondent	
IV. General Policies and Principles	
A. Responsibility to Report Misconduct	
B. Cooperation with Research Misconduct Proceedings	
C. Confidentiality	
D. Non-Retaliation	
E. Interim Administrative Actions and Notifying PHS/ORI of Special	10
Circumstances	10
V. The Standing Committee on Research Misconduct	
A. Composition and Appointment	
B. Meeting Schedule	
C. Voting Procedures	
D. Conflict of Interest or Bias	
E. Role of the University Counsel	
F. Amendments to the Guidelines and Procedures	
G. Education of the Academic Community	
VI. Conducting an Assessment & Inquiry	
A. Procedures for Making Allegations B. Initial Review	
C. Conduct of Inquiry	
1. Notice to Respondent	
2. Protection of Evidence	
3. Inquiry Process – General Requirements	
D. Inquiry Procedures	
1. Stage One	
2. Stage Two	
E. The Inquiry Report	
1. Content of Inquiry Report	
2. Solicitation of Comments	18

	-
1. Notification to Complainant and Respondent	9
2. Notification to PHS/ORI (if applicable)19	
VII. Investigative Phase	
A. Initiation and Purpose	
B. Appointment of Investigative Committee	0
C. Charge to the Investigative Committee	
D. Investigative Process	
E. Time for Completion22	
VIII. The Investigation Report23	
A. Decision by the Investigative Committee23	
B. Referral to SCRM	
C. Comments on the Investigative Report and Access to Evidence24	4
1. Respondent24	
2. Complainant	
IX. Disposition by the SCRM	
X. Final Disposition	
A. Decision by the DO	5
B. Communication of Decision	
C. Appeals	6
D. Notice to PHS/ORI or Other Funding Agencies of Institutional Findings and	
Actions	6
Appendix A: Research Integrity Officer Responsibilities	8
I. General	
II. Notification, Reporting and Cooperation with PHS/ORI	8
III. Research Misconduct Proceeding	
A. General29	
B. Allegation Receipt	
C. Inquiry	
D. Investigation	

## I. Introduction

## A. General Policy

The University of Colorado at Boulder, herein referred to as the "University," has the responsibility to foster a research environment that promotes the responsible conduct of research, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.

To fulfill its obligations and ensure the public trust, the University must prevent, identify, and investigate research misconduct. The University obligations arise under Article V of the Laws of the Regents, *University of Colorado Administrative Policy Statement on Misconduct in Research and Authorship* and the requirements of federal agencies, including the National Institutes of Health/Public Health Service and the National Science Foundation.

The faculties of the schools and colleges of the University have formed a joint committee—the Standing Committee on Research Misconduct (SCRM)—to fulfill its obligation of investigating allegations of research misconduct. These Guidelines and Procedures are intended to provide guidance with respect to the manner in which the University, through the SCRM, will carry out these responsibilities.

Nothing in these Guidelines and Procedures is intended to override or contradict provisions of other regulations or policies of the University of Colorado or of funding agencies.

Although these Guidelines and Procedures set forth the presumptive time frames for the conduct of proceedings before the SCRM or any committees that the SCRM appoints, these time frames are not absolute and may be modified as necessary for the SCRM or its committees to adequately perform their functions. Failure to complete an inquiry, investigation, or other process within these time frames shall not be grounds for dismissal of an allegation of research misconduct, but any undue delay may be considered by the SCRM or other appropriate official when reviewing the SCRM's findings and recommendations.

### **B.** Scope

These Guidelines and Procedures apply to:

- 1. any person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with the University of Colorado at Boulder.
- 2. any person who is alleged to have committed research misconduct prior to his or her employment, agency or affiliation with the University of

Colorado at Boulder, provided the SCRM determines that such allegations of research misconduct have the potential to impact the reputation of the University.

The University has academic dishonesty procedures that generally take precedence for allegations involving student course work.

In the event that potential research misconduct is alleged to have occurred in the course of federally-funded research, the SCRM shall attempt to comply with both these Guidelines and Procedures and the funding agency's requirements for the investigation of research misconduct. In any such case, the SCRM shall refer to the requirements delineated by each federal agency, including, for example, the Public Health Service requirements contained in 42 C.F.R. 93 and the National Science Foundation requirements described in Section 930 of the NSF Grant Policy Manual. In the event that these Guidelines and Procedures materially conflict with the requirements of any funding agency, the SCRM will apply the requirements of the funding agency.

## **II. Definitions**

## A. Research

The University broadly defines "research" to include all forms of scholarship within the responsibilities of faculty, staff, or students, that is designed or intended to contribute to generalizable knowledge in a field of academic inquiry.

## **B. Research Misconduct**

Research misconduct includes but is not limited to:

- 1. Fabrication, falsification, plagiarism and other forms of misrepresentation of ideas, and other serious deviations from accepted practices in proposing, carrying out, reviewing, or reporting results from research;
- Material failure to comply with Federal or University requirements for protection of researchers, human subjects, or the public;
- 3. Material failure to comply with federal or University requirements for ensuring the welfare of laboratory animals;
- 4. Failure to comply with established standards regarding author names on publications;
- 5. Retaliation of any kind against a person who, in good faith, reported or provided information about suspected or alleged research misconduct.

Research misconduct does not include honest error or honest differences in interpretations or judgments of data. However, where a person's conduct otherwise constitutes research misconduct, the burden of proof lies with that person to establish by a preponderance of the evidence that his or her conduct represents honest error or differences in interpretation.

Allegations falling into categories 2, 3 and 4 above will be investigated through these Guidelines and Procedures only to the extent that there is not an alternative investigative process to address such misconduct.

If, in the course of an investigation, the SCRM or its committees determines that the allegations of research misconduct relate to federally-funded research and the federal funding agency's definition of research misconduct is more limited than the definition set forth in these Guidelines and Procedures, the federal funding agency's definition of research misconduct shall apply for determining whether such research misconduct shall be reported to the federal funding agency or other appropriate authority. The University's definition of research misconduct, however, shall continue to apply for the University's internal administrative purposes, including the imposition of discipline against any person who is determined to have engaged in conduct that meets the University's definition of research misconduct.

## C. Public Health Service Office of Research Integrity (PHS/ORI)

As used in these Guidelines and Procedures, PHS/ORI refers to the Office of Research Integrity within the Public Health Service of the National Institutes of Health (NIH). This office oversees research misconduct investigations involving research funded by the NIH.

## **III.** Roles and Responsibilities

## A. Research Integrity Officer

The Vice Chancellor for Research shall appoint the Research Integrity Officer (RIO). The RIO is the institutional official who has primary responsibility for implementing these Guidelines and Procedures. The RIO's duties are described in Appendix A, but generally include advising any person who is considering whether to submit an allegation of research misconduct about the requirements of these Guidelines and Procedures, receiving allegations of research misconduct, coordinating the work of the SCRM and its committees, administering these Guidelines and Procedures to provide timely notice and an opportunity to respond to any person alleged to have engaged in research

misconduct, and providing timely notifications of research misconduct inquiries and investigations to appropriate University and federal agency officials.

The Research Integrity Officer shall be responsible for (1) notifying the SCRM of any requirements of funding organizations concerning research misconduct; (2) communicating with such agencies as required by agency guidelines; and/or (3) acting as liaison between the SCRM and the appropriate dean, vice chancellor, or other University official if that party is required to communicate with the funding agency on research matters.

## **B. Standing Committee on Research Misconduct**

The Standing Committee on Research Misconduct (SCRM) is a faculty committee composed of representatives from each of the colleges and schools at the Boulder campus that is responsible for inquiries and investigations of allegations of research misconduct. The basic responsibilities of the SCRM are to promote exemplary ethical standards of research conduct, to publicize the Guidelines and Procedures for reporting research misconduct, to receive allegations of misconduct, to ensure thorough, fair and expeditious proceedings for the evaluation of allegations, and to recommend possible disciplinary action, policy changes or other actions to remedy the misconduct and to prevent similar misconduct in the future.

## C. Deciding Official

The Deciding Official (DO) is the institutional official who receives the investigative report of the SCRM and determines the appropriate institutional response. The University has designated the Provost as the DO, but the DO shall not be the same person as the RIO. To the extent possible, the DO should have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment; the fact that the DO received an allegation of research misconduct or referred such an allegation to the RIO shall not constitute direct prior involvement.

## D. Complainant

The Complainant is the individual who presents a written allegation of research misconduct to the RIO or SCRM. The University requires any person who makes an allegation of research misconduct to proceed in good faith and with a reasonable basis for believing that research misconduct occurred.

## E. Respondent

The Respondent is the person against whom an allegation of research misconduct has been made. As further described in these Guidelines and Procedures, the Respondent has rights that the SCRM and its committees shall attempt to preserve during the inquiry and investigation processes. In the event that the SCRM or its committees fail to provide the rights identified in these Guidelines and Procedures, the DO may consider any such failure when determining the appropriate institutional response to an allegation of research misconduct.

## **IV. General Policies and Principles**

## A. Responsibility to Report Misconduct

University employees have an obligation to report observed or suspected research misconduct to the RIO or to the SCRM. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may contact the RIO to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, but are appropriately addressed to another University entity or third party, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem. Except to the extent necessary to comply with reporting requirements or state law or to defend any legal action which might be asserted against the University, the RIO will maintain confidential any such discussions or consultations regarding concerns of possible research misconduct.

## **B. Cooperation with Research Misconduct Proceedings**

In accordance with the University of Colorado Administrative Policy Statement on Misconduct in Research and Authorship, members of the University community are obligated to cooperate with and provide evidence relevant to a research misconduct allegation to the RIO, the SCRM, and other institutional officials. Any member of the University community who fails or refuses to cooperate with the inquiry or investigative processes shall be reported to the appropriate dean or vice chancellor; such non-cooperation may constitute the basis for disciplinary action. Nothing herein will be interpreted in such a way as to infringe on an employee's right to invoke the protection of the Fifth Amendment to the U.S. Constitution with regard to self-incrimination. During both inquiry and investigation, the RIO and the SCRM shall elicit the cooperation of the Complainant, the Respondent, and any other persons who have knowledge of the alleged research misconduct. Any person's failure to provide such cooperation, however, shall not preclude the University's investigation of potential research misconduct.

## C. Confidentiality

The RIO, the SCRM, and its committees shall take reasonable steps to maintain the confidentiality of an allegation of research misconduct through the inquiry and investigative stages. The RIO, the SCRM, and its committees shall request that the Complainant, the Respondent, and any other involved persons maintain confidentiality during the inquiry and investigative processes, including through the use of confidentiality agreements.

During the course of the inquiry and investigative stages, the RIO, the SCRM, and its committees may disclose information related to an allegation of research misconduct through the inquiry and investigative stages to the extent required by law. The RIO or the SCRM may also disclose information related to the inquiry and investigative processes if the seriousness of the alleged research misconduct warrants disclosure pending the outcome of the inquiry or the investigation. Without limitation such instances include where the disclosure is necessary: (1) to prevent an immediate health hazard; (2) to protect the University's resources or reputation; (3) to protect the interests of the academic community; (4) to protect any person's resources or reputation; (5) to comply with the University' s obligations to any state or federal agency, or (6) to correct misinformation made available to the public about the alleged research misconduct and the University's response.

To the extent possible, the RIO and/or the SCRM shall limit disclosure of the identity of the Complainant, Respondent, or witnesses in the inquiry and investigative processes. For example, unless the circumstances merit direct identification of the participants in their reports and other documents, the SCRM and its committees should refer to the participants as "Complainant," "Respondent," and "Witness 1." In the event that the SCRM or its committees refer to individuals using generic identifiers, it should also include a confidential appendix containing those persons' identities.

The SCRM may disclose the final inquiry report and/or investigative report as necessary for it to meet its obligation of discouraging research misconduct in the University community, to remediate the harm caused by research misconduct, or as necessary to comply with the requirements of funded research. In the event that the SCRM finds that a Respondent has not engaged in research misconduct, the SCRM may disclose the final inquiry report and investigative report as necessary to protect the reputation of the Respondent.

Notwithstanding any other provision in these Guidelines and Procedures, the University, the RIO, the SCRM, and its committees shall disclose any information reasonably necessary for it to comply with state or federal law.

## **D. Non-Retaliation**

Members of the University community may not retaliate in any way against Complainants, witnesses, or committee members. Institutional members should immediately report any alleged or apparent retaliation to the RIO. The RIO shall review the allegation of retaliation and, if warranted, make all reasonable and practical efforts to redress any retaliation that has already occurred and to prevent any further retaliation.

## E. Interim Administrative Actions and Notifying PHS/ORI of Special Circumstances

Throughout the research misconduct inquiry and investigation, the RIO will monitor the proceedings to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the federally-supported research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and the funding agency, take appropriate interim action to protect against any such threat.

Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results, delaying publication, or notifying appropriate persons of errors in published research.

The RIO shall, at any time during a research misconduct proceeding, notify PHS/ORI immediately if he/she has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- HHS resources or interests are threatened;
- Research activities should be suspended;
- There is a reasonable 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 HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

# V. The Standing Committee on Research Misconduct

## A. Composition and Appointment

The Standing Committee on Research Misconduct is a Boulder campus committee established to carry out the *University of Colorado Administrative Policy Statement on Misconduct in Research and Authorship*. The SCRM shall include: (1) at least one member from each school or college, (2) a member representing the Boulder Faculty Assembly (BFA), (3) a staff member, nominated by the Staff Council, and (4) a student member, nominated by the United Government of Graduate Students.

The Chair of the SCRM shall seek nominations for faculty members to serve on the committee from the appropriate deans of the schools and colleges. Committee membership should reflect the diversity of the faculty and should comply with University policies for constituting committees. Members of the SCRM shall be appointed for staggered three-year terms, except for initial appointments. Nominations received by the Chair shall be submitted to the Vice Chancellor for Research for appointment to the SCRM.

During the spring semester of each academic year, the members of the SCRM elect a Chair. The Chair of the SCRM takes office at the beginning of the fall semester following his or her election and serves until the SCRM elects a subsequent Chair.

The RIO serves as an ex officio and non-voting member of the SCRM.

## **B. Meeting Schedule**

The SCRM shall meet at least twice each academic year, once during the fall semester and once during the spring semester. If there is no business before the committee, one of these meetings may be conducted electronically or by telephone, at the discretion of the Chair and with the prior agreement of all members of the committee. Additional meetings shall be called by the Chair as necessary.

## **C. Voting Procedures**

The SCRM shall be considered to have a quorum when a simple majority of its members are present. Unless otherwise described in these Guidelines and Procedures, any formal action by the SCRM may occur only after a vote occurring at a meeting where a quorum is present. Unless otherwise described

in these procedures, the SCRM may take a formal action upon the majority vote of the quorum. The votes of the SCRM shall be recorded only by indicating the number of members voting for or against a motion. The names of the members shall not be recorded or reported in the minutes.

## **D. Conflict of Interest or Bias**

To ensure impartiality in any proceedings before the SCRM, members are expected to reveal any actual or potential conflicts of interest to the SCRM, including: (1) previous personal knowledge of or involvement in the matter forming the basis of the research misconduct allegation; (2) close personal, professional or financial relationship with the Complainant, Respondent, or any other participant in the inquiry or investigative processes.

A member with an actual conflict of interest or bias should withdraw from the relevant inquiry process. Any member may also withdraw or limit participation if he or she feels that participation may create the appearance of impropriety, even if there is no actual conflict of interest. The Chair of the SCRM may also disqualify any member determined by the Chair or the SCRM to have an actual conflict of interest or bias. If a member withdraws or is disqualified from particular proceedings, that member shall take no part in those proceedings as a member of the Committee, including attending meetings, asking questions, observing the proceedings, and discussing the allegations with other members. A disqualified member may, however, be called as a witness during the inquiry or investigative processes.

## E. Role of the University Counsel

The SCRM and its committees may seek advice and assistance from the Office of the University Counsel as it deems necessary.

The Office of the University Counsel shall be notified of the meetings of the SCRM and provided with minutes of SCRM proceedings. University Counsel may send a representative to attend meetings of the SCRM or proceedings of any inquiry or Investigation committee appointed hereunder if the University Counsel considers that such attendance is in the best interests of the University.

## F. Amendments to the Guidelines and Procedures

These Guidelines and Procedures may be amended by a two-thirds vote of the SCRM members. Amendments may be proposed by any member of the SCRM.

## G. Education of the Academic Community

Deans, directors, chairs and graduate advisors shall be reminded annually of the *University of Colorado Administrative Policy on Research Misconduct and Authorship* and of these Guidelines and Procedures. The University shall also inform all faculty, students, and staff of (1) the need for integrity in research performance and (2) the role of the SCRM in considering allegations of research misconduct.

# VI. Conducting an Assessment & Inquiry

## A. Procedures for Making Allegations

All persons having knowledge of research misconduct or having reason to believe that such misconduct may have occurred, should submit written allegations of research misconduct to the Research Integrity Officer or the Chair of the SCRM. Written allegations may also be given to any member of the SCRM, who shall direct them to the Chair. All allegations must be presented in the form of a written complaint addressed to the SCRM.

Individuals who are uncertain about whether to file an allegation may consult with the RIO prior to filing a written complaint. Except as described in the section of these Guidelines and Procedures detailing confidentiality, the RIO will maintain confidential any such discussions or consultations regarding concerns of possible research misconduct.

## **B. Initial Review**

Upon receiving a written allegation of research misconduct, the SCRM Chair will immediately assess the allegation to determine whether it (a) is sufficiently credible and specific so that potential evidence of research misconduct may be identified, and (b) meets the definition of research misconduct described under these Guidelines and Procedures or under any federal standard applicable to the research. The Chair may utilize available resources such as the RIO, members of the SCRM, or University Counsel in making the decision.

The assessment period should be brief. In conducting the assessment, the SCRM chair need not interview the Complainant, Respondent, or other witnesses. The SCRM chair need not conduct any research or gather any data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently specific so that a potential instance of research misconduct may be identified.

Should multiple complaints about the Respondent be received, the SCRM Chair shall determine how best to proceed. Generally, multiple complaints will be handled as follows:

- 1. If an *inquiry* is already in process, the new complaint will be forwarded to the current Inquiry Committee. The current Inquiry Committee may recommend to the Standing Committee that the new complaint be included as part of the ongoing inquiry, that a new Inquiry Committee be formed to explore the new complaint, or that the new complaint be rejected as being duplicative with the allegations already being reviewed.
- 2. If an *investigation* is underway when a new complaint arrives, the chair of the Standing Committee will confer with the chair of the Investigative Committee to determine if the new complaint is most appropriately included in a revised charge to the Investigative Committee, or whether it should be referred to an Inquiry Committee.
- 3. If a complaint is received after an Investigation has been *completed*, the SCRM Chair will determine whether the new complaint merits an Inquiry or is redundant with the prior complaint(s) that have already been investigated.

If the Chair determines that the Complainant has stated a possible instance of research misconduct, the complaint will be referred for inquiry as described below. If not, the Chair shall notify the Complainant and the SCRM of the decision not to pursue the allegations. Such decision may be over-ruled by a majority vote of the SCRM.

## C. Conduct of Inquiry

#### 1. Notice to Respondent

The Respondent is normally not informed of an allegation until an Inquiry Committee has completed Phase I and determined that the inquiry procedure should proceed. Once this determination has been made, the RIO, on behalf of the SCRM, must make a good faith effort to notify the Respondent in writing. The Respondent will be informed of the specifics of the allegation and will be provided with university and campus rules and procedures governing the inquiry process; in the case of funded research, the RIO will provide Respondent with the relevant federal regulations.

The respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO and SCRM, the Deciding Official may terminate the institution's review of an allegation that has been admitted. In the case of allegations that fall under the purview of the Public Health Service, the institution's acceptance of the admission and any proposed settlement must be approved by PHS/ORI.

If the Inquiry Committee, as part of its Phase I inquiry, determines that a complaint should not be pursued, it will so advise the SCRM. If the SCRM concurs, it will inform the Respondent of the complaint and the reasons for not pursuing it.

#### 2. Protection of Evidence

The RIO shall, on or before the date on which the Respondent is notified of the allegation, take all reasonable and practical steps to obtain custody of all records and evidence necessary to conduct the inquiry. The RIO shall inventory and sequester all such records and evidence. The RIO shall confer with the Respondent to identify the records and evidence needed for the inquiry and the best means of preserving and maintaining the integrity of the records and evidence.

Where the 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. The RIO may consult with NIH/PHS or other similar parties for advice and assistance in this regard.

#### 3. Inquiry Process – General Requirements

Upon receipt of a written complaint of research misconduct that falls within its purview, the SCRM shall appoint a subcommittee (the "Inquiry Committee") to conduct an inquiry to determine whether any or all allegations of the complaint warrant a full investigation. The Chair shall appoint such a committee and designate its chair. The Inquiry Committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with either the Complainant or Respondent.

The inquiry is a two-stage, fact-finding, nonadversarial proceeding intended to provide an initial review of the evidence so that a preliminary evaluation can be made as to whether there is sufficient evidence of research misconduct to warrant full investigation. The inquiry is intended only to provide a means of initially evaluating the merits of the allegations of research misconduct to identify and dismiss non-meritorious allegations. Consequently, because of the limited nature of the inquiry proceedings, an inquiry does not require the SCRM or a subcommittee to fully review all of the evidence related to the allegation.

The inquiry committee shall request confidentiality from all participants in the inquiry, and each interested party shall be interviewed separately. Any person—whether a Complainant, Respondent, or witness—may have an advisor or attorney present at any interview of such person to act as such person's personal advisor. Such advisors may assist in the presentation of information but may not speak for these persons or conduct cross-examinations. The inquiry

proceedings shall not be recorded, although the members of the Inquiry Committee may take informal written notes during the proceedings.

The inquiry shall be initiated and conducted as expeditiously as possible. The inquiry, including preparation of the final inquiry report and the decision of the SCRM on whether an investigation is warranted, shall be completed within 60 calendar days of the initial written notification of the Respondent unless the SCRM determines that circumstances warrant a longer period. If a time extension is granted, the final report of the Inquiry Committee must include the reasons for the extension.

## **D. Inquiry Procedures**

#### 1. Stage One

The Inquiry Committee begins its proceedings by reviewing the written allegations of research misconduct and the supporting materials, if any, to determine whether to pursue further investigation. This stage of the inquiry is intended to allow the Inquiry Committee to identify baseless and groundless allegations of research misconduct. In this initial stage, the Inquiry Committee may interview or submit written questions to the Complainant, but is not required to undertake these activities.

The Inquiry Committee, in extraordinary cases where it is unable to form an opinion whether the written allegations are baseless or groundless, may interview additional witnesses, but shall conduct the interviews in a manner designed to protect the confidentiality of the inquiry process, including, to the extent possible, the Respondent's identity. In these cases, the Respondent will be informed of the allegations before any additional interviews are conducted.

Upon a majority vote of the members of the Inquiry Committee determining that some or all of the allegations of research misconduct are potentially meritorious, the Inquiry Committee may proceed to the second stage of the inquiry without further action by the SCRM. The Inquiry Committee shall notify the SCRM of its intention to proceed to the second stage of the inquiry.

The members of the Inquiry Committee may vote to recommend that the SCRM dismiss any baseless and groundless allegations before proceeding to the second stage of the inquiry. If the Inquiry Committee votes to recommend dismissal of some or all of the allegations, the Inquiry Committee shall submit its written recommendation and reasons to the SCRM. The SCRM shall review the Inquiry Committee's recommendation and vote whether to accept it.

If a majority of the SCRM accepts the Inquiry Committee's recommendation of dismissal of some or all of the allegations, the inquiry shall be deemed concluded as to those allegations, and the RIO shall inform the Complainant and

Respondent of the SCRM's determination and the bases for its determination. If the SCRM determines that some or all of the Complainant's allegations were made without reasonable basis in fact and with malicious intent, the SCRM may refer the Complainant to appropriate entities with the University or other institutions.

If a majority of the SCRM rejects the Inquiry Committee's recommendation of dismissal, in whole or in part, it shall return the allegations that it did not dismiss to the Inquiry Committee for the second stage of the inquiry.

#### 2. Stage Two

If the Inquiry Committee or the SCRM decides that some or all of the allegations of research misconduct are potentially meritorious, the RIO shall notify the Complaint in writing of this determination.

The RIO shall inform the Respondent in writing about the nature of the research misconduct allegations, including a copy of the written allegations and any supporting materials. The Inquiry Committee shall request that the Respondent provide a written response to the allegations of research misconduct within 14 calendar days, but the Inquiry Committee may grant reasonable extension of this deadline at its discretion.

After receiving and reviewing the Respondent's written response to the allegations of research misconduct, or if the Respondent does not respond within the allowed period of time, the Inquiry Committee shall invite the Respondent for a personal interview to discuss the details of the alleged misconduct. This interview shall be fact-finding rather than adversarial. If the Respondent declines a personal interview, or in addition to such a personal interview, the Inquiry Committee may also interview the Respondent by telephone or through solicited responses to questions or other methods.

The Inquiry Committee, at its discretion, may interview other individuals to obtain information pertinent to the inquiry. Any such interviews may be conducted in person, by telephone, or through solicited responses to written questions, or other methods. Additional sources of information, such as documents and physical evidence, may be considered by the Inquiry Committee.

Upon concluding its inquiry, the Inquiry Committee shall decide by recorded simple majority vote whether sufficient credible evidence exists to warrant a full investigation of any or all of the allegations. The Inquiry Committee shall provide its recommendation in a fully documented written report to the SCRM for appropriate action.

## E. The Inquiry Report

At the conclusion of the second stage of the inquiry proceedings, the Inquiry Committee shall prepare a written report for consideration by the SCRM.

#### 1. Content of Inquiry Report

The Inquiry Committee's report shall include the following:

- the name and position of the Respondent;
- a description of the allegations of research misconduct;
- grant support (if applicable), including, for example, grant numbers, grant applications, contracts and publications listing the source of support;
- the names and titles of the committee members who conducted the inquiry;
- a summary of the inquiry process used;
- a list of the research records reviewed;
- summaries of any interviews;
- the basis for recommending or not recommending that the allegations warrant a full investigation;
- whether any other actions should be taken if an investigation is not recommended; and
- any comments on the report by the Respondent or Complainant.
- 2. Solicitation of Comments

Before submitting its report to the SCRM, the Inquiry Committee shall provide a copy of its proposed report to the Respondent for review. If the Respondent wishes to submit any comments on the proposed report to the SCRM, the Inquiry Committee shall include those comments with the final report that is transmitted to the SCRM. The Respondent's comments shall be received by the Inquiry Committee within ten days after the Respondent's receipt of the proposed report.

Upon receipt of comments by the Respondent, the Inquiry Committee may modify its proposed report before submitting a final report to the SCRM. The Inquiry Committee is not required to provide the Respondent with its modifications before submitting the final report to the SCRM

Before submitting the final report to SCRM, the Inquiry Committee may submit the report to University Counsel for legal sufficiency.

## F. SCRM Review of Inquiry Report and Determination

Upon its review of the Inquiry Committee's report and a majority vote the SCRM may:

(a) dismiss some or all of the allegations of research misconduct. The inquiry shall be deemed concluded as to any dismissed allegation. The RIO shall inform the Complainant and the Respondent of the SCRM's determination and the bases for its determination. If the SCRM determines that some or all of the Complainant's allegations were made without reasonable basis in fact and with malicious intent, the SCRM may refer the Complainant to appropriate entities with the University or other institutions.

(b) initiate a full investigation of some or all of the allegations of research misconduct. The SCRM shall refer any appropriate allegations for investigation by the Investigating Committee.

#### 1. Notification to Complainant and Respondent

The RIO shall inform the Complainant and the Respondent of the SCRM's determination and the bases for its determination. The RIO will provide the Respondent with a copy of the final Inquiry report.

The SCRM may, but is not required to, provide a copy of the Inquiry report to the Complainant. The SCRM shall not provide the Complainant with a copy of the report unless the Complainant agrees to be bound by a confidentiality agreement preventing disclosure of the contents of the report.

If either the Complainant or Respondent wishes to submit any comments upon the report to the SCRM, they will be included in the final record (and will be provided to the Investigating Committee if applicable). Such comments do not constitute an appeal of the SCRM's decision, which is final.

#### 2. Notification to PHS/ORI (if applicable)

Within 30 calendar days of the decision by the SCRM that an investigation is warranted, the RIO will so inform PHS/ORI and provide PHS/ORI with a copy of the inquiry report. The RIO will provide the following information to PHS/ORI upon request: (1) the institutional 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 to be considered in the investigation.

If the SCRM decides that an investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by PHS/ORI of the reasons why an investigation was not conducted. These documents must be provided to PHS/ORI or other authorized HHS personnel upon request.

## **VII. Investigative Phase**

## A. Initiation and Purpose

Unless the SCRM determines otherwise due to extraordinary circumstances, the investigation phase must begin within 30 calendar days after the determination by the SCRM that an investigation is warranted. The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth. The ultimate purpose of the investigation is to determine whether research misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations.

## **B.** Appointment of Investigative Committee

As soon as possible after the SCRM votes to pursue an investigation, the SCRM, in consultation with the appropriate dean or vice chancellor, shall appoint an ad hoc committee of three to five members, including a chair, to serve as an Investigative Committee. The Investigative Committee is charged with conducting a thorough and unbiased investigation of the allegations of misconduct.

The SCRM may select Investigative Committee members from inside or outside the University, but no member of the SCRM may serve on the Investigative Committee. In selecting members, the SCRM should consider: (1) any conflicts of interest or bias that would prevent a person from serving as an impartial member of the Investigative Committee; (2) the member's area of expertise and ability to provide substantive assistance to the investigative process.

The RIO shall notify the Respondent and Complainant of the names of potential Investigative Committee members, to ensure that Investigative Committee members do not have a bias or conflict of interest in considering the case. If a potential member's impartiality is questioned, the SCRM will determine whether the potential member should be excluded from the Investigation Committee. If, during the course of an investigation, a member's impartiality is questioned, the SCRM will determine whether the potential member should be removed and replaced.

## C. Charge to the Investigative Committee

The RIO will convene the first meeting of the Investigative Committee at which the Chair of the SCRM and the RIO will review with the Investigation Committee the charge, the inquiry report, and these Guidelines and Procedures. The RIO will inform the members of the Investigative Committee of the confidentiality requirements of these Guidelines and Procedures and obtain the members' agreement to these requirements. The RIO shall provide each member with these Guidelines and Procedures, as well as any federal standards applicable to the investigation. The RIO will be available throughout the investigation to advise the Investigative Committee as needed.

The SCRM will provide the Investigation Committee with a written charge that:

- Describes the allegations and related issues identified during the inquiry;
- Identifies the Respondent;
- Informs the committee that it must conduct the investigation as prescribed in these Guidelines and Procedures;
- Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
- Informs the committee that the Respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion;
- Informs the committee that it must determine by a preponderance of the evidence whether the Respondent committed the research misconduct intentionally, knowingly, or recklessly.
- Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and, if applicable, 42 CFR § 93.313.

### **D. Investigative Process**

The Investigative Committee has the responsibility for conducting a thorough and unbiased investigation. In accordance with this mandate, the Investigative Committee shall:

- 1. Begin its proceedings by studying the information and evidence collected by the Inquiry Committee.
- 2. Determine what additional evidence the Investigative Committee needs to make an informed determination as to whether research misconduct has occurred, including interviews of witnesses (including witnesses already interviewed by the Inquiry Committee) and review of additional evidence.

- 3. Provide the Respondent with an opportunity to provide oral or documentary evidence related to the allegations or research misconduct.
- 4. Provide the Respondent with an opportunity to identify witnesses with knowledge in the area of the alleged research misconduct.
- 5. Provide the Respondent with an opportunity to review and respond to any evidence that the Investigative Committee relies upon in making its determinations.
- 6. Preserve the evidence that it relies upon in making its determinations.

When the Investigative Committee conducts any interviews as part of its investigation, it shall 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 the investigation.

The Chair of the Investigative Committee shall control the proceedings and determine the admissibility of evidence. The Investigative Committee shall not be bound by the Colorado Rules of Evidence and may admit any evidence that the Chair deems reasonably related to the allegations of research misconduct. The Chair shall have the ability to limit the presentation of irrelevant or repetitious evidence.

Any party appearing before the committee may have an advisor present, who may be an attorney. The advisor may assist the party in the presentation of information but may not speak on the party's behalf.

## E. Time for Completion

The Chair of the Investigative Committee shall keep the RIO informed of the status of its investigation. The Investigative Committee shall normally complete its investigation, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to SCRM, within 120 days of the Investigative Committee's first meeting. However, if the RIO determines that the investigation cannot be completed within this 120-day period, he/she may extend the time within which the Investigative Committee is to complete its investigation. The rationale for this extension should be included in the final report of the Investigation Committee. If the investigation falls under the jurisdiction of the Public Health Service, the RIO will submit to PHS/ORI a written request for an extension, setting forth the reasons for the delay and, if such an extension is granted and PHS/ORI direct the filing of periodic progress reports, the RIO will ensure that such periodic progress reports are filed with PHS/ORI.

## **VIII. The Investigation Report**

## A. Decision by the Investigative Committee

When it considers that its task has been completed, the Investigation Committee shall determine by majority vote whether the allegations of misconduct are supported by a preponderance of evidence. The Investigation Committee shall reach one of the following decisions as to each allegation of research misconduct:

- 1. A finding of research misconduct;
- 2. A finding of no culpable research misconduct, but serious research error; or
- 3. A finding of no misconduct and no serious research error.

The Investigative Committee shall communicate this decision to the SCRM in an initial written investigative report. The investigative report shall:

- Describe the nature of the allegation of research misconduct, including identification of the Respondent;
- Describe any external support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing this support;
- Describe the specific allegations of research misconduct considered in the investigation;
- Describe the institutional policies and procedures under which the investigation was conducted;
- Identify and summarize the sources of evidence that the Investigative Committee relied upon in making its determination;
- Include 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 or other form of conduct outlined in University policies and rules; (2) identify whether the research misconduct was committed intentionally, knowingly, or recklessly; (3) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the Respondent, including any effort by Respondent to establish that he or she did not engage in research misconduct because of honest error or a difference of opinion; (4) identify the specific evidence that the Investigative Committee relied upon in making its determination; (5) identify whether the research misconduct would require any publications

to need correction or retraction; (6) identify the person(s) responsible for the research misconduct.

If the Investigation Committee determines that the Respondent did not engage in an alleged act of research misconduct, the final report should indicate whether the Investigation Committee finds that allegation was made without reasonable basis in fact and with malicious intent.

## **B. Referral to SCRM**

After completing its report, the Investigative Committee shall transmit the report to the SCRM. The SCRM shall consider the report to determine whether it shall request additional information, explanation, or investigation from the Investigative Committee.

If the SCRM requests any additional information, explanation, or investigation from the Investigating Committee, it shall return the report to the Investigating Committee for further response. Upon completing any additional response, the Investigating Committee shall return the report to the SCRM.

When the SCRM determines that the Investigating Committee's report is complete and no further response is necessary, it shall accept the report as final and inform the Investigating Committee that it has completed its obligations.

## C. Comments on the Investigative Report and Access to Evidence

#### 1. Respondent

Upon receipt of the final investigation report, the RIO shall provide the Respondent with a copy of the final investigation report for comment and, concurrently, a copy of, or supervised access to the evidence upon which the report is based.

The Respondent will be allowed 30 days from the date he/she received the final investigation report to provide the RIO with his/her written response to the final investigation report. The RIO shall provide Respondent's written response to the SCRM.

The SCRM shall consider the Investigative Committee's report, as well as any comments by the Respondent before preparing the SCRM final report. Respondent's response will be included as an attachment to the SCRM final report.

#### 2. Complainant

At its option, the SCRM may, but is not required to, provide the Complainant a copy of the investigation report, or relevant portions of it, for Complainant's response. The SCRM shall not provide the Complainant with a copy of the report unless the Complainant agrees to be bound by a confidentiality agreement preventing disclosure of the contents of the report. If the SCRM allows the Complainant to receive the report, the Complainant will be allowed 30 days from the date he/she received the final investigation report to provide the RIO with his/her written response to the final investigation report.

## IX. Disposition by the SCRM

Upon receipt of the Investigation Committee's final investigation report and the responses thereto, if any, from the Respondent or Complainant, the SCRM shall review the same and create a final SCRM report. The final SCRM report is not intended to be a separate investigation of the allegations. Rather, it shall include recommendations based on the findings included in the Investigative Committee Report regarding:

- Possible disciplinary action, policy changes, or other actions that might ensure that similar misconduct does not occur in the future.
- Steps to correct or ameliorate the effects of the misconduct.
- Steps to be taken to prevent retaliation against the Complainant or other persons providing information in the investigation and to restore the positions and reputations of persons who have made allegations in good faith.
- Whether the Respondent's reputation has been unjustly damaged by the investigation and, if so, what steps might be taken to repair that damage.
- Whether any allegation is judged to have been made without reasonable basis in fact and with malicious intent.

The final report of the SCRM, along with the final report of the Investigation Committee, shall be submitted to the Deciding Official and to the Respondent.

## X. Final Disposition

## A. Decision by the DO

Upon receipt of the final reports of the SCRM and the Investigation Committee, the DO will determine in writing: (1) whether the University accepts the investigation report, its findings, and the SCRM's recommendations; and (2) set forth the institution's actions in response thereto. If this determination varies from the findings of the investigation committee and/or the recommendations of the SCRM, the DO will, as part of his/her written determination, explain the basis for the decision.

## **B.** Communication of Decision

When the DO has reached a final decision on the case, the DO will so notify both the Respondent and the Complainant in writing.

The DO, in consultation with the RIO and the Office of University Counsel, will determine whether other university officials, PHS/ORI, 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. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

## C. Appeals

Appeals of the DO's final decision shall be handled in accordance with the University's normal grievance and appeal processes.

## D. Notice to PHS/ORI or Other Funding Agencies of Institutional Findings and Actions

To the extent applicable, unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation submit the following to PHS/ORI or other funding agencies that require such reporting: (1) a copy of the final investigation report with all attachments; (2) a statement of whether the institution accepts the findings of the investigation report; (3) a statement of whether the institution found misconduct and, if so, who committed the misconduct; (4) a description of any pending or completed administrative actions against the Respondent; and (5) a description of any pending or completed administrative actions to correct or ameliorate the effects of the misconduct and/or to ensure that that similar misconduct does not occur in the future.

The RIO must maintain and provide to PHS/ORI upon request "records of research misconduct proceedings" as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested

by PHS/ORI to carry out its review of an allegation of research misconduct or of the institution's handling of such an allegation.

## Appendix A: Research Integrity Officer Responsibilities

## I. General

The Research Integrity Officer (RIO) has lead responsibility for ensuring that the institution:

- Takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.
- Has written policies and procedures for responding to allegations of research misconduct and reporting information about that response to PHS/ORI, as required by 42 CFR Part 93.
- Complies with its written policies and procedures and the requirements of 42 CFR 93.
- Informs its institutional members who are subject to 42 CFR Part 93 about its research misconduct policies and procedures and its commitment to compliance with those policies and procedures.
- Takes appropriate interim action during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the PHS supported research process.

## II. Notification, Reporting and Cooperation with PHS/ORI

The RIO has lead responsibility for ensuring that the institution:

- Files an annual report with PHS/ORI containing the information prescribed by PHS/ORI.
- Sends to PHS/ORI with the annual report such other aggregated information as PHS/ORI may prescribe on the institution's research misconduct proceedings and the institution's compliance with 42 CFR Part 93.
- Notifies PHS/ORI immediately if, at any time during the research misconduct proceeding, it has reason to believe that health or safety of the public is at risk, HHS resources or interests are threatened, research activities should be suspended, there is reasonable 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 institution believes that the research misconduct proceeding may be made public prematurely, or the research community or the public should be informed.

- Provides PHS/ORI with the written finding by the responsible institutional official that an investigation is warranted and a copy of the inquiry report, within 30 days of the date on which the finding is made.
- Notifies PHS/ORI of the decision to begin an investigation on or before the date the investigation begins.
- Within 120 days of beginning an investigation, or such additional days as may be granted by PHS/ORI, (or upon completion of any appeal made available by the institution) provides PHS/ORI with the investigation report, a statement of whether the institution accepts the investigation's findings, a statement of whether the institution found research misconduct and, if so, who committed it, and a description of any pending or completed administrative actions against the Respondent.
- Seeks advance PHS/ORI approval if the institution plans to close a case at the inquiry, investigation, or appeal stage on the basis that the Respondent has admitted guilt, a settlement with the Respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage.
- Cooperates fully with PHS/ORI during its oversight review and any subsequent administrative hearings or appeals, including providing all research records and evidence under the institution's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.

### **III. Research Misconduct Proceeding**

#### A. General

The RIO is responsible for:

- Promptly taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner.
- Taking all reasonable and practical steps to ensure the cooperation of Respondents and other institutional members with research misconduct proceedings, including, but not limited to their providing information, research records and evidence.

- Providing confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy.
- Determining whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional or financial conflict of interest and taking appropriate action, including recusal, to ensure that no person with such a conflict is involved in the research misconduct proceeding.
- Keeping the Deciding Official (DO) and others who need to know apprised of the progress of the review of the allegation of research misconduct.
- In cooperation with other institutional officials, taking all reasonable and practical steps to protect or restore the positions and reputations of good faith Complainants, witnesses, and committee members and to counter potential or actual retaliation against them by Respondents or other institutional members.
- In conjunction with the DO, making all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.
- Assisting the DO in implementing his/her decision to take administrative action against any Complainant, witness, or committee member determined by the DO not to have acted in good faith.
- Maintaining records of the research misconduct proceeding, as defined in 42 CFR § 93.317, in a secure manner for 7 years after completion of the proceeding, or the completion of any PHS/ORI proceeding involving the allegation of research misconduct, whichever is later, unless custody of the records has been transferred to PHS/ORI or PHS/ORI has advised that the records no longer need to be retained.

#### **B. Allegation Receipt**

The RIO is responsible for:

- Consulting confidentially with persons uncertain about whether to submit an allegation of research misconduct. The RIO is not required to file a complaint with regard to allegations discussed during these confidential sessions.
- Receiving allegations of research misconduct and transmitting them to the SCRM Chair.

#### C. Inquiry

The RIO is responsible for:

• On or before the date on which the Respondent is notified, or the inquiry begins, whichever is earlier, taking all reasonable and practical steps to

obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventorying the records and evidence and sequestering them in a secure manner. 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 the instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

- Providing the Inquiry Committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging witness interviews and recording or transcribing those interviews.
- Being available or present throughout the inquiry to advise the committee as needed and consulting with the committee prior to its decision whether to recommend that an investigation is warranted on the basis of the criteria in these policies and procedures and 42 CFR § 93.307(d).
- Determining whether circumstances clearly warrant a period longer than 60 days to complete the inquiry (including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted), approving an extension if warranted, and documenting the reasons for exceeding the 60-day period in the record of the research misconduct proceeding.
- Within 30 days of a SCRM decision that an investigation is warranted, providing PHS/ORI with the written finding and a copy of the inquiry report and notifying those institutional officials who need to know of the decision.
- Notifying the Respondent (and the Complainant, if the SCRM determines that doing so is appropriate) whether the inquiry found an investigation to be warranted and including in the notice copies of or a reference to 42 CFR Part 93 and the University of Colorado research misconduct policies and procedures.
- Providing to PHS/ORI, upon request, the institutional policies and procedures under which the inquiry was conducted, the research records and evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents, and the allegations to be considered in the investigation.
- If the SCRM decides that an investigation is not warranted, securing and maintaining for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by PHS/ORI of the reasons why an investigation was not conducted.

#### **D.** Investigation

The RIO is responsible for:

- On or before the date on which the investigation begins: (1) notifying the Respondent in writing of the allegations to be investigated and (2), if applicable, notifying PHS/ORI of the decision to begin the investigation and providing PHS/ORI a copy of the inquiry report;
- Prior to notifying Respondent of the allegations, taking all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry.
- Assisting the SCRM chair in preparing a charge for the Investigation Committee in accordance with the institution's policies and procedures.
- Convening the first meeting of the investigation committee and providing committee members a copy of the institution's policies and procedures and 42 CFR Part 93.
- Providing the investigation committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging interviews with witnesses and recording or transcribing those interviews.
- Being available or present throughout the investigation to advise the committee as needed.
- On behalf of the institution, the RIO is responsible for ensuring that the investigation committee: (1) uses diligent efforts to conduct an investigation that includes an examination of all research records and evidence relevant to reaching a decision on the merits of the allegations and that is otherwise thorough and sufficiently documented; (2) takes reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical; (3) takes reasonable steps to 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 records or transcribes each interview, provides the recording or transcript to the interviewee for correction, and includes the recording or transcript in the record of the research misconduct proceeding; and (4) pursues 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, and continues the investigation to completion.

- When applicable, upon determining that the investigation cannot be completed within 120 days of its initiation (including providing the draft report for comment and sending the final report with any comments to PHS/ORI), submitting a request to PHS/ORI for an extension of the 120day period that includes a statement of the reasons for the extension. If the extension is granted, the RIO will file periodic progress reports with PHS/ORI.
- Assisting the investigation committee in preparing a draft investigation report that meets the requirements of 42 CFR Part 93 and University policies and procedures, sending the Respondent (and Complainant at SCRM's option) a copy of the draft report for his/her comment within 30 days of receipt, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the Respondent (and, optionally, the Complainant) and ensuring that the comments are included and considered in the final investigation report.
- Transmitting the draft investigation report to institutional counsel for a review of its legal sufficiency.
- Assisting the investigation committee in finalizing the draft investigation report and receiving the final report from the committee.
- If applicable, transmitting to PHS/ORI within the time period for completing the investigation, a copy of the final investigation report with all attachments, a statement of whether the institution accepts the findings of the report, a statement of whether the institution found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the Respondent.
- When a final decision on the case is reached, the DO will normally notify both the Respondent and the Complainant in writing
- Maintaining and providing to PHS/ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including the results of all interviews and the transcripts or recordings of those interviews.