

Procedure for Conducting the Investigation

I. Purpose of the Investigation

Following referral from an inquiry, the investigation is to explore in detail the allegations, to examine the evidence in depth and to determine specifically 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 will be set forth in the investigation report.

II. Securing the Research Records

The RIO will immediately secure any additional pertinent research records that were not secured during the inquiry. This should occur before or at the time the Respondent is notified that an investigation has begun. The need for records may occur for any number of reasons. The procedures to be followed for securing records during the investigation are the same procedures that apply during the inquiry. (See Exhibit A, IV.D.)

III. Notification of the Respondent

The RIO will notify the Respondent as soon as reasonably possible after the determination is made to open an investigation. The notification should include:

- A. a copy of the inquiry report;
- B. the specific allegations;
- C. the sources of federal funding;
- D. the definition of research misconduct;
- E. the procedures to be followed in the investigation, including the appointment of the Investigation Committee and experts;
- F. the opportunity for the Respondent to be interviewed, to provide information, to be assisted by counsel, to challenge the membership of the committee and experts based on bias or conflict of interest and to comment on the draft report;
- G. the fact that ORI and/or the Federal Sponsor may perform an oversight review of the report regarding federal issues; and
- H. an explanation of the Respondent's right to request a hearing before ORI or the relevant Federal Sponsor's appeals board if there is a finding of research misconduct under the federal definition.

IV. Designation of an Official or a Committee to Conduct the Investigation

The RIO is responsible for designating others to conduct the investigation.

A. Use of an Investigation Committee

The RIO will normally appoint a committee of three or more persons to conduct the investigation. Appointment of the committee will be done jointly with the Vice Provost—Academic Personnel consistent with the provisions herein (see V.A, below).

B. Use of an Investigation Official

In cases in which there is an admission of research misconduct by the Respondent, the RIO may choose to conduct the investigation directly or designate another qualified individual to do

so. In such cases, the investigation official will nevertheless obtain the necessary expert and technical advice to properly consider all issues.

C. Investigation process

The investigation, whether conducted by a committee or an individual, will follow each procedural step set forth below. The investigation must be completed within 120 days from the first Investigation Committee meeting unless an extension of time is obtained. For research funded by federal sponsors, extensions may be granted by ORI or the sponsor for good cause. For all other sponsored research, an extension may be granted by the RIO for good cause.

V. Appointment of the Investigation Committee

If an Investigation Committee is to be appointed, the RIO will use the following procedures:

A. Committee membership

1. The Investigation Committee will be appointed jointly by the RIO and the Vice Provost—Academic Personnel. The Vice Provost will annually request that the chair of the Davis Division of the Academic Senate provide a list of names of Academic Senate and non-Senate members who will serve as panel members of the inquiry and investigation committees. A majority of the members will be selected from this list unless a waiver is mutually agreed upon by the RIO and Senate Chair. In the event of a waiver, the RIO and the Vice Provost will consider the names forwarded by the Senate Chair in determining who should be appointed to the Investigation Committee. The members of the Inquiry Committee may be selected to continue as members of the Investigation Committee. Additional appointments may be added in order to provide necessary expertise.
2. The Investigation Committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses and conduct the investigation.

B. Experts

Experts may be appointed or carried over from the inquiry as noted in Exhibit A, VII.B, to advise the committee on scientific or other issues.

C. Bias or conflict of interest

The RIO will take reasonable steps to ensure that the members of the committee and the experts have no bias or personal or professional conflicts of interest with the Respondent, Reporter or the case in question. (See Exhibit A, VII.C.)

D. Objection by Respondent

The RIO will notify the Respondent of the proposed committee membership within 10 days. If the Respondent submits a written objection to any appointed member of the Investigation Committee or expert based on bias or conflict of interest within 10 days, the RIO will determine whether to replace the challenged member or expert with a qualified substitute.

E. Service on Inquiry Committee

Serving on the Inquiry Committee for an allegation does not in and of itself constitute either conflict of interest or bias on the part of the members.

F. Confidentiality

Members of the committee and experts will agree in writing to observe the confidentiality of the proceedings and any information or documents reviewed as part of the investigation. Outside of

the official proceedings of the committee, they may not discuss the proceedings with the Respondent, Reporter, witnesses or anyone not authorized by the RIO to have knowledge of the investigation.

VI. Charge to the Committee and the First Meeting

A. Charge to the committee

1. 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, define research misconduct and identify the name of the Respondent. The charge will state that the committee is to evaluate the evidence and testimony of the Respondent, Reporter, and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.
2. During the investigation, if additional information becomes available that substantially changes the research misconduct subject matter of the investigation or would suggest additional Respondents, the committee will notify the RIO, who will determine whether it is necessary to notify the Respondent of the new subject matter or to provide notice to additional Respondents.

B. The first meeting

The RIO, with the assistance of Campus Counsel, 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 these instructions and, where federal funding is involved, the applicable federal regulation.

VII. Developing an Investigation Plan

At the initial meeting, the committee should begin development of its investigative plan and complete it as soon as reasonably possible. The investigation plan will include:

- A. an inventory of all previously secured evidence and testimony;
- B. a determination of whether additional evidence needs to be secured;
- C. which witnesses need to be interviewed, including the Reporter, Respondent and other witnesses with knowledge of the research or events in question; and
- D. a proposed schedule of meetings, briefing of experts, interviews, anticipated analyses of evidence (scientific, forensic or other) and developing a plan for the investigative report.

VIII. General Approaches to Conducting the Investigation

During the investigation, the committee will take the following steps:

A. Avoid bias or conflict of interest

All necessary steps must be taken to avoid bias or conflict of interest between the committee and experts and the Respondent, Reporter and witnesses.

B. Refer other issues

The RIO must be advised of any necessary interim actions to protect the research funds, human or animal subjects or other steps required by regulation or policy. (See Section 240-01, VI.G.3.)

C. Consult with the Research Integrity Officer and Campus Counsel

The RIO and Campus Counsel should be consulted throughout the investigation on compliance with these procedures and federal regulations, appropriate investigatory and interviewing methods and strategies, legal issues and the standard of proof. The RIO and Campus Counsel will be present or available throughout the investigation to advise the committee.

IX. Reviewing the Evidence

The Investigation Committee will obtain and review all relevant documentation and perform or cause to be performed necessary analyses of the evidence, including scientific, forensic, statistical, or other analyses as needed.

X. Conducting Interviews

The Investigation Committee will conform to the following guidelines:

A. Conducting the interviews

The Investigation Committee will conduct the interviews as described in Exhibit A, X, except that at the investigative stage interviews should be in-depth and all significant witnesses should be interviewed. Each witness should have the opportunity to respond to inconsistencies between his or her testimony and the evidence or other testimony, subject to the need to take reasonable steps to maintain the confidentiality of the testimony of the Respondent and other witnesses.

B. Preparing for interviews

The Investigation Committee will prepare carefully for each interview. All relevant documents and research data should be reviewed in advance and specific questions or issues that the committee wants to cover during the interview should be identified. The committee should appoint one individual to take the lead on each interview. If significant questions or issues arise during an interview that require committee deliberation, the committee should take a short recess to discuss the issues. Committee deliberations should never be held in the presence of the interviewee.

C. Objectivity

The Investigation Committee will conduct all interviews in a professional and objective manner, without implying guilt or innocence on the part of any individual.

D. Transcribing interviews

Any interview with the Respondent, Reporter, or any witness will be transcribed.

E. Recording admissions

If the Respondent admits to the research misconduct, he or she should be asked to sign a statement attesting to the occurrence and extent of the misconduct, acknowledging that the statement was voluntary and stating that the Respondent was advised of his or her right to seek the advice of counsel. The committee should consult with Campus Counsel on the specific form and procedure for obtaining this statement. An admission may be used as evidence in compiling an Investigation Report. Any disciplinary action will be referred to the Academic Senate or other unit as appropriate if the respondent is not a member of the faculty.

XI. Committee Deliberations

A. Burden and standard of proof

In reaching a conclusion on whether there was research misconduct and who committed it, the burden of proof is on the institution to support its conclusions and findings by a preponderance of the evidence.

B. Definition of research misconduct

The committee will consider whether fabrication, falsification or plagiarism occurred in proposing, conducting, reviewing or reporting research.

C. Sufficient evidence

The committee will consider whether there is sufficient evidence of intent such that the institution can meet its burden of proving research misconduct by a preponderance of the evidence. The committee will also consider whether the Respondent has presented substantial evidence of honest error or differences in interpretations or judgments of data such that research misconduct cannot be proven by a preponderance of the evidence.

XII. The Investigation Committee Report

A. Elements of the Investigation Report

1. The final report from the Inquiry Committee;
2. Any additional relevant information provided by the Office of Research, such as the committee structure, process and cover letter and any specific information required by ORI or a federal or other sponsor that must receive a copy of the Investigation Report;
3. A description of the policies and procedures under which the investigation was conducted;
4. description of how and from whom information relevant to the investigation was obtained;
5. the findings, and explanation for the basis of the findings; and
6. the actual text or an accurate summary of the views of any individual(s) found to have engaged in research misconduct.

B. The report initially submitted to the Deciding Official will not include sanctions or disciplinary action unless some administrative action occurred to prevent harm to subjects. The investigation report will be amended to include sanctions or disciplinary action once the Academic Senate or other appropriate body has made final decisions on those actions. If the report must be submitted to ORI or an external sponsor, a description of any sanctions imposed and administrative actions taken by the University will be included in an amended report once the action has been recommended.

C. Outline for an Investigation Report

The following annotated outline may be used, unless an external sponsor or exceptional circumstances suggest a different approach.

1. Background

Include sufficient background information to ensure a full understanding of the issues including those that would concern ORI and/or the Federal Sponsor under the definition of research misconduct. This section should include a chronology of events, detail the facts leading to the inquiry and include a description of the research at issue, the persons involved in the alleged research misconduct and the role of the Reporter.

2. Allegations

List all the allegations of research misconduct raised by the Reporter and any additional research misconduct allegations that arose during the inquiry and investigation. The source and basis for each allegation or issue should be cited except to the extent that the confidentiality of a Reporter requesting anonymity is compromised or where the identity of the source is irrelevant or unnecessary. The allegations identified in this section will form the structure or context in which the subsequent analysis and findings are presented.

3. External Support

For each allegation of research misconduct under the definition, identify any application or external support for the research or report (e.g., publication) at issue containing the alleged fabrication, falsification or plagiarism.

4. Institutional Inquiry: Process and Recommendations

Summarize the inquiry process, including the composition of the committee (names, degrees, departmental affiliation and expertise) and the charge to the committee. List the persons interviewed, the evidence secured and reviewed and the measures taken to ensure its security, the policies and procedures used, and any other factors that may have influenced the proceedings.

5. Institutional Investigation: Process

Summarize the investigation process, including the composition of the committee (names, degrees, departmental affiliation, and expertise) and the charge to the committee. List the persons interviewed, how the interview was conducted and by whom, the evidence secured and reviewed and the measures taken to ensure its security, the policies and procedures used, and any other factors that may have influenced the proceedings.

6. Institutional Investigation: Analysis

For each allegation, include:

a. Background

Describe the particular matter (e.g., experiment or component of a clinical protocol) in which the alleged research misconduct occurred and why and how the issue came to be under investigation.

b. Analysis

- 1) The analysis should take into account all the relevant statements, claims (e.g., a claim of a significant positive result in an experiment), rebuttals, documents and other evidence including circumstantial evidence related to the issue. The source of each statement, claim or other evidence should be cited (e.g., laboratory notebook with page and date, medical chart documents and dates, relevant manuscripts, transcripts of interview, etc.).
- 2) Any use of additional expert analysis should be noted (forensic, statistical or special analysis of the physical evidence, such as similarity of features or background in contested figures).
- 3) Summarize accurately or quote relevant statements, including rebuttals, made by the Reporter, Respondent and other pertinent witnesses and reference/cite the appropriate sources.
- 4) Summarize each argument that the Respondent raised in his or her defense against the research misconduct allegation and cite the source of each argument. Any inconsistencies among the Respondent's various arguments should be noted.
- 5) The analysis should be consistent with the terms of the definition of research misconduct. It should describe the relative weight given to the various witnesses and pieces of evidence, noting inconsistencies, credibility and persuasiveness.
- 6) Describe any evidence that shows that the Respondent acted with intent, that is, any evidence that the Respondent knowingly engaged in the alleged fabrication, falsification, or plagiarism.
- 7) Describe the evidence supporting the possibility that honest error or differences of scientific opinion occurred with respect to the issue.

c. Conclusions

- 1) A finding of research misconduct must be supported by a preponderance of the evidence.
- 2) Concisely state the Investigation Committee's finding for each identified issue. If the Investigation Committee finds research misconduct on one or more issues, the report should identify the type of misconduct for each issue (fabrication, falsification, or plagiarism) and should indicate the extent and seriousness of the fabrication, falsification, or plagiarism, including its effect on research findings, publications, research subjects, and the laboratory or project in which the research misconduct occurred.

7. Recommended Actions

Identify any remedial actions that should be taken to ensure the appropriate expenditure of research funds and to protect the integrity of the research. (see Section 240-01, IV.E.2) The final investigation report should include any sanctions or disciplinary action undertaken during the inquiry or investigation.

8. Attachments

Copies of all significant documentary evidence referenced in the report should be appended to the report, if possible (relevant notebook pages or other research records, relevant committee or expert analyses of data, transcripts or summary of each interview, Respondent and Reporter responses to the draft report(s), manuscripts, publications or other documents, including grant progress reports and applications, etc.). It is also helpful to include a "List of Attachments" and a side-by-side comparison that identifies the allegedly false statement, misrepresentation or area of plagiarism with the actual data or material that is alleged to have been falsified/fabricated/plagiarized.

D. Documenting the Investigative File

1. Index of evidence

The investigation committee should maintain an index of all the relevant evidence it secured or examined in conducting the investigation, including any evidence that may support or contradict the report's conclusions. Evidence includes, but is not limited to, research records, transcripts or recordings of interviews, committee correspondence, administrative records, grant applications and awards, manuscripts, publications, and expert analyses.

2. Purpose of documentation

The purpose of the documentation is to substantiate the investigation's findings.

3. 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 committees. The RIO will keep the file for seven years after completion of the case to permit later assessment of the case. ORI and/or the Federal Sponsor will be given access to the records upon request.

E. Comments on the draft report

1. Respondent

The RIO will provide the Respondent with a copy of the draft Investigation Report for comment and rebuttal. The report may be redacted to protect the privacy of the Reporter

or others interviewed during the course of the investigation. The Respondent will be allowed 14 calendar days to review and comment on the draft report. The Respondent's comments will be attached to the final report. The findings of the final report should take into account the Respondent's comments in addition to all other evidence.

2. Reporter

The RIO may provide the Reporter, if he or she is identifiable, with those portions of the draft investigation report that address the Reporter's role and opinions in the investigation.

3. Campus Counsel

The draft investigation report will be transmitted to the Campus Counsel for a review of its legal sufficiency. Counsel's comments should be incorporated into the report as appropriate.

4. Confidentiality

In distributing the draft report, or portions thereof, to the Respondent, 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 request the recipient to sign a confidentiality statement or to come to his or her office to review the report.