Saint Mary's College of California
Policy for Responding to Allegations of Research Misconduct

Responsible Officers	Senior Vice President for Academic Affairs and Provost
Responsible Offices	Academic Affairs
Issuance Date	September 12, 2025
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Applicability	This policy applies to Saint Mary's administrators, faculty, and all other employees who apply for or participate in external grants, contracts, and subawards that are awarded to Saint Mary's College of California.

I. POLICY SUMMARY

PURPOSE

Saint Mary's College of California (SMC) is committed to the highest standards of honesty, accountability and integrity in all research and scholarly activities. SMC expects all members to uphold ethical principles in the conduct, reporting, and dissemination of research.

Allegations of research misconduct will be addressed promptly, fairly, and in accordance with applicable regulations. This policy affirms SMC's dedication to the responsible conduct of research.

SCOPE

This statement of policy and procedures is intended to carry out SMC's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93.[1] Other federal agencies have published their own research misconduct regulations; to the extent those regulations apply to an allegation of research misconduct and are inconsistent with this policy, SMC shall comply with the applicable regulatory requirements. This policy also applies to research that is not federally funded, although such cases need not be reported to the federal government.

This policy applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) 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 SMC and:

(1) applications or proposals for PHS or other extramural support for research, research training, or activities related to that research or research training;
(2) PHS or other extramurally supported research, research training programs, or activities that are related to research or research training, such as the operation of data banks or the dissemination of research information;
(3) research records produced during PHS-supported or other extramurally supported research, research training, or activities related to that research or research training; and
(4) research proposed, performed, reviewed, or reported, as well as any research record

[1] Code of Federal Regulations, Title 42, Chapter I, Subchapter H, Part 93, Public Health Service Policies on Research Misconduct, § 93.101(e). Retrieved 09/10/2025 from the Electronic Code of Federal Regulations https://www.ecfr.gov/current/title-42/part-93#p-93.101(e).

generated from that research, regardless of whether an application or proposal for PHS or other extramural funds resulted in an awarded grant, contract, cooperative agreement, subaward, or other form of PHS support.[2]

This policy does not apply to authorship or collaboration disputes and applies only to allegations of research misconduct that occurred within six years of the date SMC received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).[3]

II. DEFINITIONS

Administrative Unit Head. The person charged with the responsibility of supervising or directing a unit within the college.

Allegation. Any written or oral statement or other indication of possible Research Misconduct made to the Research Integrity Officer.

Complainant. A person who makes an allegation about research misconduct. A complainant may or may not be affiliated with the college and may be anonymous.

Deciding Official (DO). The institutional official who makes final determinations on allegations of research misconduct and any institutional actions, ordinarily the Vice Provost for Institutional and Educational Effectiveness. The Deciding Official does not serve as the Research Integrity Officer and is not directly involved in SMC's preliminary assessment,inquiry, or investigation. The DO's involvement, if any, in the appointment of a person to assess allegations of research misconduct, or to serve on an inquiry or investigation committee, is not considered to be direct involvement.

Department of Health and Human Services (DHHS). U.S. Department of Health and Human Services.

Evidence. Any document, tangible or intangible item, testimony, or other matter having evidentiary value offered or obtained during a research misconduct proceeding.

Good Faith. Good faith means that an allegation is made or testimony is provided with the honest belief in the truth of one's statements based on information known to the complainant or witness at the time. An allegation of misconduct or testimony in a research misconduct proceeding is not made in good faith if done with knowing or reckless disregard of information that would negate the allegation or testimony.

Inquiry. A preliminary information gathering process to determine whether an allegation of misconduct in research or research-related activities has substance and warrants an investigation.

[2] 42 CFR § 93.102, https://www.ecfr.gov/current/title-42/section-93.102.
[3] 42 CFR § 93.105, https://www.ecfr.gov/current/title-42/section-93.105.

Investigation. The formal evaluation and examination of all relevant facts and evidence to determine whether research misconduct occurred and, if so, who is responsible.

Office of Research Integrity (ORI). The Office of Research Integrity within the U.S. Department of Health and Human Services oversees and directs U.S. Public Health Service research integrity activities on behalf of the secretary of health and human services with the exception of the regulatory research integrity activities of the U.S. Food and Drug Administration. Research that is proposed to, or funded by, the PHS is under the purview of the ORI and applicable federal regulations at 42 CFR 93.

Plagiarism. The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Preponderance of Evidence. Preponderance of Evidence means that the provided information is convincing enough to conclude, based on the information, that there is a greater than 50% chance that a claim is true.

Public Health Service (PHS). U.S. Public Health Service.

Research. Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Research may be defined in additional detail in certain contexts. Research conducted in any field or discipline is applicable to this policy.

Research Integrity Officer (RIO). The RIO is the SMC institutional official responsible for:
(1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified;
(2) overseeing inquires and investigations; and
(3) the other responsibilities described in this policy.

Research Misconduct. Research misconduct is the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results. Research misconduct does not include honest error or differences of opinion.

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes or changing or omitting data or results such that the research is not accurately represented in the research record
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research Misconduct Proceeding. Research misconduct proceeding means any action related to an allegation of research misconduct undertaken pursuant to this policy, including but not limited to allegation assessments, inquiries, investigations, and appeals.

Research Record. Research record means the record of research data or results that embody the facts resulting from scientific or scholarly inquiry, including but not limited to research

proposals, laboratory records (both physical and electronic), progress reports, abstracts, theses, dissertations, oral presentations, internal or external reports, journal articles, books, and any documents and materials provided to, or accessed by, the RIO or an institutional official in the context of an allegation or research misconduct proceeding.

Research-related Activities. Research-related activities are ancillary activities that occur in support of research. Such activities include but are not limited to research proposals, progress reports, presentations of preliminary results, presentations in meetings or conferences, posters, drafts, final written reports, and publications. For purposes of this policy, the terms "research" and "research-related activities" are broadly referred to as "Research."

Respondent. Respondent means the person against whom an allegation of research misconduct is directed or the person who is the subject of a research misconduct proceeding.

Retaliation. Retaliation means an adverse action taken against a complainant, witness, or panel member by SMC or one of its members in response to a good faith allegation of research misconduct or good faith cooperation with a research misconduct proceeding. Retaliation against any individual involved in a research misconduct proceedings are prohibited and subject to SMC sanctions.

SMC Member. Any person engaged, participating in, or directly or indirectly supervising an SMC research-related activity, including but not limited to an administrator, full- or part-time faculty member, staff member, or other employee.

III. POLICY TEXT

General Policies and Principles

A. Responsibility to Report Misconduct

All SMC members will report observed, suspected, or apparent research misconduct to the RIO . If an individual is unsure whether a suspected incident falls within the definition of research misconduct, they may meet with or 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, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.[4]

At any time, an SMC member may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

B. Cooperation with Research Misconduct Proceedings

SMC members will cooperate with the RIO and other SMC officials in the review of allegations and the conduct of inquiries and investigations. SMC members, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other

[4] 42 CFR 93.100(b), https://www.ecfr.gov/current/title-42/part-93#p-93.100(b).

SMC officials.

C. Confidentiality

The RIO shall, as required by 42 CFR § 93.106:

(1) limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and

(2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding. The RIO should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

D. Protecting complainants, witnesses, and committee members

SMC members may not retaliate in any way against complainants, witnesses, or committee members. SMC members should immediately report any alleged or apparent retaliation against complainants, witnesses or committee members to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

E. Protecting the Respondent

As requested and as appropriate, the RIO and other SMC officials shall make all reasonable and practical efforts 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.[5]

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and the policies and procedures of SMC.

F. Interim Administrative Actions and Notifying ORI or Agency of Special Circumstances

Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the PHS or other extramurally supported research process. In the event of such a threat, the RIO will, in consultation with other SMC officials and ORI or other agency contact, 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, or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI immediately if they have 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, or the resources or interests of another extramural sponsor;
- Research activities should be suspended;

[5] 42 CFR § 93.304(c) https://www.ecfr.gov/current/title-42/part-93#p-93.304(c).

- 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; or
- 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. [6]

IV. IMPLICATIONS OF POLICY

A. Rights and Responsibilities

1. Research Integrity Officer (RIO)

The Provost will serve as the RIO and will have primary responsibility for implementation of SMC's policy on research misconduct. The RIO's responsibilities include the following duties related to research misconduct proceedings:

- Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;
- Receive allegations of research misconduct;
- Assess each allegation of research misconduct to determine whether it falls within the definition of research misconduct and warrants an inquiry;
- As necessary, take interim action and notify ORI of special circumstances;
- Sequester research data and evidence pertinent to the allegation of research misconduct and maintain it securely in accordance with this policy and applicable law and regulation;
- Provide confidentiality to those involved in the research misconduct proceeding
- Notify the respondent and provide opportunities for them to review, comment, and/or respond to allegations, evidence, and committee reports;
- Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- Appoint the chair and members of the inquiry and investigation committees and ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;
- Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;
- In cooperation with other SMC officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and counter potential or actual retaliation against them by respondents or other institutional members;
- Keep the Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;
- Notify and make reports to ORI as required by 42 CFR Part 93 or to other agency in compliance with applicable regulatory requirements;
- Ensure that administrative actions taken by the college and ORI are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement

[6] 42 CFR § 93.305(g) https://www.ecfr.gov/current/title-42/part-93/section-93.305#p-93.305(g)

agencies, professional societies, and licensing boards of those actions; and
- Maintain records of the research misconduct proceeding and make them available to ORI or other sponsoring agency.

2. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. As a matter of good practice, the complainant should be interviewed at the inquiry stage and given the transcript or recording of the interview for correction. The complainant must be interviewed during an investigation, and be given the transcript or recording of the interview for correction.[7]

3. 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;[8]
- An opportunity to comment on the inquiry report and have their comments attached to the report;9
- Be notified of the results of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to 42 CFR Part 93 and SMC's policies and procedures on research misconduct;10
- 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 SMC decides to begin an investigation), and be notified in writing of any new allegations not addressed in the inquiry or in the initial notice of investigation within a reasonable time after the determination to pursue those allegations;11
- Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;12
- 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;13 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 SMC and addressed in the final

[7] 42 CFR §93.310(g) https://www.ecfr.gov/current/title-42/part-93/section-93.310#p-93.310(g)
[8] 42 CFR § 93.307(c)https://www.ecfr.gov/current/title-42/part-93/section-93.307#p-93.307(c)
[9] 42 CFR §93.307(g)(3)https://www.ecfr.gov/current/title-42/part-93#p-93.307(g)(3)
[10] 42 CFR §308 https://www.ecfr.gov/current/title-42/section-93.308
[11] 42 CFR §309(a) https://www.ecfr.gov/current/title-42/part-93/section-93.309#p-93.309(a)
[12] 42 CFR §310(g) https://www.ecfr.gov/current/title-42/part-93#p-93.310(g)
[13] Ibid.

report.[14]

- The respondent should be given the opportunity to admit that research misconduct occurred and that they committed the research misconduct. With the advice of the RIO and/or other institutional officials, the Deciding Official may terminate SMC's review of an allegation that has been admitted, if SMC's acceptance of the admission and any proposed settlement is approved by ORI or other sponsoring agency.

4. 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 under the criteria in 42 CFR § 93.307(d). Any finding that an investigation is warranted must be made in writing by the DO and must be provided to ORI, together with a copy of the inquiry report meeting the requirements of 42 CFR § 93.309, within 30 days of the finding. If it is found that an investigation is not warranted, the DO and the RIO will ensure that detailed documentation of the inquiry is retained for at least 7 years after termination of the inquiry, so that ORI may assess the reasons why SMC decided not to conduct an investigation.[15] The DO will receive the investigation report and, after consulting with the RIO and/or other SMC officials, decide the extent to which this institution accepts the findings of the investigation and, if research misconduct is found, decide what, if any, SMC administrative actions are appropriate. The DO shall ensure that the final investigation report, the findings of the DO and a description of any pending or completed administrative actions are provided to ORI, as required by 42 CFR § 93.315, or otherwise provided to the sponsoring agency.

V. PROCEDURES

A. Conducting the Assessment and Inquiry

1. Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether it is within the jurisdictional criteria of 42 CFR § 93.102(b), and whether the allegation falls within the definition of research misconduct in 42 CFR § 93.103.[16] An inquiry must be conducted if these criteria are met.

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.

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[14] 42 CFR §93.312(a) https://www.ecfr.gov/current/title-42/part-93#p-93.312(a)
[15] 42 CFR §93. 309(c) https://www.ecfr.gov/current/title-42/part-93/section-93.309#p-93.309(c)
[16] 42 CFR § 93.102(b)https://www.ecfr.gov/current/title-42/part-93/section-93.102#p-93.102(b)

2. Initiation and Purpose of the Inquiry

If the RIO determines that the criteria for an inquiry are met, they 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.[17]

3. 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.[18] The RIO may consult with ORI for advice and assistance in this regard.

4. Appointment of the Inquiry Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair 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.[19]

5. 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;
- 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 is within the jurisdictional criteria of 42 CFR § 93.102(b); 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 policy

[17] 42 CFR § 93.307(b)https://www.ecfr.gov/current/title-42/part-93/section-93.307#p-93.307(b)
[18] 42 CFR §§, 93.307(c) https://www.ecfr.gov/current/title-42/part-93/section-93.307#p-93.307(c)
[19] 42 CFR § 93.305(f)https://www.ecfr.gov/current/title-42/part-93/section-93.305#p-93.305(f)

and 42 CFR § 93.309(a).

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.

6. 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 this policy and 42 CFR § 93.307(d). 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, SMC shall promptly consult with ORI or other sponsoring agency to determine the next steps that should be taken.

7. 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 90 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 90-day period.[20] The respondent will be notified of the extension.

B. The Inquiry Report

1. 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 PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS 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.[21]

SMC's legal counsel should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the inquiry committee. The inquiry report should include:

- the names and titles of the committee members and experts who conducted the inquiry;

[20] 42 CFR § 93.307(h) https://www.ecfr.gov/current/title-42/part-93/section-93.307#p-93.307(h)
[21] 42 CFR § 93.309(a) https://www.ecfr.gov/current/title-42/part-93/section-93.309#p-93.309(a)

- a summary of the inquiry process used;
- a list of the research records reviewed;
- summaries of any interviews; and
- whether any other actions should be taken if an investigation is not recommended.

2. 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 business days, and include a copy of SMC's policies and procedures on research misconduct.[22] SMC may notify the complainant whether the inquiry found an investigation to be warranted and provide relevant portions of the inquiry report to the complainant for comment within 10 business days. A confidentiality agreement should be 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.

3. Institutional Decision and Notification

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.

Notification to ORI:

- Within 30 calendar days of the DO's decision that an investigation is warranted, the RIO will provide ORI with the DO's written decision and a copy of the inquiry report. The RIO will also notify those institutional officials who need to know of the DO's decision. The RIO must provide the following information to ORI upon request:
  (1) the SMC 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.[23]
- 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 of the reasons why an investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request.

C. Conducting the Investigation

1. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted.[24] The purpose of the investigation is to develop a factual

[22] 42 CFR § 93.308(a) https://www.ecfr.gov/current/title-42/part-93/section-93.308#p-93.308(a)
[23] 42 CFR § 93.309(a) and (b) https://www.ecfr.gov/current/title-42/section-93.309
[24] 42 CFR § 93.310(a) https://www.ecfr.gov/current/title-42/part-93/section-93.310#p-93.310(a)

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. Under 42 CFR § 93.313 the findings of the investigation must be set forth in an investigation report.

2. Notifying ORI or Sponsor Agency and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the RIO must: (1) notify the ORI Director of the decision to begin the investigation and provide ORI 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.[25] In the case of non-PHS sponsors, the RIO should comply with applicable regulatory requirements related to agency notification and research records sequestration.

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 SMC'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.[26]

3. Appointment of the Investigation Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair 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. When necessary to secure the necessary expertise or to avoid conflicts of interest, the RIO may select committee members from outside SMC.

4. Charge to the Committee and the First Meeting

Charge to the Committee:

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

[25] 42 CFR § 93.310(b) and (c) https://www.ecfr.gov/current/title-42/section-93.310

[26] 42 CFR § 93.310(d) https://www.ecfr.gov/current/title-42/section-93.310

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;
- 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 policy, 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 and 42 CFR § 93.313.

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 policy and procedures and 42 CFR Part 93. The RIO will be present or available throughout the investigation to advise the committee as needed.

5. Charge to the Committee and the First Meeting 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;[27]
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;[28]
- 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;[29] 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.[30]

[27] 42 CFR § 93.310(e) https://www.ecfr.gov/current/title-42/part-93/section-93.310#p-93.310(e)
[28] 42 CFR § 93.310(f) https://www.ecfr.gov/current/title-42/part-93/section-93.310#p-93.310(f)
[29] 42 CFR § 93.310(g) https://www.ecfr.gov/current/title-42/part-93/section-93.310#p-93.310(g)
[30] 42 CFR § 93.310(j) https://www.ecfr.gov/current/title-42/part-93/section-93.310#p-93.310(j)

6. Time for Completion

The investigation is to be completed within 180 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 or other extramural sponsor. However, if the RIO determines that the investigation will not be completed within this 180-day period, they will submit to ORI a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.[31]

D. The Investigation Report

1. 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;
- Describes and documents the PHS or other extramural support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS or other extramural support;
- Describes the specific allegations of research misconduct considered in the investigation;
- Includes SMC's policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI or other agency previously;
- 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.[32] 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 they did not engage in research misconduct because of honest error or a difference of opinion;
  (3) identify the specific PHS or other extramural support;
  (4) identify whether any publications need correction or retraction;
  (5) identify the person(s) responsible for the misconduct; and
  (6) list any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.[33]

2. Comments on the Draft Report and Access to Evidence

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

[31] 42 CFR § 93.311https://www.ecfr.gov/current/title-42/section-93.311
[32] 42 CFR § 93.313 https://www.ecfr.gov/current/title-42/section-93.313
[33] Ibid

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.[34]

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 require that the recipient sign a confidentiality agreement.

3. Decision by Deciding Official

The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's comments are included and considered, and transmit the final investigation report to the DO, who will determine in writing:

(1) whether SMC accepts the investigation report, its findings, and the recommended institutional actions; and

(2) the appropriate institutional actions in response to the accepted findings of research misconduct. 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 normally notify both the respondent and the complainant in writing. After informing ORI or other agency, the DO will determine whether 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.

4. Notice to ORI or Other Agency of Institutional Findings and Actions

Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation, submit the following to ORI or other agency: (1) a copy of the final investigation report with all attachments; (2) a statement of whether SMC accepts the findings of the investigation report; (3) a statement of whether SMC found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent.[35]

5. Maintaining Records for Review by ORI

The RIO must maintain and provide to ORI upon request "records of research misconduct proceedings" as that term is defined by 42 CFR § 93.318. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure

[34] 42 CFR §§ 93.312, https://www.ecfr.gov/current/title-42/section-93.312

[35] 42 CFR § 93.405 https://www.ecfr.gov/current/title-42/section-93.405

manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation.[36] The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or ofSMC's handling of such an allegation.[37]

E. Completion of Cases; Reporting Premature Closures to ORI

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. For allegations that include PHS funded research, the RIO must notify ORI 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, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315.[38] For allegations that include non-PHS funded research, SMC must comply with any other notice obligation to a government agency or other funder.

F. Institutional Administrative Actions

If the DO determines that research misconduct is substantiated by the findings, they will decide on the appropriate actions to be taken, after consultation with the RIO. The administrative actions may include:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
- Restitution of funds to the grantor agency as appropriate; and
- Other action appropriate to the research misconduct.

VI. RELATED INFORMATION

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 SMC's responsibilities under 42 CFR Part 93.

If the respondent, without admitting to the misconduct, elects to resign their position after SMC 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

[36] 42 CFR § 93.318 https://www.ecfr.gov/current/title-42/part-93#p-93.318(a)
[37] 42 CFR §§ 93.300(g) https://www.ecfr.gov/current/title-42/part-93/section-93.300#p-93.300(g), 93.403(b) and (d) https://www.ecfr.gov/current/title-42/section-93.403
[38] 42 CFR § 93.315 https://www.ecfr.gov/current/title-42/section-93.315

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 concurrence where required by 42 CFR Part 93, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation.[39] 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 SMC 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.[40] 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 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.

VII. FREQUENTLY ASKED QUESTIONS

Not applicable.

VIII. SOURCES

- U.S. Department of Health and Human Services (HHS) Office of Research Integrity (ORI) website, https://ori.hhs.gov.
- U.S. Department of Health and Human Services ORI Sample Policy & Procedures for Responding to Research Misconduct Allegations website at: https://ori.hhs.gov/sample-policy-procedures-responding-research-misconduct-allegations and policy template at: https://ori.hhs.gov/sites/default/files/2025-06/Sample%20Policies%20and%20Procedures_prepared%20for%20publication.docx

[39] 42 CFR § 93.304(c) https://www.ecfr.gov/current/title-42/part-93/section-93.304#p-93.304(c)
[40] Ibid

- U.S. Department of Health and Human Services (HHS) regulation on research misconduct: 42 CFR Part 93, Public Health Service Policies on Research Misconduct. Electronic Code of Federal Regulations https://www.ecfr.gov/current/title-42/part-93.

IX. REVISION HISTORY

- Adopted by Saint Mary's Academic Senate, October 3, 2025
- Originally Adopted by Academic Affairs, September 12, 2025