

RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT: PROCEDURES

OFFICE OF RESEARCH, INNOVATION, AND ECONOMIC DEVELOPMENT RESEARCH INTEGRITY AND COMPLIANCE

April 2022

I. Introduction

This procedure supports the California State University, Sacramento (Sacramento State) Policy on Research Integrity and is to be used and closely followed by the Offices of Research, Innovation, and Economic Development in response to allegations of research misconduct involving a 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 this institution.

Allegations of research misconduct involving non-federally funded research or allegations of research integrity violations other than fabrication, falsification or plagiarism may follow the same procedures for research misconduct. Therefore, any reference to research misconduct in this procedure extends to violations of research integrity. In the event that the Research Misconduct procedures are not followed, the Provost and Vice President for Academic Affairs and/or the Associate Vice President for Research, Innovation, and Economic Development will determine what procedure applies in accordance with the funder or other Sacramento State policies and procedures.

II. Definitions

- A. *Allegation*—a report of possible research misconduct through any means of communication to the RIO, the DO, or funding agency.
- B. Campus counsel --the Sacramento State legal counsel who is responsible for advising the RIO, the inquiry and investigation committees and the Deciding Official on relevant legal issues. Campus Counsel does not represent the Respondent, the Complainant or any other person participating during the assessment, inquiry, investigation or any follow-up action, except the officials responsible for managing or conducting the research misconduct process as part of their official duties.
- C. Complainant -- anyone who makes an allegation of research misconduct.
- D. Conflict of interest--the real or apparent interference of one person's interests with the interests of another, where potential bias may occur due to prior or existing personal, professional or economic relationships.
- E. Deciding Official (DO)--the Provost and Vice President for Academic Affairs. The Deciding Official will not be the same individual as the RIO and should have no direct prior involvement in the preliminary assessment, inquiry or investigation.

- F. *Employee*--any person paid by, under the control of, or affiliated with the University of California. For the purpose of this policy, "employee" also includes independent contractors and guest researchers.
- G. Sponsor -- the federal sponsoring agency of the research project, for example, PHS, NIH, NSF, DOE, NASA, DOD and FDA, or the non-federal sponsoring agency of the research projects, for example, State, local, for-profit, and not-for-profit entities.
- H. *Good faith allegation*—an allegation made with the honest belief that research misconduct may have occurred.
- I. Inquiry--preliminary information-gathering and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.
- J. Investigation—the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct and identify whether any publications need correction or retraction.
- K. Office of Inspector General (OIG)—the independent oversight of the agency's programs and operations at each federal agency. The office is responsible for promoting efficiency and effectiveness in agency programs and for preventing and detecting fraud, waste, and abuse.
- L. Office of Research Integrity (ORI)—the Federal agency responsible for overseeing and investigating research integrity and misconduct issues as they relate to PHS funded research.
- M. Remedial action--actions necessary to protect research funds. These actions are not disciplinary but are intended to ensure the appropriate expenditure of research funds and to protect the integrity of the research.
- N. Research--a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research).
- O. Research Integrity— research integrity, also known as the responsible conduct of research (RCR), is the practice of scientific investigation with integrity. It involves the

awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research. Research integrity encompass the following nine areas: Authorship, Collaborative Research, Conflicts of Interest and Commitment, Research Data Management, Financial Responsibility, Mentoring, Peer Review, Human Research Protection, and Animal Care and Use.

- P. Research Integrity Officer (RIO)—the Associate Vice President for Research, Innovation, and Economic Development or the person delegated this responsibility.
- Q. Research misconduct--fabrication, falsification or plagiarism in proposing, performing or reviewing research or in reporting research results. It does not include honest error or differences of opinion.
 - a. Fabrication--making up data or results and recording or reporting them.
 - b. Falsification--manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
 - c. Plagiarism--the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- R. Research record--the physical and/or electronic record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, progress reports, abstracts, theses or dissertations, oral presentations, internal reports, journal articles and any documents and materials provided to the United States Department of Health and Human Services or a University official by a Respondent in the course of a research misconduct proceeding.
- S. *Respondent*--the person(s) against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

III. Requirements

A. Time limits

1. Federal law imposes specific time limits upon many of the steps described below including:

- a. Complete inquiry process within 60 days of the first meeting of the inquiry committee unless a delay is clearly warranted.
- b. Initiate investigation within 30 days of completion of inquiry if investigation is indicated.
- c. Submit investigation report to the federal sponsor within 120 days of initiation of investigation.
- 2. This policy applies only to research misconduct occurring within six years preceding the date an allegation of research misconduct is received. The exceptions to the sixyear statute of limitations are as follows:
 - a. If, for the potential benefit of the Respondent, the Respondent continues or renews any incident of alleged research misconduct that occurred before the six year limitations period through the citation, republication or other use of the research record that is alleged to have been fabricated, falsified or plagiarized.
 - b. The alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

B. Evidentiary standards

The following evidentiary standards apply to allegations of research misconduct:

- 1. Sacramento State has the burden of proving research misconduct.
- 2. Standard of proof
 - a. A finding of research misconduct must be established by a preponderance of the evidence, meaning that the evidence demonstrates that it is more likely than not that the Respondent committed research misconduct as defined in this policy.
 - b. A finding of research misconduct requires:
 - 1) A significant departure from accepted practices of the relevant research community; and
 - 2) The misconduct is committed intentionally, knowingly or recklessly.

- c. The destruction, absence of, or Respondent's failure to provide research records documenting the questioned research may be considered evidence of research misconduct where the preponderance of the evidence establishes the Respondent intentionally, knowingly or recklessly had research records and destroyed them, had the opportunity to maintain the records but failed to do so, or maintained the records and failed to produce them in a timely manner and that the Respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.
- d. For purposes of this policy, misconduct is committed recklessly when an individual makes a false, fabricated or plagiarized representation with callous disregard as to whether or not it is true or requires attribution to another. Such callous disregard can be demonstrated by evidence that shows the representation is:
 - 1) In fact false, misleading, or plagiarized; and
 - 2) The individual had a high degree of awareness of the probable falsity or misleading nature or source of the representation or in fact entertained serious doubts as to the truth of the representation. This subjective awareness of the falsity or misleading nature of a representation can be inferred from evidence indicating that there were obvious reasons to doubt the accuracy of the representation and the individual did not act reasonably in dispelling those doubts.

IV. Rights and Responsibilities

A. Research Integrity Officer

The Associate Vice President for Research, Innovation, and Economic Development will serve as the RIO who will have primary responsibility for implementation of the institution's policies and procedures on research misconduct. A detailed listing of the responsibilities of the RIO is set forth in Appendix A.

- 1. The RIO is not a voting member of the inquiry or investigation committees.
- 2. The RIO's role may be delegated.

B. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. The complainant is entitled to be interviewed at the *inquiry* stage and given the transcript or recording of their interview for correction. The complainant must be interviewed during an *investigation*, and be given the transcript or recording of their interview for correction.

On case-by-case determinations, the RIO may provide to the complainant for comment: (1) relevant portions of the *inquiry* report (within a timeframe that permits the inquiry to be completed within 60 days of its initiation); and (2) the draft *investigation* report or relevant portions of it. Comments on the draft investigation report must be submitted within 30 days of the date on which the complainant received the draft report. The institution must consider any comments made by the complainant on the draft investigation report and include those comments in the final investigation report.

C. Respondent

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation. The respondent is entitled to:

- A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry;
- An opportunity to comment on the inquiry report and have his/her comments attached to the report;
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to federal law and the institution's policies and procedures on research misconduct;
- Be notified in writing of the allegations to be investigated within a reasonable time
 after the determination that an investigation is warranted, but before the
 investigation begins (within 30 days after the institution decides to begin an
 investigation);
- When new allegations of research misconduct are received during the inquiry or investigation that were not previously evaluated during the preliminary assessment, the RIO will determine whether those allegations should be reviewed as part of the

inquiry or investigation, or whether a separate preliminary assessment must be conducted;

- Be interviewed during the investigation, have the opportunity to correct their recording or transcript, and have the corrected recording or transcript included in the record of the investigation;
- Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation; and
- Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by the institution and addressed in the final report.
- The respondent will have the opportunity to request an institutional appeal.

The respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the concurrence of the RIO and/or other institutional officials, the Deciding Official may terminate the institution's review of an allegation that has been admitted, if the institution's acceptance of the admission and any proposed settlement is approved by ORI, OIG, and/or the sponsor.

D. Deciding Official

The DO will receive the inquiry report and after consulting with the RIO and/or other institutional officials, decide whether an investigation is warranted.

The DO will receive the investigation report and, after consulting with the RIO and/or other institutional officials, decide the extent that Sacramento State accepts the findings of the investigation and, if research misconduct is found, will follow Section X.B. of this procedure for Administrative Action.

V. Conducting the Assessment and Inquiry

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified and whether the allegation falls within the definition of research misconduct. An inquiry must be conducted if these criteria are met. Before proceeding to an inquiry, the RIO may consult with scientific peers who have the appropriate technical expertise to determine whether or not the allegation falls under the definition of research misconduct.

The assessment period should be brief, preferably concluded within a week. In conducting the assessment, the RIO need not interview the complainant, respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that *potential* evidence of research misconduct may be identified. The RIO shall, on or before the date on which the respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding, as provided in paragraph C. of this section.

B. Initiation and Purpose of the Inquiry

If the RIO determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.

C. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the RIO must make a good faith effort to notify the respondent in writing, if the respondent is known. If the inquiry subsequently identifies additional respondents, they must be notified in writing. On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number

of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. The RIO may consult with ORI, OIG, or the sponsor for advice and assistance in this regard.

D. Appointment of the Inquiry Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and a chair from amongst the inquiry committee as soon after the initiation of the inquiry as is practical. The inquiry committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry.

E. Charge to the Committee and First Meeting

The RIO will prepare a charge for the inquiry committee that:

- Sets forth the time for completion of the inquiry (60 days after First Meeting);
- Describes the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
- States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct; and, (2) the allegation may have substance, based on the committee's review during the inquiry.
- Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this procedure.

At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for

conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The RIO will be present or available throughout the inquiry to advise the committee as needed.

F. Inquiry Process

The inquiry committee will normally interview the complainant, the respondent, and key witnesses as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence, including the testimony obtained during the inquiry. After consultation with the RIO, the committee members will decide whether an investigation is warranted based on the criteria in the Policy on Integrity in Research and this procedure. The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the institution shall promptly consult with ORI, OIG, and/or the sponsor to determine the next steps that should be taken. See Section IX.

G. Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted, must be completed within 60 calendar days of initiation of the inquiry, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period. The respondent will be notified of the extension.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that includes the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) the funder, including, for example, grant numbers, grant applications, contracts and publications listing funder support; (4) the basis for recommending or not recommending that the allegations warrant an investigation; (5) any comments on the draft report by the respondent or complainant.

B. Notification to the Respondent and Opportunity to Comment

The RIO shall notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within 10 days, and include a copy of or refer to applicable federal law and the institution's policies and procedures on research misconduct. The institution may notify the complainant whether the inquiry found an investigation to be warranted and may provide relevant portions of the inquiry report to the complainant for comment within 10 days. A confidentiality agreement is a condition for access to the report.

Any comments that are submitted by the respondent or complainant will be attached to the final inquiry report. Based on the comments, the inquiry committee may revise the draft report as appropriate and prepare it in final form. The committee will deliver the final report to the RIO.

C. Institutional Decision and Notification

1. Decision by Deciding Official

The RIO will transmit the final inquiry report and any comments to the DO, who will determine in writing whether an investigation is warranted. The inquiry is completed when the DO makes this determination.

2. Notification to ORI and Federal Sponsor's OIG

Within 30 calendar days of the DO's decision that an investigation is warranted, the RIO will provide ORI or the federal sponsor's OIG with the DO's written decision and a copy of the inquiry report. The RIO must provide the following information to federal oversight 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.

3. Notifying Non-Federal Sponsors

Non-Federal Sponsors will be informed of inquiries, investigations and outcomes of research misconduct proceedings based on contractual obligations. The DO, after consulting appropriate institutional officials, may inform non-federal sponsors even if notification is not contractually required.

4. Documentation of Decision Not to Investigate

If the DO 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 ORI or sponsors of the reasons why an investigation was not conducted. These documents must be provided to authorized personnel upon request (ORI, DHHS, Federal Sponsor's OIG, or non-federal sponsor's authorized official).

VII. Conducting the Investigation

A. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted. The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on 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. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation must be set forth in an investigation report.

B. Notification; Sequestration of Research Records

On or before the date on which the investigation begins, the RIO must: (1) notify the ORI Director, Federal Sponsor's OIG, and/or non-federal sponsors of the decision to begin the investigation and provide a copy of the inquiry report; and (2) notify the respondent in writing of the allegations to be investigated. The RIO must also give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.

The RIO will, prior to notifying respondent of the allegations, take 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. The need for additional sequestration of

records for the investigation may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

C. Appointment of the Investigation Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an investigation committee and a chair from among the investigation committee as soon after the beginning of the investigation as is practical. The investigation committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The RIO will define the subject matter of the investigation in a written charge to the committee that:

- Describes the allegations and related issues identified during the inquiry;
- Identifies the respondent;
- Informs the committee that it must conduct the investigation as prescribed in paragraph E. of this section;
- Defines research misconduct;
- 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 in order to determine that the respondent

committed research misconduct it must find that a preponderance of the evidence establishes that: (1) research misconduct, as defined in this procedure, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the respondent committed the research misconduct intentionally, knowingly, or recklessly; and

• Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy.

First Meeting

The RIO will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of this statement of procedures, campus policy and applicable federal law. The RIO will be present or available throughout the investigation to advise the committee as needed.

E. Investigation Process

The investigation committee and the RIO must:

- Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
- Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation; and

 Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.

F. Time for Completion

The investigation is to be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to ORI, OIG, and/or the sponsor. However, if the RIO determines that the investigation will not be completed within this 120-day period, he/she will submit a written request for an extension, setting forth the reasons for the delay.

VIII. The Investigation Report

A. Elements of the Investigation Report

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

- Describes the nature of the allegation of research misconduct, including identification of the respondent. The respondent's c.v. or resume may be included as part of the identification;
- Describes and documents the federal support, or other support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing support;
- Describes the specific allegations of research misconduct considered in the investigation;
- Includes the Sacramento State Policy on Research Integrity and these procedures, unless previously provided;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
- Includes a statement of findings for each allegation of research misconduct identified during the investigation. Each statement of findings must: (1) identify

whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion; (3) identify the specific sponsors; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current sponsors or known applications or proposals for support that the respondent has pending.

B. Comments on the Draft Report and Access to Evidence

1. Respondent

The RIO must give the respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed 30 days from the date they received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.

Complainant

The complainant may receive a copy of the draft investigation report, or relevant portions of it, for comment when circumstances are appropriate. The complainant's comments must be submitted within 30 days of the date on which they received the draft report and the comments must be included and considered in the final report.

3. Confidentiality

In distributing the draft report, or portions thereof, to the respondent, and complainant the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may require that the recipient sign a confidentiality agreement.

C. Institutional Review and Decision

The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's and complainant's comments are

included and considered, and transmit the final investigation report to the DO, who will determine in writing whether the institution accepts the investigation report, its findings, and the recommended institutional actions. If research misconduct is found, the DO will follow Section X.B. of the procedure for Administrative Action. If this determination varies from the findings of the investigation committee, the DO will, as part of their written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the DO may return the report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, the RIO will notify the respondent in writing and will normally notify the complainant in writing. After informing ORI, OIG, and/or the sponsor, the DO will determine whether 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.

D. Appeals

The respondent may appeal the final decision that could result in a reversal or modification of the institution's findings of research misconduct. Appeals shall be made in writing to the DO. Appeals will be handled in accordance with the Investigation Process of this procedure. The appeal must be completed within 120 days of its filing, unless ORI, OIG, and/or the sponsor finds good cause for an extension, based upon the institution's written request for an extension that explains the need for the extension.

Respondent may consult with legal counsel or a non-lawyer personal advisor (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal advisor to the appeals interviews or meetings on the case.

E. Notice of Institutional Findings and Actions

Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation or the 120-day period for completion of any appeal, submit the following to ORI, OIG, and/or the sponsor: (1) a copy of the final investigation report with all attachments and any appeal; (2) a statement of whether the institution accepts the findings of the investigation report or the outcome of the appeal; (3) a statement of whether the institution found misconduct and, if so, who committed the

misconduct; and (4) a description of any pending or completed administrative actions against the respondent.

F. Maintaining Records for Review

The RIO must maintain and provide to ORI, OIG, and/or the sponsor upon request records of research misconduct proceedings. 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 federal proceeding involving the research misconduct allegation. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI, OIG, or the sponsor to carry out its review of an allegation of research misconduct or of the institution's handling of such an allegation.

IX. Completion of Cases; Reporting Premature Closures

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify ORI, OIG, and/or the sponsor in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage.

X. Institutional Administrative Actions

The determination of the DO with respect to research misconduct shall be binding. The appeal of any disciplinary determination shall be handled in accordance with the applicable academic or staff personnel policy or collective bargaining agreement.

A. Remedial Action

If the DO determines that research misconduct is substantiated by the findings, they may take any remedial actions which are deemed necessary to protect research funding and integrity. These remedial actions may include:

 Notifying publishers of the findings so that they may withdraw or correct all pending or published abstracts and papers emanating from the research where research misconduct was found;

- Coordinating with department chairs to redirect funds by removing the responsible person from the particular project, and special monitoring of future work; and
- Other action appropriate to the research misconduct.

B. Administration of Discipline

Other relevant procedures for administration of discipline should be adhered to respective of the Respondent's employment status. Specifically, if Respondent is:

- 1. An academic appointee, the matter will be referred to the Vice Provost, Faculty Affairs for review under applicable personnel policies;
- 2. A student, the matter will be referred to the Vice President, Student Affairs for review under applicable student policies;
- 3. A staff member, the matter will be referred to the respective administrator and Human Resources for review under applicable staff policies.

XI. Other Considerations

A. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the institution's responsibilities.

If the respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation, the RIO and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence.

B. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI, OIG, and/or sponsor concurrence, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation. Depending on the particular circumstances and the views of the respondent, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation should first be approved by the DO.

C. Protection of the Complainant, Witnesses and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the institution or ORI determines that research misconduct occurred, the RIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding. The DO will determine, after consulting with the RIO, and with the complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The RIO is responsible for implementing any steps that the DO approves.

D. Allegations Not Made in Good Faith

If relevant, the DO will determine whether the complainant's allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the DO determines that there was an absence of good faith they will determine whether any administrative action should be taken against the person who failed to act in good faith.

E. Record Retention

After completion of a case and all ensuing related actions, the RIO will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the RIO or inquiry or investigation committees. The RIO will keep the files for at least seven years after completion of the case to permit later assessment of the case. The funder or ORI will be given access to the records upon request.

XII. 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 funding agencies.
- Complies with its written policies and procedures and the federal requirements.
- Informs its institutional members 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 funded research process.

II. Notice and Reporting to ORI and Cooperation with ORI

The RIO has lead responsibility for ensuring that the institution:

- Files an annual report with ORI containing the information prescribed by ORI.
- Sends to ORI with the annual report such other aggregated information as ORI may prescribe on the institution's research misconduct proceedings and the institution's compliance with 42 CFR Part 93.
- 3. Notifies 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.

- 4. Provides 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.
- 5. Notifies ORI of the decision to begin an investigation on or before the date the investigation begins.
- 6. Within 120 days of beginning an investigation, or such additional days as may be granted by ORI, (or upon completion of any appeal made available by the institution) provides 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.
- 7. Seeks advance 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.
- 8. Cooperates fully with 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

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The RIO is responsible for:

- 1. 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.
- 2. 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.
- 3. Providing confidentiality to those involved in the research misconduct proceeding, other applicable law, and institutional policy.
- 4. 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.
- 5. Keeping the Deciding Official (DO) and others who need to know apprised of the progress of the review of the allegation of research misconduct.
- 6. 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.
- 7. 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.
- 8. 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.
- 9. Maintaining records of the research misconduct proceeding in a secure manner for 7 years after completion of the proceeding, or the completion of any ORI proceeding involving the allegation of research misconduct, whichever is later, unless custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained.

10. Ensuring that administrative actions taken by the institution and ORI are enforced and taking appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards, of those actions.

B. Allegation Receipt and Assessment

The RIO is responsible for:

- 1. Consulting confidentially with persons uncertain about whether to submit an allegation of research misconduct.
- 2. Receiving allegations of research misconduct.
- **3.** Assessing each allegation of research misconduct to determine if an inquiry is warranted because the allegation falls within the definition of research misconduct, and is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

C. Inquiry

The RIO is responsible for:

- 1. Initiating the inquiry process if it is determined that an inquiry is warranted.
- 2. At the time of, or before beginning the inquiry, making a good faith effort to notify the respondent in writing, if the respondent is known.
- 3. 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, except that 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.
- 4. Appointing an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical.

- 5. Preparing a charge for the inquiry committee in accordance with the institution's policies and procedures.
- 6. Convening the first meeting of the inquiry committee and at that meeting briefing the committee on the allegations, the charge to the committee, and the appropriate procedures for conducting the inquiry, including the need for confidentiality and for developing a plan for the inquiry, and assisting the committee with organizational and other issues that may arise.
- 7. 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.
- 8. Being available or present throughout the inquiry to advise the committee as needed and consulting with the committee prior to its decision on whether to recommend that an investigation is warranted on the basis of the criteria in the institution's policies and procedures.
- 9. 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.
- 10. Assisting the inquiry committee in preparing a draft inquiry report, sending the respondent a copy of the draft report for comment (and the complainant if the institution's policies provide that option) within a time period that permits the inquiry to be completed within the allotted time, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent (and the complainant if the institution's policies provide that option), and ensuring that the comments are attached to the final inquiry report.
- 11. Receiving the final inquiry report from the inquiry committee and forwarding it, together with any comments the RIO may wish to make, to the DO who will determine in writing whether an investigation is warranted.
- 12. Within 30 days of a DO decision that an investigation is warranted, providing ORI with the written finding and a copy of the inquiry report and notifying those institutional officials who need to know of the decision.

- 13. Notifying the respondent (and the complainant if the institution's policies provide that option) whether the inquiry found an investigation to be warranted and including in the notice copies of or a reference to federal regulations and the institution's research misconduct policies and procedures.
- 14. Providing to ORI and/or the Federal Sponsor, 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.
- 15. If the DO 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 ORI and/or the Federal Sponsor of the reasons why an investigation was not conducted.

D. Investigation

The RIO is responsible for:

- 1. Initiating the investigation within 30 calendar days after the determination by the DO that an investigation is warranted.
- 2. On or before the date on which the investigation begins: (1) notifying ORI and/or Federal Sponsor of the decision to begin the investigation and providing a copy of the inquiry report; and (2) notifying the respondent in writing of the allegations to be investigated.
- 3. 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.
- 4. In consultation with other institutional officials as appropriate, appointing an investigation committee and committee chair as soon after the initiation of the investigation as is practical.
- 5. Preparing a charge for the investigation committee in accordance with the institution's policies and procedures.

- 6. Convening the first meeting of the investigation committee and at that meeting: (1) briefing the committee on the charge, the inquiry report and the procedures and standards for the conduct of the investigation, including the need for confidentiality and developing a specific plan for the investigation; and (2) providing committee members a copy of the institution's policies and procedures and federal regulations.
- 7. 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.
- 8. Being available or present throughout the investigation to advise the committee as needed.
- 9. On behalf of the institution, the RIO is responsible for each of the following steps and 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) interviews 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.
- 10. 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), submitting a request to ORI and/or the Federal Sponsor for an extension of the 120-day period that includes a statement of the reasons for the extension. If the extension is granted, the RIO will file periodic progress reports with ORI/Federal Sponsors.
- 11. Assisting the investigation committee in preparing a draft investigation report, sending the respondent (and complainant at the institution'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 complainant at the institution's option) and ensuring that the comments are included and considered in the final investigation report.
- 12. Transmitting the draft investigation report to institutional counsel for a review of its legal sufficiency.
- 13. Assisting the investigation committee in finalizing the draft investigation report and receiving the final report from the committee.
- 14. Transmitting the final investigation report to the DO and: (1) if the DO determines that further fact-finding or analysis is needed, receiving the report back from the DO for that purpose; (2) if the DO determines whether or not to accept the report, its findings and the recommended institutional actions, transmitting to 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; or (3) if the institution provides for an appeal by the respondent that could result in a modification or reversal of the DO's finding of research misconduct, ensuring that the appeal is completed within 120 days of its filing, or seeking an extension from ORI and/or Federal Sponsor in writing (with an explanation of the need for the extension) and, upon completion of the appeal, transmitting a copy of the investigation report with all attachments, a copy of the appeal proceedings, a statement of whether the institution accepts the findings of the appeal proceeding, 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.
- 15. When a final decision on the case is reached, the RIO will normally notify both the respondent and the complainant in writing and will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of involved journals, collaborators of the respondent, or other relevant parties should be notified of the outcome of the case.
- 16. Maintaining and providing to ORI and/or Federal Sponsor 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.