

# Guidelines and Procedures for Responding to Allegations of Research Misconduct

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## **Table of Contents**

I. Introduction	4
A. General Policy	4
B. Scope	4
II. Definitions	6
A. Allegations	6
B. Inquiry	
C. Investigation	
D. Research	
E. Research Misconduct	
F. Preponderance of the Evidence	
G. Research Records	
H. Retaliation	
I. Public Health Service Office of Research Integrity (PHS/C	
J. Serious Research Error	
III. Roles and Responsibilities	
A. Research Integrity Officer	
B. Standing Committee on Research Misconduct	
C. Deciding Official	12
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 S	
Circumstances	
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.	17
F. Amendments to the Guidelines and Procedures	
VI. Conducting an Assessment & Inquiry	
A. Procedures for Making Allegations	
B. Initial Review	
C. Conduct of Inquiry	
Inquiry Process – General Requirements	
Notice to Respondent      Protection of Evidence	۱ ک
D. Inquiry Procedures	
1. Stage One	
2. Stage Two	

E. The Inquiry Report	22
1. Content of Inquiry Report	
F. SCRM Review of Inquiry Report and Determination	
1. Notification to Complainant and Respondent	
2. Notification to PHS/ORI (if applicable)	
VII. Investigative Phase	
A. Initiation and Purpose	24
B. Appointment of Investigative Committee	
C. Charge to the Investigative Committee	25
D. Investigative Process	26
E. Time for Completion	
VIII. The Investigation Report	28
A. Decision by the Investigative Committee	
B. Referral of Investigation Report to SCRM	29
IX. Disposition by the SCRM	30
X. Final Disposition	30
A. Decision by the Deciding Official	30
B. Communication of Decision	31
C. Appeals	31
D. Notice to PHS/ORI or Other Funding Agencies of Institutional Finding	gs and
Actions	
XI. History	
Appendix A: Research Integrity Officer Responsibilities	33
I. General	
II. Notification, Reporting and Cooperation with PHS/ORI	
III. Research Misconduct Proceeding	
A. General	
B. Allegation Receipt	
C. Inquiry	
D. Investigation	37

## 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, Scholarship, and Creative Activities* 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 relevant 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 to permit 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

- 1. These Guidelines and Procedures apply to:
  - 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, such as officials; faculty; scientists and trainees; technicians, research coordinators and other

- research staff; teaching and support staff; students<sup>1</sup>; post-doctoral and other fellows; volunteers and guest researchers; contractors, subcontractors and subawardees and their employees.
- b. any person (as defined in B.1.a) 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.

#### 2. Limited Application after Six Years

Misconduct alleged to have occurred more than six years prior to the University's receipt of the allegation (an "Untimely Allegation") will generally not be reviewed through these procedures. Upon prior approval by the Deciding Official, SCRM may accept an Untimely Allegation for review. Untimely Allegations that may be deemed worthy of review include:

- conduct that is identified in the process of an ongoing inquiry or investigation of alleged misconduct;
- allegations received from a federal agency after the six-year period;
- allegations of misconduct that were not discovered and were not reasonably discoverable prior to expiration of the six-year period;
- continued or renewed conduct through the citation, re-publication, or other use by respondent of the research record at issue;
- allegations of research misconduct that may have an adverse effect on public health or safety;
- instances when review is required by law or is otherwise deemed to be in the best interest of the university;
- instances when a longer limitation period (or no limitation period) is imposed by contract or funding entity.

#### 3. Coordination with Funding Agency Requirements

If alleged research misconduct appears to have occurred in the course of federally-funded research, the SCRM shall attempt to comply with both these

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<sup>&</sup>lt;sup>1</sup> The University has academic dishonesty procedures that generally take precedence for allegations involving student course work. As such, most (but not all) course-related work is covered by student disciplinary/honor code policies, rather than by this policy. Allegations of student misconduct are covered under this policy only if the work in question meets the definition of research and the alleged misconduct meets the definition of research misconduct. Examples include research misconduct associated with student theses and dissertations; UROP or similar projects, papers submitted to conferences, online postings, journals, projects requiring approval by a regulatory committee such as the IRB, IACUC, or IBC. Work conducted by students in their role as a CU employee is also covered by this policy.

Guidelines and Procedures and the relevant funding agency's requirements for the investigation of research misconduct. In any such case, the SCRM shall refer to the requirements delineated by the applicable 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. If any of 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. Allegations

Allegation means a disclosure of possible research misconduct through any reliable means of communication to the Research Integrity Officer or chair of the Standing Committee on Research Misconduct. (See Section VI.A)

Good faith allegation means an allegation made with the honest belief that research misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for, or willful ignorance of, facts that would disprove the allegation.

#### **B.** Inquiry

*Inquiry* means preliminary gathering of information and initial fact-finding to determine whether an allegation warrants an investigation.

#### C. Investigation

*Investigation* means the formal examination and evaluation of all relevant facts to determine if research misconduct has occurred and, if so, to determine the responsible person(s) and the seriousness of the misconduct.

#### D. Research

Research is broadly defined to include all forms of research scholarship and creative activities within the responsibilities of faculty, staff, or students that are designed as original works or are intended to contribute to generalizable knowledge in a field of academic inquiry. The terms research and research,

scholarship and creative activities may be used interchangeably throughout this policy.

#### E. Research Misconduct

Research misconduct includes the following misconduct:

- 1. Fabrication, falsification, plagiarism;
  - Fabrication: making up research records as defined in Section II.G of these Guidelines, and recording or reporting them.
  - Falsification: manipulating research materials, equipment or processes, or changing or omitting data/results such that the research is not accurately represented in the research record.
  - Plagiarism: appropriation of another's ideas, processes, results or words without giving them appropriate credit
  - Other serious deviations from accepted practice in proposing, carrying out, reviewing or reporting results from research may include but not limited to:
    - breach of any duty of confidentiality with respect to information related to the research process, including as part of peer review of manuscripts or grant proposals;
    - stealing, tampering with, or destroying research materials:
    - directing or encouraging others to engage in research misconduct.
- 2. Failure to comply with established standards regarding author names on publications<sup>2</sup>;
- 3. Retaliation of any kind against a person who, in good faith, reported or provided information about suspected or alleged research misconduct.

In order to constitute research misconduct, there must be a finding, by a preponderance of the evidence, that the conduct represents a serious deviation from accepted practices AND that it was committed recklessly, knowingly, or intentionally.

7

<sup>&</sup>lt;sup>2</sup> Allegations of "failure to comply with established standards regarding author names on publications" will be investigated by SCRM only if there is not an alternative investigative process to address such misconduct (such as through departmental chairs and Directors).

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.

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 purposes of 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.

#### F. Preponderance of the Evidence

Preponderance of the evidence means the standard of proof used when making findings of fact and conclusions as to whether research misconduct occurred. A preponderance of the evidence exists when the totality of the evidence demonstrates that an allegation of misconduct is more probably true than not.

If the evidence weighs so evenly that the applicable committee or deciding official is unable to say that there is a preponderance on either side, then the decision maker should determine that there is insufficient evidence to conclude that research misconduct occurred.

In applying the preponderance of the evidence standard, both direct and indirect (circumstantial) evidence may be considered. If witness statements are relevant, then it is appropriate to consider the credibility of witnesses and the weight to be given to their statements, taking into consideration their means of knowledge, strength of memory, opportunities for observation, the reasonableness or unreasonableness of their statements, the consistency or lack of consistency of their statements, their motives, whether their statements are contradicted or supported by other evidence, any evidence of bias, prejudice or interest, and the person's manner and demeanor when providing statements.

#### G. Research Records

Research records means data, documents, or other written or non-written accounts or objects — whether in electronic or other form -- that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of research misconduct.

A research record includes, but is not limited to the following: grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct when the University has established by a preponderance of the evidence that the respondent (1) intentionally, knowingly, or recklessly had research records and destroyed them, (2) had the opportunity to maintain such records but did not do so, or maintained the records and failed to produce them in a timely manner and (3) the respondent's conduct constitutes significant departure from accepted practices of the relevant research community.

#### H. Retaliation

Retaliation means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to a good faith allegation of research misconduct or good faith cooperation with research misconduct proceeding. (See also section IV.D. on non-retaliation protections.)

# I. 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, within the Department of Health and Human Services. This office oversees research misconduct investigations involving research funded by the National Institutes of Health.

#### J. Serious Research Error

Serious research error means deviations from accepted practices that are committed negligently (rather than recklessly, knowingly, or intentionally) but do not rise to the level of research misconduct. Serious research error may include a failure to properly mentor those working under a researcher (including post-doctoral researchers, graduate students, undergraduates, or other junior colleagues)<sup>3</sup>.

In order to constitute serious research error, there must be a finding, by a preponderance of the evidence, that the conduct represents a significant deviation from accepted practices AND that it was committed negligently.

## III. Roles and Responsibilities

#### A. Research Integrity Officer

The Vice Chancellor for Research and Innovation 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, and 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.

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

As more fully described in Section V of these Guidelines and Procedures, 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 SCRM shall:

1. Take appropriate action to promote awareness of the need to avoid activities that amount to or might be misinterpreted as Research Misconduct; encourage

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10

<sup>&</sup>lt;sup>3</sup> When assessing "failure to properly mentor" the SCRM or its committees shall consider a Respondent's expected mentorship role with respect to assigned mentees by the standards of the Respondent's respective discipline.

- each unit to adopt and promulgate standards for authorship, and otherwise enhance ethics in research-related activities.
- 2. Publicize its existence as the group to whom suspected Research Misconduct is to be reported.
- 3. Receive and review allegations that the Research Integrity Officer and SCRM Chair have determined to warrant an inquiry of Misconduct in Research.
- 4. Strike an appropriate balance between protecting the rights of the Respondent and protecting the Complainant and witnesses from possible retaliation. The course of action in this regard must be suitable to the circumstances of each individual case.
- 5. Promptly report to the appropriate dean, vice chancellor and university counsel any allegation(s) judged to be without reasonable basis in fact or that should be handled via another university review process or a separate entity. 4
- 6. Promptly notify the appropriate dean and vice chancellor, as well as the appropriate regulatory agencies and/or sponsor at any time during a Misconduct in Research proceeding if it has reason to believe that any of the following conditions exist:
  - a. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
  - b. Resources or interests are threatened.
  - c. Research activities should be suspended.
  - d. There is reasonable indication of possible violations of civil or criminal law.
  - e. Federal action is required to protect the interests of those involved in the Misconduct in Research proceeding.
  - f. The research institution believes the Misconduct in Research proceeding may be made public prematurely so that the appropriate regulatory agency may take appropriate steps to safeguard evidence and protect the rights of those involved.
  - g. The research or academic community or public should be informed.
- 7. Periodically review and update these operating procedures as necessary to carry out APS 1007 and meet federal requirements.
- 8. Take appropriate steps to inform all persons of their obligation to comply with these operating rules and procedures.

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<sup>&</sup>lt;sup>4</sup> See footnote 2, for example.

## C. Deciding Official

The Deciding Official (DO) is the institutional official who receives and reviews the investigative report of the SCRM; makes the final determination regarding whether research misconduct occurred; and determines the appropriate institutional response. The Chancellor has designated the Provost as the DO. The DO should have no direct prior involvement in the institution's assessment, inquiry, or investigation of an allegation; 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. In the event that the Provost has a conflict of interest in a case, the Chancellor shall appoint another individual as the DO.

#### D. Complainant

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

A research misconduct case sometimes does not include a specific, named Complainant, such as when an allegation is presented by an entity (e.g., another university, ORI or NSF, a journal) or an anonymous source. In such instances, the RIO, SCRM Chair, or DO will reasonably determine the extent to which provisions in these Procedures referring to a Complainant will apply.

#### 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.

# IV. General Policies and Principles

#### A. Responsibility to Report Misconduct

Members of the University community are expected 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 keep 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 1007 on Misconduct in Research, Scholarship and Creative Activities, 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 of the allegations, inquiries, investigations, resolutions and related documentation and communication 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 necessary to gather relevant documentation and otherwise conduct their inquiry and investigation. The RIO or the SCRM may also disclose information related to the

allegation and information gathered during the related inquiry and investigative processes if the seriousness of the alleged research misconduct warrants disclosure pending the outcome of the inquiry or the investigation. See Section IV.E for more information. 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 may refer to the participants as "Complainant," "Respondent," and "Witness n." In the event that the SCRM or its committees choose to refer to individuals in their reports using generic identifiers, it shall 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 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 if the SCRM deems it appropriate and 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 and Whistleblower Protection

Members of the University community may not retaliate against Complainants, witnesses, or committee members (Regent Policy 1C). Any alleged or apparent retaliation against such individuals should be immediately reported to the RIO. The RIO shall review the allegation of retaliation and, if warranted, take reasonable and practical efforts to redress any retaliation that has already occurred and to prevent 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. If there is any threat of harm to public health, federal funds and equipment, or the integrity of the federally-supported research process, 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.

# F. Termination or Resignation of Respondent Prior to Completing Inquiry or Investigation

The termination of the respondent's employment with the University, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not necessarily preclude or terminate the misconduct procedures.

For example, if the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation may proceed. If the respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

# 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.

As necessary, 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.

Many faculty are unable to serve on committees during the summer. For this reason, inquiries and investigations may be delayed or suspended during the summer break. Per Section VII.E of these Guidelines, the RIO may grant review extensions to the SCRM committees, if deemed reasonable and necessary.

#### C. Voting Procedures

Unless otherwise described in these procedures, the SCRM may take a formal action upon the majority vote of the quorum (defined as a simple majority of its members). Only those members of the SCRM who were substantially involved in the discussion of an item may vote on that item. Electronic voting is allowed when approved by majority vote of the quorum at a given meeting. 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, members of the SCRM, inquiry and investigation committees, the RIO, and the Deciding Official 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.

Any individual with an actual conflict of interest or bias should withdraw from participation in the relevant processes. 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 or as a representative of the Complainant or Respondent, 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, the Research Integrity Officer, and the Deciding Official may seek advice and assistance from the Office of the University Counsel as they deem 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 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.

# 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 allegations of research misconduct to the Research Integrity Officer or the Chair of the SCRM. Allegations may also be given to any member of the SCRM, who shall direct them to the RIO or Chair. While allegations may be presented in either oral or written form, they must be addressed to the SCRM (or RIO), contain sufficient detail to allow initial review (as described in Section VI.B below), and be presented in good faith.

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

#### **B.** Initial Review

Upon receiving an allegation of research misconduct, the RIO, in consultation with the SCRM Chair, will 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.

Allegations that should be handled via another university review process or are determined to fall under the jurisdiction of another entity (such as a different university) will be forwarded to the appropriate person or office at the university or other entity, as appropriate.

Should multiple complaints about the same Respondent be received, the SCRM Chair shall have the discretion to determine how best to proceed. Generally, multiple complaints are expected to 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.

The assessment period should be brief. In conducting the assessment, the RIO need not interview the Complainant, Respondent, or other witnesses nor 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.

The RIO will provide the results of the assessment to the SCRM Chair. If the Chair determines that the allegation represents a possible instance of research misconduct, the complaint will be referred for inquiry as described below. If not, the RIO shall notify the Complainant 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. Inquiry Process – General Requirements

The SCRM Chair shall appoint members of the SCRM to the Inquiry 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 fact-finding, non-adversarial proceeding intended to provide an evaluation as to whether there is sufficient evidence of research misconduct to warrant full investigation. The inquiry is intended to provide an initial evaluation of the merits of the allegations and to identify and dismiss non-meritorious allegations. Because of the limited nature of the inquiry proceedings, an inquiry

does not require the SCRM or the Inquiry Committee to gather and review all available evidence related to the allegation at this stage, but the inquiry committee may choose to do so.

The Inquiry Committee will pursue diligently all allegations, including any additional instances of possible research misconduct that may arise during the inquiry. The Respondent will be informed promptly of any additional allegations.

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 a personal advisor. Such advisors may assist in the presentation of information but may not speak for the party they are accompanying. The inquiry proceedings shall not be recorded, although all participants, including 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 normally be completed within 90 calendar days of the initial meeting of the Inquiry (60 days for NIH-funded research). However, if the RIO determines that the inquiry cannot be completed within this 60-day period, he/she may extend the time within which the Inquiry Committee is to complete its work. If a time extension is granted, the final report of the Inquiry Committee must include the reasons for the extension.

#### 2. Notice to Respondent

The RIO, on behalf of the SCRM, must make a good faith effort to notify the Respondent in writing of the allegation, and provide the Respondent 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.

Following a formal notification of the allegations, the Respondent should be given the opportunity to admit that research misconduct occurred and that they committed the research misconduct. If the Respondent chooses to admit to the allegations, the Inquiry Committee should evaluate and opine upon the adequacy of the scope of the admission and include that opinion as part of its report to the SCRM; this process may involve collection of corroborative evidence or other inquiry. After evaluating the Inquiry Committee's report, the SCRM, with the advice of the RIO, has the option of recommending to the Deciding Official that they terminate the institution's review of the allegations that have been admitted. In this case, the SCRM may also provide the Deciding Official with recommendations regarding corrective or disciplinary actions, parallel to the process described in Section IX of these Procedures. The Deciding Official has

the option to accept the recommendation to terminate the institution's review of the allegations, or may return the allegations to SCRM for investigation. 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.

#### 3. Protection of Evidence

The RIO shall, as soon as possible and preferably 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 or Coordinator 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.

#### **D. Inquiry Procedures**

The Inquiry Committee begins its proceedings by reviewing the allegations of research misconduct and the supporting materials, if any, to determine whether to gather additional evidence and/or refer to the Investigation Committee for further investigation. 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 a reasonable extension of this deadline at its discretion. The Inquiry Committee may, at its option, interview or submit written questions to the Complainant.

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 normally shall invite the Respondent to meet with the Inquiry Committee to discuss the details of the alleged misconduct. This interview shall be fact-finding rather than adversarial. If the Respondent declines to meet with the committee, or in addition to such a meeting, the Inquiry Committee may also solicit responses to written questions.

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/video, or through solicited responses to written questions, or other methods. These interviews will be conducted in a manner designed to protect the confidentiality of the inquiry process, including, to the extent possible, the Respondent's identity, and the witnesses/experts will be asked to sign

Confidentiality Agreements. Additional sources of information, such as documents and physical evidence, may be gathered and considered by the Inquiry Committee.

#### 1. Summary of Relevant Evidence

Once it has completed its review of the evidence, the Inquiry Committee will prepare a Summary of Relevant Evidence document (SRE). This document summarizes the information obtained from any interviews that the committee conducted as well as any documents the committee reviewed. The document is intended to be an objective summary of the relevant information obtained to date, and is not expected to include any conclusions or determinations.

Once finalized, the Research Integrity Officer will provide the SRE to the Respondent. The Respondent has 10 calendar days from delivery to review the SRE and may, if they desire, provide a written response to the RIO, within that ten-day period, that identifies any inaccuracies or omissions they feel exist in the SRE. If no response is received within 10 calendar days, the SRE will be deemed to be sufficient.

The SCRM Chair may, but is not required to, direct the RIO to provide the Complainant with a copy of the SRE, or relevant portions of it, for Complainant's response. The RIO shall not provide the Complainant with a copy of the SRE unless the Complainant agrees to be bound by a confidentiality agreement permitting review of the information solely to provide feedback to the inquiry committee and prohibiting disclosure of the contents. A Complainant will be allowed 10 days from the date an SRE is delivered to provide the RIO with a written response. If received within that time frame, the RIO shall provide the Complainant's written response to the Inquiry Committee.

The Inquiry Committee will review the response from the Respondent (and, if applicable, the Complainant) and determine whether any changes to the SRE, or any additional information gathering, is warranted. The SRE, the response(s), if any, as well as the Inquiry Committee's evaluation of the response(s), will be included in the committee's Inquiry report.

#### 2. Vote

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 and shall draft the inquiry report.

#### E. The Inquiry Report

At the conclusion of the inquiry proceedings, the Inquiry Committee shall prepare a written report for consideration by the SCRM (the "inquiry report").

#### 1. Content of Inquiry Report

The inquiry report shall include the following:

- 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;
- the Summary of Relevant Evidence
- any response(s) by the Respondent or Complainant to the Summary of Relevant Evidence, as well as the Inquiry Committee's evaluation of the response(s)
- the basis for recommending or not recommending that the allegations warrant a full investigation;
- whether the Inquiry Committee recommends that any other actions be taken if an investigation is not recommended; and
- the name and position of the Respondent, Complainant and witnesses should be included in an appendix and shared only with those with a need to know.

Before submitting the final report to SCRM and the Vice Chancellor for Research & Innovation, the Inquiry Committee may submit the report to University Counsel for legal sufficiency review.

# F. SCRM Review of Inquiry Report and Determination

The SCRM will meet to discuss the Inquiry Report; the Vice Chancellor of Research and Innovation will be invited to join this discussion. 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.
- (b) accept for review and/or initiate additional investigation of those allegations of research misconduct not dismissed. The SCRM shall refer any research misconduct allegations requiring further investigation to an Investigating Committee.
- (c) If the SCRM determines that some or all of the Complainant's allegations were not made in good faith, the SCRM may refer the Complainant to appropriate entities within the University or to other institutions.

#### 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 further 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 by the investigation committee.

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 acceptance for review and the determination by the SCRM that further investigation is warranted. The purpose of the investigation is to review and further develop the factual record by exploring the allegations in detail and examining the evidence in depth. The ultimate goal of the investigation committee 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 research misconduct, including any additional instances of possible research misconduct that may arise during the investigation. The Respondent will be informed promptly of any additional allegations.

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 or the RIO will review with the Investigation Committee the charge, the inquiry report, and these Guidelines and Procedures. At least one member of the Inquiry Committee should also be present to address any questions about that committee's report. 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:

- Begin its proceedings by studying the information and evidence collected by the Inquiry Committee.
- 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.
- Provide the Respondent with an opportunity to provide oral or documentary evidence related to the allegations or research misconduct.
- Provide the Respondent with an opportunity to identify witnesses with knowledge in the area of the alleged research misconduct.
- Provide the Respondent with an opportunity to review and respond to any evidence that the Investigative Committee relies upon in making its determinations.
- Preserve the evidence that it relies upon in making its determinations.

The Investigative Committee shall request confidentiality from all participants in the investigation. When appropriate, each party or witness shall be interviewed separately. Interviews may be recorded and transcribed; the recording or transcript may be provided to the interviewee for correction and included 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. All aspects of the investigation should be completed within 180 days (120 days for NIH-funded research) of the Investigative Committee's first meeting. This includes conducting the investigation, preparing the report of findings, receiving comments on the draft report, sending the final report to SCRM, preparation of the SCRM's report and recommendations, and review and action by the Deciding Official.

If the RIO determines that the investigation cannot be completed within this 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 directs the filing of periodic progress reports, the RIO will ensure that such periodic progress reports are filed with PHS/ORI.

#### F. Summary of Relevant Evidence

Once it has completed its review of the evidence, the Investigation Committee will prepare its Summary of Relevant Evidence (SRE), which may be based, in large part, upon the SRE originally prepared by the inquiry committee. This document will summarize the information obtained from any interviews that the committees conducted as well as any documents or other evidence the committees reviewed. The document is intended to be an objective summary of the relevant information obtained by the committees to date, and is not expected to include any conclusions or determinations.

Once finalized, the Research Integrity Officer will provide a copy of the SRE to the Respondent. The Respondent has 30 calendar days from delivery to review the SRE and may, if they desire, provide a response to the RIO within that thirty-

day period that identifies any inaccuracies or omissions they feel exist in the SRE. The Respondent may wish to identify any additional questions for witnesses or other relevant evidence that they feel should be explored by the Investigation Committee. If no response is received within 30 calendar days, the SRE will be deemed sufficient.

The SCRM Chair may, but is not required to, direct the RIO to provide the Complainant with a copy of the SRE, or relevant portions of it, for Complainant's response. The RIO shall not provide the Complainant with a copy of the SRE unless the Complainant agrees to be bound by a confidentiality agreement permitting review of the information solely to provide feedback to the investigation committee and prohibiting disclosure of the contents. A Complainant will be allowed 20 days from the date that an SRE is delivered to provide the RIO with their written response. If received within that twenty-day time frame, the RIO shall provide the Complainant's written response to the Investigation Committee and the Respondent.

The Investigation Committee shall consider the Respondent's (and Complainant's, if applicable) comments, shall determine whether any changes to the SRE or additional information gathering is warranted. The investigation committee shall include the comments, if any, and the Investigation Committee's response to such comments, as an appendix to their SRE. If the Investigation Committee chooses to amend its SRE, it is not required to provide either the Respondent or Complainant with its SRE modifications before submitting their final report to the SCRM.

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

The Investigative Committee shall communicate this decision 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;
- Reference and include the SRE (and any relevant attachments) 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, 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 conclusions 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 those portions of the SRE that the Investigative Committee relied upon in making its determination; (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.

Before submitting its final report to SCRM and the Vice Chancellor for Research & Innovation, the Investigation Committee may submit the report to University Counsel for review for legal sufficiency.

## B. Referral of Investigation Report to SCRM

The SCRM will meet to discuss the Investigation Report; the Vice Chancellor of Research & Innovation will be invited to join this discussion. The SCRM shall determine whether it considers the report complete; if not, it shall request additional information, explanation, or investigation from the Investigative Committee. Upon completing any additional charge(s) from the SCRM, 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 committee work is necessary, it shall vote to accept the report as final.

# IX. Disposition by the SCRM

Upon review of the Investigation Committee's final investigation report, the SCRM shall 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 consistent with <u>APS 1007</u> and based on the findings included in the Investigative Committee Report regarding:

- Steps to correct or ameliorate the effects of the misconduct or serious research error.
- Possible disciplinary action
- Policy changes, or other actions that might ensure that similar misconduct does not occur in the future.
- 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 (DO).

## X. Final Disposition

#### A. Decision by the Deciding Official

Upon receipt of the final reports of the SCRM and the Investigation Committee, the DO will determine in writing whether the University accepts the investigation report, its findings, and the SCRM's recommendations; and the institution's actions in response thereto. If the DO disagrees with the findings of the Investigation Committee or with the recommendations of the SCRM, the DO may meet with the SCRM to discuss their differences.

1. Disagreement with Investigation Committee Report

If the disagreement pertains to the findings of the Investigation Committee, the SCRM may direct the Investigation Committee to provide a response. This may

involve additional investigation or re-evaluation of their original report. The Investigation Committee will then issue a revised report to the SCRM that includes their evaluation of the issues raised by the SCRM. This revised report and SCRM conclusions will then be provided by the SCRM to the DO as the final Investigation and SCRM reports.2. Disagreement with SCRM Report

If the DO still disagrees with the recommendations of the SCRM, the DO may meet with the SCRM to discuss their differences before issuing a final decision. 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.

#### **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. In doing so, the DO will provide the Respondent, and optionally the Complainant, with the final Investigation and SCRM Reports.

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

If expressly granted a right to do so in an existing University policy, Respondent may appeal the application of a disciplinary or personnel action resulting from the DO's determination, but the determination of the DO is otherwise final and may not be appealed. For cases under the jurisdiction of PHS/ORI, such appeals must be completed within 120 days of filing. If unable to be completed within 120 days, the Deciding Official must ask PHS/ORI in writing for an extension and provide an explanation for the request.

# 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 and involved 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 PHS/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.

## XI. History

- Original policy was entitled "Operating Rules of the Standing Committee on Research Misconduct," November 1991
- Revised 1994
- Revised and retitled February 11, 2009
- Revised October 25, 2014
- Revised May 11, 2020

# 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 the appropriate dean and vice chancellor, as well as the appropriate regulatory agencies and/or sponsors, if at any time during the research misconduct proceeding, (a) there is reason to believe that health or safety of the public is at risk (including an immediate need to protect

human or animal subjects); (b) HHS, other sponsor or institutional resources or interests are threatened; (c) research activities should be suspended (d) there is reasonable indication of possible violations of civil or criminal law; (e) federal action is required to protect the interests of those involved in the research misconduct proceeding; (f) the institution believes that the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved; or (g) the research community or the public should be informed.

- Provides PHS/ORI with a written finding 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 the case of retaliation against the RIO, (s)he will report the retaliation to the DO, who will take steps to protect the RIO.
- 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:

- As soon as possible, preferably 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 SCRM 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 (if applicable) 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, if applicable.
- 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 (if applicable) 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.
- 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.
- 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.