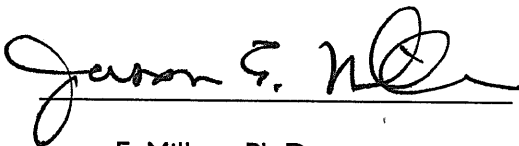


# SENATE POLICY 23-14

Motion: to approve the Policy on Misconduct in HHS-sponsored Research

Passed at the March 5, 2024 meeting of the Executive Committee of the Academic Senate

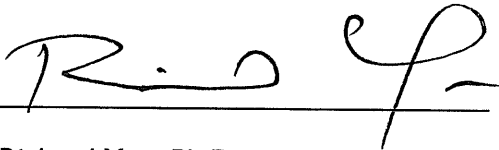
Approvals:



Jason E. Miller, Ph.D.  
Chair, Academic Senate

3/6/2024

Date



Richard Yao, Ph.D.  
President

3/7/24

Date



# CALIFORNIA STATE UNIVERSITY CHANNEL ISLANDS POLICY MANUAL

**Division of Academic Affairs**

**Approved By:** Senate Executive Ctte.  
March 5, 2024

**Approved By:** Richard Yao, President  
TBD

**Policy Number:** SP 23-14

**Effective Date:** March 8, 2024

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## Policy on Misconduct in HHS-Supported Research

**Purpose:** This policy describes the procedures related to investigating and reporting instances of alleged or apparent misconduct in research, scholarship and creative activities (RSCA). This policy is intended to conform to the “Public Health Service Policies on Research Misconduct” [42 CFR (Code of Federal Regulations) Part 93].

**Background:** California State University Channel Islands (CSUCI) adheres to and promotes the highest standards of conduct in Research, Scholarship and Creative Activities (RSCA). Misconduct in RSCA is antithetical to the values the University strives to maintain and promote and strikes at the heart of the scholarly and educational enterprise. A shared understanding of expectations and responsibilities is, therefore, critical — not only to the quality of the RSCA enterprise but also to the collegial life of this community.

**Applicability:** This policy applies to all CSUCI administrators, faculty, staff and students as well as all organizational units of the University, including auxiliary organizations; in such instances in which such persons, units, and organizations are engaged in research funded in whole or in part by HHS or other governmental funders with similar policies or policy requirements.

### **Policy:**

#### **I. Definitions**

- A. *Complainant* means the individual bringing an allegation of research misconduct.
- B. *Deciding Official (DO)* means the institutional official who makes final determinations about allegations of research misconduct and any institutional actions. The Deciding Official does not serve as the Research Integrity Officer and is not directly involved in the institution’s preliminary assessment, inquiry, or investigation. The Deciding Official’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.
- C. *Research Integrity Officer (RIO)* means the person who has primary responsibility for implementation of the institution’s policies and procedures on research misconduct.

- D. *Research misconduct* means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
1. Fabrication is making up data or results and recording or reporting them.
  2. 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.
  3. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
  4. Research misconduct does not include honest error or differences of opinion.
- E. *Respondent* means the individual who is the subject of an allegation of Research Misconduct.
- F. *Witness* mean any individual who testifies or provides information with regard to an allegation or whose research record is used as evidence during the course of a research misconduct proceeding.

## II. Responsibilities

- A. Campus Counsel is responsible for advising the RIO, the inquiry and investigation committees and the DO on relevant legal issues. Campus Counsel does not represent the Respondent 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.
- B. The President, or designee, shall serve as the DO, who shall make the final determination as to whether research misconduct has taken place, and who shall initiate appropriate administrative action against those found to have committed research misconduct in accordance with the relevant Collective Bargaining Agreement(s).
- C. The Provost and Vice President for Academic Affairs shall appoint the RIO who shall have primary responsibility for implementation of the institution's policies and procedures on research misconduct.
- D. The RIO shall be responsible for (1) filing required annual assurances with agencies funding research as well as aggregated information on allegations, inquiries, and investigations, (2) informing and cooperating with funding agencies as set forth below, or as otherwise required by law, (3) maintaining appropriate policies and procedures relating to procedures and the importance of compliance with these policies and procedures, (4) informing University faculty and administrative staff of these policies, (5) taking immediate and appropriate action as soon as misconduct on the part of employees or individuals within the University's control is suspected or alleged, and (6) directing the maintenance of and access to documents, evidence, reports, and any other materials generated in the course of or due to an allegation, inquiry, or investigation of misconduct. On behalf of the University, the RIO shall also be responsible for notifying the U.S. Health and Human Services (HHS) Office of Research Integrity (ORI) if it is ascertained at any stage of an inquiry or investigation that any of the following conditions exist:
1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.

2. HHS resources or interests are threatened.
  3. Research activities should be suspended.
  4. There is reasonable indication of possible violations of civil or criminal law.
  5. Federal action is required to protect the interests of those involved in the research misconduct proceeding.
  6. The research institution believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
  7. The research community or public should be informed.
- E. The RIO shall (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.
- F. Institutional members may not retaliate in any way against complainants, witnesses, or committee members. Institutional 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.
- G. The RIO and other institutional 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.
- H. 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 the institution. Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case

### **III. Allegations of Misconduct in Research**

Any individual who believes an act of research misconduct has occurred or is occurring should notify the RIO. Upon receipt of an allegation of research misconduct, the RIO shall 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. An inquiry must be conducted if these criteria are met. The RIO shall also inform the Dean, the Associate Vice President for Faculty Affairs, the Provost, and all appropriate agencies or law enforcement authorities. The Dean shall reduce to writing any oral allegation of misconduct and seek

approval as to its content from the individual making the allegation. The Allegation of Misconduct will not be entered into the respondent's Personal Action File or Working Personal Action File until the completed report proving they perpetrated misconduct has been filed.

#### **IV. The Inquiry**

**A.** Inquiries will be conducted following the procedures outlined in this policy, and in compliance with specific requirements outlined in 42 CFR Part 93. 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. 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. The inquiry may be conducted by the academic program dean, a qualified panel or committee, or by such other arrangements that have the approval of the RIO. The RIO shall ensure that those conducting the inquiry a) do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and b) 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.

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 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 inquiry and submission of the inquiry report must be completed within 60 days of its initiation unless circumstances clearly warrant a longer period.

#### **B. 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 U.S. Public Health Service (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. Institutional counsel should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the inquiry committee.

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 42 CFR Part 93 and the institution's policies and procedures on research misconduct. 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, who will provide copies of the report to the DO, Provost, and Associate Vice President for Faculty Affairs. Within 30 calendar days of the decision that an investigation is warranted, the RIO will provide ORI with a copy of the inquiry report. The Inquiry Report will not be entered into the respondent's Personal Action File or Working Personal Action File until the completed report proving they perpetrated misconduct has been filed.

**C. Disposition of Inquiry Report and Related Materials**

If an investigation is not warranted, the RIO shall secure and maintain for seven 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.

**V. Conducting the Investigation**

**A.** Investigations will be conducted following the procedures outlined in this policy, and in compliance with specific requirements outlined in 42 CFR Part 93. The investigation must begin within 30 calendar days after the determination 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. Under 42 CFR § 93.313 the findings of the investigation must be set forth in an investigation report.

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.

**B. 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.

**C. 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.

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. However, if the RIO determines that the investigation will not be completed within this 120-day period, he/she 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.

**D. 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 support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support;
- Describes the specific allegations of research misconduct considered in the investigation;
- Includes the institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI 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. 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 PHS 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.

The RIO will provide copies of the investigation report to the DO, Provost, and Associate Vice President for Faculty Affairs. The Investigation Report will not be entered into the respondent's Personal Action File or Working Personal Action File until the completed report proving they perpetrated misconduct has been filed.

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 he/she received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.

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.

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

The RIO must maintain and provide to ORI upon request "records of research misconduct proceedings" as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for seven years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or of the institution's handling of such an allegation. The respondent will have the right to representation during these proceedings including a legal or union representation.



## **VI. 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 under 42 CFR Part 93.

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 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.<sup>39</sup> 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, he/she will determine whether any administrative action should be taken against the person who failed to act in good faith.

### **E. Time Limits**

SP 23-14: Policy on Misconduct in HHS-Sponsored Research

42 C.F.R. Part 93 generally applies only to research misconduct occurring within six years of the date HHS or an institution receives an allegation. The six-year limitation does not apply if the respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized. The six-year limitation does not apply if ORI or the institution, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

**EXHIBITS:**

None