

# To: Legislative History

**From:** Dr. Caren Frost (Associate Vice President for Research Integrity & Compliance; Research Integrity Officer (RIO); Research Professor in the College of Social Work) and Zachary Mitchell (Research Integrity Officer)

Policy Owner(s): Caren Frost (Associate Vice President for Research Integrity & Compliance)

Date: 2/7/2023

Re: Revisions to Policy 7-001 (Research Misconduct)

# Introduction

This revision memo summarizes the proposed revisions to Policy 7-001, Policy for Research Misconduct. The current version of the Policy is missing important timeframe and time limitations for establishing and evaluating the scope of research misconduct (item #1, below).

Several administrative changes are needed to better define and describe timelines for completing research misconduct activities (item #2, 4, and 5, below) and describe institutional notification practices (item #3, below).

# **Proposed Changes**

- 1. The current version of the policy is missing important timeframe and time limitations for establishing and evaluating the scope of research misconduct.
  - Relevant Federal regulation(s):
    - 42 C.F.R. § 93.105(a) establishes a "six-year limitation" from the date of allegation for investigating research misconduct.
    - 42 C.F.R. § 93.105(b) provides several exceptions to the six-year limitation, including the "subsequent use exception".
  - Per guidance from the Federal Office of Research Integrity (ORI), "An institution that does not adequately address the scope of the potential research misconduct...may compromise the effective handling of the investigational process and may allow undetected research misconduct to remain in the literature or to be used in applications for PHS funds." <a href="https://ori.hhs.gov/sites/default/files/2021-05/Scope%200f%20Research%20Misconduct%2005-27-2021.pdf">https://ori.hhs.gov/sites/default/files/2021-05/Scope%200f%20Research%20Misconduct%2005-27-2021.pdf</a>.

To fully address the scope of research misconduct at the University of Utah, it is necessary that the six-year limitation and appropriate exceptions be added to the Policy for Research Misconduct.

These additions are included as items II.Q and III.A in the updated Policy. Note that internal references to section III.A have been added throughout, as needed. III.B.5.a.iii

2. The current version of the policy uses "business" days for performing activities related to research misconduct. However, the timeframes for performing research misconduct activities established in 42 C.F.R. § 93 are calendar days.

To bring the University's Policy for Research Misconduct in line with the Federal regulations, "business days" has been changed to "calendar days" throughout the document.

3. The University of Utah Research Integrity Officer (RIO) works closely with the Office of General Counsel (OGC) throughout all stages of research misconduct allegations and proceedings. However, the OGC is not currently listed as a recipient of the Inquiry and Investigation initiation notifications.

To ensure that the University's Policy accurately describes the process and procedures, sections III.D.1. (Inquiry notification) and III.G.1 (Investigation Stage notification) have been updated to include "Office of General Counsel."

4. The current policy states that the Inquiry committee has 60 days from appointment to complete the Inquiry stage. However, the Inquiry stage extends beyond the committee's review to include time for the respondent to respond to the Inquiry committee's report.

To better describe the Inquiry stage and committee timeline, section III.E.8 has been updated to state that the Inquiry committee has 60 days from appointment to complete their review and issue a report.

5. The current policy states that a faculty Respondent has 10 days from Investigation committee's final report to appeal any formal sanctions from the Vice President of Research (VPR). However, because VPR sanctions are issued separately from the Investigation committee's final report, the Respondent should have 10 days from the receipt of the VPR sanctions notification.

To ensure that faculty Respondents are given all 10 days to appeal formal sanctions, section III.H.1 has been updated accordingly.

# **Regulation Development Process**

Dr. Caren Frost became aware of the need to add time limitations and exceptions to the scope of the University's Research Misconduct Policy during the August 2022 Association of Research Integrity Officers Annual Meeting.

Initial discussions and draft revisions were shared with the Office of General Counsel and other University Policy administrators, including Allyson Hicks and Trina Rich. These discussions identified the additional administrative changes that better define and describe timelines for completing research misconduct activities and describe institutional notification practices.

# **Proposed University of Utah Regulation Revision**

General Regulation Information		
Regulation proposed for enactment/revision	Policy 7-001: Policy for Research Misconduct	
Policy owner(s)	Associate Vice President for Research Integrity and Compliance	
Policy officer(s)	Vice President for Research	
Contact person(s)	Caren Frost and Zachary Mitchell	
Other related regulations with proposed revisions	None	
Planned effective date of revisions	Upon approval of the Board of Trustees – estimated for February 14, 2023	
Brief (1-2 sentence) description of revisions and reason for revision	This policy change adds a maximum amount of time that may elapse between research misconduct occurring and a complaint being filed for the policy to apply to the research misconduct, changes business days to calendar days through, and clarifies timelines for several research misconduct activities.	

# Consultation and Approval

### Groups and Stakeholders Consulted

Office of General Counsel

### Required Approval Steps and Date (if applicable)

Council of Academic Deans (if applicable)	Not applicable
Institutional Policy Committee	January 13, 2023
Academic Senate Executive Committee	January 23, 2023
Vice President or Designee	January 13, 2023
Academic Senate (if applicable)	February 6, 2023
Board of Trustees (if applicable)	February 14, 2023

# Policy 7-001 Policy for Research Misconduct

Revision <u>34</u>. Effective date: <u>April 12, 2022February 14, 2023</u>

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### **Purpose and Scope** I.

### A. Purpose.

The University of Utah, in concordance with the federal Office of Research Integrity and National Institutes of Health (NIH), supports an environment of Research integrity and promotes the responsible conduct of Research. It is incumbent on the University to create an atmosphere of accountability, honesty, and trust to ensure that researchers, who can be employees of the University as well as community members participating in Research activities, are working toward the goal of rigorous Research that promotes knowledge for the progress of the common good. As noted by the NIH, "fraudulent or socially irresponsible research undercuts the public's trust of and support for science." Having mechanisms for reporting and handling reports of Research Misconduct are crucial for maintaining the public trust and for being accountable to society for the Research conducted at the institution.

This policy provides definitions, timelines, and process descriptions for reviewing and managing Research Misconduct activities. This document provides a description of the Research Misconduct process once the University receives an Allegation of Research Misconduct.

Misconduct in Research is a matter of concern to the University, individual scientists, sponsors of Research, and the general public. The policies and

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procedures in this policy are established to respond to Allegations or Evidence of Misconduct in Research.

B. Scope.

This policy applies to all instances of alleged or apparent Research Misconduct, as defined <u>in this policy and limited to the timeframes described</u> in this policy. The policy applies to any University employee (faculty, student, staff), including a University of Utah Hospitals and Clinics employee, or other individual who participates in a Research Project. This policy is the exclusive procedure for handling Allegations of Research Misconduct. Other unprofessional behaviors in the Research context are handled through other procedures and offices at the University of Utah.

### II. Definitions

The following definitions apply for the limited purposes of this policy and any associated regulations.

- A. "Allegation" means any written or oral statement or other indication of possible Research Misconduct made to the Research Integrity Officer.
- B. "Complainant" means a person who makes a Good Faith Allegation of Misconduct in a scholarly, creative, or Research activity.
- C. "Conflict of Interest" means the real or apparent interference of one person's interests with the interests of another person where potential bias may occur due to prior or existing personal, professional, or financial relationships.
- D. "Evidence" means any document, tangible item, electronic record, or testimony offered or obtained during a Research Misconduct proceeding that tends to prove or disprove the existence of an alleged fact. "Evidence" includes the destruction, absence of, or respondent's failure to provide Research Records adequately documenting the questioned Research if the Respondent's conduct constitutes a significant departure from accepted practices of the relevant Research community and it is established by a Preponderance of the Evidence

that the respondent Intentionally, Knowingly, or recklessly destroyed Research Records, had the opportunity to maintain Research Records but did not do so, or maintained Research Records and failed to produce them in a timely manner.

- E. "Good Faith" means, regarding an Allegation of Research Misconduct, the Allegation is made with the honest belief that Research Misconduct may have occurred. An Allegation is not in Good Faith if made with reckless disregard for or willful ignorance of facts that would disprove the Allegation.
- F. "Inquiry" means information-gathering and initial fact-finding to determine whether an Allegation or apparent instance of Research Misconduct may have substance and, therefore, warrants an investigation.
- G. "Intentionally" means acting with an intent to cause a certain result.
- H. "Investigation" means a formal examination and evaluation of all relevant facts to determine if an instance of Misconduct has taken place. If Misconduct has already been confirmed, an Investigation may, nevertheless, be conducted to determine the extent of any adverse effects resulting from the Research Misconduct.
- I. "Knowingly" means acting with awareness that conduct would result in certain consequences.
- J. "Misconduct" or "Misconduct in Research" or "Research Misconduct" means Fabrication, Falsification, and/or Plagiarism that seriously deviates from those practices that are commonly accepted within the Research community for proposing, conducting, or reporting Research. Misconduct does not include honest error or honest difference in interpretations or judgments of data.
  - 1. "Fabrication" means making up results and recording or reporting the fabricated results.
  - 2. "Falsification" means manipulating Research materials, equipment, or processes, or changing or omitting data or results such that the Research and/or its results are not accurately represented in the Research Record.

- "Plagiarism" means the appropriation of another person's ideas, processes, results, or words without giving appropriate credit and without specific approval, including those learned of through confidential review of others' Research proposals and manuscripts.
- K. "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.
- L. "Research" means Research as defined by 45 CFR 46.102(d), which is "a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." Research includes obtaining information, biospecimens, or other data through interventions or interactions with human subjects or live animals.
- M. "Research Record" means any biodata, data, document, computer file, computer diskette, flash drive, or any other written or non-written account or object that reasonably may be expected to provide Evidence or information regarding the proposed, conducted, or reported Research that constitutes the subject of an Allegation of Misconduct. "Research Record" includes, but is not limited to: a grant or contract application, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer programs, files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; patient research files; and any documents and materials provided to the U.S. Department of Health and Human Services or an institutional official by a Respondent in the course of the Research Misconduct proceeding.
- N. "Respondent" means a University employee against whom an Allegation of Misconduct is directed or an employee whose actions are the subject of an Inquiry or Investigation.

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- O. "Retaliation" means any action taken by the University or an individual that adversely affects the employment or other institutional status of an individual because the individual has, in Good Faith, made an Allegation of Misconduct or of inadequate institutional response or has cooperated in Good Faith with an Investigation of such Allegations.
- P. 1. "Research Integrity Officer" or "RIO" means the University official responsible for assessing Allegations of Research Misconduct and determining when such Allegations warrant an Inquiry and for overseeing Inquiries and Investigations. At the University of Utah, the RIO is the associate vice president for research integrity.
- Q. "Subsequent Use" means a Respondent citing, republishing, or otherwise using for the benefit of the Respondent a Research Record that is described in an <u>Allegation.</u>
  - <u>1.</u> <u>"Subsequent Use" does not include a citation to a time-limited publication</u> <u>without scientific context.</u>

### III. Policy

- A. Time Limitations for Applicability of this Policy
  - Except for an Allegation described in Section III.A.2, this policy applies only to Research Misconduct that occurred within the six years preceding the date that the University, federal office or funder, or sponsor receives an Allegation.
  - <u>This policy applies to Research Misconduct that occurred more than six</u> years before the University, federal office or funder, or sponsor receives an <u>Allegation if:</u>
    - <u>a.</u> <u>there is a Subsequent Use within the six years preceding the date that the</u> <u>University, federal office or funder, or sponsor receives the Allegation; or</u>
    - b. at the RIO's discretion, the RIO determines that the University should apply the policy because:

- i. a federal agency refers the Allegation to the University;
- <u>ii.</u> <u>the Research Misconduct described in the Allegation was not</u> <u>reasonably discoverable at an earlier time:</u>
- <u>iii.</u> the alleged Research Misconduct may have a substantial adverse effect on public health or safety:
- iv. the application of this policy to the Allegation is required by law or is otherwise in the best interest of the University; or
- <u>v</u>. <u>a contract for the research, federal office or funder, or sponsor of the</u> research requires application of the policy to a period longer than six years.
- B. A.-Allegations of Research Misconduct
  - An individual who alleges or receives an Allegation of Research Misconduct shall refer the Allegation to the RIO, who shall coordinate the Inquiry, Investigation, and hearing phases as needed.
  - The Allegation stage begins when the RIO receives a report of Research Misconduct.
    - a. An individual may submit an Allegation anonymously or nonanonymously.
    - Allegations can be reported through any means, including e-mail, the ethics hotline, telephone, in-person, and/or from the federal Office of Research Integrity.
  - 3. A person who submits an Allegation shall include in the Allegation, at a minimum the following information about the potential Research Misconduct:
    - a. name of Respondent, if known;
    - b. summary of the situation of alleged Research Misconduct, including when the alleged Research Misconduct occurred; and

- c. documentation and/or Evidence related to the Research Misconduct Allegation.
- If an Allegation identifies more than one individual who could be a Respondent, the allegation may be considered as a single case; however, separate reports shall be created for each Respondent.
- 5. Within five <u>businesscalendar</u> days of receiving an Allegation of Research Misconduct, the RIO shall determine whether the Allegation warrants an Inquiry.
  - a. The RIO shall determine that the Allegation warrants an Inquiry if:
    - i. the Allegation describes actions that meet the definition of Fabrication,
       Falsification, or Plagiarism (FFP); and
    - ii. the Allegation is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified.
    - <u>iii.</u> the alleged Research Misconduct occurred within the applicable timeframe described in Section III.A.
  - b. If the RIO determines the Allegation should move to the Inquiry stage, the RIO shall notify the Office of the Vice President for Research and the Office of General Counsel.
- C. B. Sequestration Following Allegation of Research Misconduct
  - If the RIO determines that an Inquiry into an Allegation of Research Misconduct is warranted, the RIO shall sequester documentation related to the Allegation.
    - a. The RIO shall work with the University forensic information technology (IT) team to determine how to best sequester documentation and data.
    - b. The University IT team shall ensure confidentiality into the process and shall sign a non-disclosure form.

- c. In addition, if requested by the RIO, the appropriate departmental and/or college IT shall assist in the sequestration process.
- d. Reasonable efforts will be made to keep the process of sequestering data confidential.
- e. The RIO may sequester documentation in any format, including paper records, electronic records, and may sequester from servers, e-mails, or other locations.
- To ensure that data and information related to an Allegation of Research Misconduct are not tampered with, the RIO shall sequester the data and information before or immediately following notification to the Respondent of the Allegation.
- 3. Where appropriate, the Respondent shall be given copies of, or reasonable supervised access to, the Research Records.
- D. C. Notification of Respondent
  - Once plans are made for sequestration of documentation and data, the RIO shall notify the Respondent, the vice president for research, <u>the Office of</u> <u>General Counsel</u>, and the appropriate dean in writing about the Allegation and the Inquiry initiation and process.
  - The Respondent shall assist the RIO in sequestration of data, documentation, and information from their systems, such as, e-mails, paper and electronic notebooks, and information from the Respondent's computer(s) from the timeframe of the Allegation(s).
    - a. The RIO shall sequester data regardless of whether the Respondent assists with the sequestration; however, the Respondent shall provide information about the locations of any additional documentation and data.
- **E. D.** Inquiry into Allegations of Research Misconduct

- 1. The purpose of the Inquiry stage is to determine if an Allegation of Research Misconduct warrants an Investigation. The Inquiry stage includes the review of information and facts around the Allegation, and, in some cases, interviewing certain individuals about the Allegation. Because the Inquiry committee is not charged with making any final determination on Research Misconduct, an Inquiry does not require a full review of all the Evidence related to the Allegation.
- Except as described in Section III. <u>DE</u>.3, an Inquiry committee shall conduct an Inquiry phase and determine whether the Allegation warrants an Investigation.
- The RIO may, at the RIO's discretion and only under extraordinary circumstances, review the Allegation and data/information collected during sequestration and determine that the Allegation warrants an Investigation without an Inquiry phase.
- The RIO shall appoint an Inquiry committee of between one and five individuals and appoint one of the members as a chair of the Inquiry committee.
  - a. In appointing the Inquiry committee, the RIO shall ensure that:
    - i. the committee has expertise in the subject of the Research;
    - ii. the committee includes representation from the Respondent's college; and
    - iii. no committee member has an unresolved personal, professional, or financial Conflict of Interest with the Complainant, Respondent, or witnesses.
- 5. The RIO shall provide the name and department affiliation of each member of an Inquiry committee to the Respondent in writing.
- The Respondent may, within five <u>businesscalendar</u> days of receiving the names of the members of the Inquiry committee, request that the RIO

replace any committee member that the Respondent believes has an unresolved personal, professional, or financial Conflict of Interest with the Complainant, Respondent, or witnesses.

- A respondent shall submit a request to replace a committee member to the RIO in writing and shall describe in the request the reason the Respondent would like to have the committee member replaced.
- b. The RIO shall determine whether a committee member identified by the Respondent has an unresolved personal, professional, or financial Conflict of Interest with the Complainant, Respondent or witnesses, and if so, appoint an alternate committee member to replace the member to which the Respondent raises an objection.
- c. The RIO shall communicate the name and department affiliation of the alternate member to the Respondent, and the Respondent may request a replacement for the alternate member as described in this section.
- The members of the Inquiry committee and University IT employees who participate in sequestration of records or the Inquiry shall sign non-disclosure agreements (NDA) prior to beginning the Inquiry process.
- The Inquiry committee shall complete the Inquiry stagereview and issue a formal written report within 60 businesscalendar days of the appointment of the committee members.
- The Inquiry committee shall review the Evidence to determine whether the Allegation or apparent instance of Misconduct may have substance and therefore warrants an Investigation.
  - a. The Inquiry committee does not determine if FFP occurred, as that is the purpose of the Investigation.
  - b. The Inquiry committee shall review pertinent documentation and data related to the Allegation.

- c. The Inquiry committee may conduct interviews if needed to gather general information, but the committee should maintain as much confidentiality as possible by limiting the number of interviews.
  - i. The RIO shall assist in determining if interviews with pertinent individuals are allowed during the Inquiry stage.
- 10. If the Inquiry committee identifies new Allegations or respondents, the Inquiry committee may review the Allegations as one case but shall create a separate report for each Respondent.
- 11. The Inquiry committee shall issue a formal final written report with the findings from the Inquiry and the Inquiry committee's determination of whether the Allegation warrants an Investigation. The Inquiry committee shall include in their final report:
  - a. the name, positions, and affiliations of the Respondent;
  - b. a description of the Allegations of Research Misconduct;
  - c. a description of Evidence reviewed;
  - d. a description of interviews conducted;
  - e. any external funding support for the Research under Inquiry, including, for example, grant numbers, grant applications, contracts, and publications listing external support;
  - f. the basis for recommending that the alleged actions do or do not warrant an Investigation; and
  - g. any comments on the report by the Respondent, as described in Section III.
    <u>DE</u>.13.
- 12. The Inquiry committee shall provide the final written report to the Respondent and RIO and may provide the final written report to the Complainant.

- The Respondent may, within ten <u>businesscalendar</u> days of receiving the final report, provide written comment on the report to the Inquiry committee and the RIO. This written comment becomes part of the final report.
- E. E. Documentation of Inquiry Not Resulting in Investigation
  - If the Inquiry committee determines that an Investigation is not warranted, the Inquiry committee shall include in the record sufficiently detailed documentation of the Inquiry to permit a later assessment of the reasons for determining that an Investigation was not warranted.
    - a. The RIO shall retain these records in a secure manner for at least seven years after the termination of the Inquiry, and when appropriate shall, upon request, provide the records to authorized personnel.
- <u>G.</u> F.-Investigation Stage
  - If the Inquiry phase determines that the Allegation falls within the definition of Research Misconduct and may have substance, the RIO shall notify the vice president for research <u>and Office of General Counsel</u> that the Inquiry committee has determined the Allegation warrants an Investigation.
    - a. Within 30 business<u>calendar</u> days of the vice president for research receiving notification that the Allegation warrants an Investigation, the RIO shall notify the Respondent in writing that an Investigation will be forthcoming.
    - b. If the research is federally funded, the RIO shall notify the federal office that funds the research, as described in Section III.
    - c. The RIO shall notify the cognizant senior vice president of the Investigation.
  - 2. After notifying the Respondent of the Investigation, the RIO shall identify an Investigation committee of either three or five individuals including:

- a. at least two individuals who have expertise in the subject of the Research under Investigation; and
- b. at least one individual from the same department or college as the Respondent.
- The RIO shall assure that no committee member has an unresolved personal, professional, or financial Conflict of Interest with the Complainant, Respondent, or witnesses.
- 4. The RIO shall appoint one of the Investigation committee members as the chair of the committee.
- 5. The RIO shall send the Respondent in writing the name and department affiliations of the Investigation committee members.
- 6. The Respondent may, within five <u>businesscalendar</u> days of receiving the notification of the members of the Investigation committee, request that the RIO replace any Investigation committee member that the respondent believes has an unresolved personal, professional, or financial Conflict of Interest with the Complainant, Respondent, or witness.
  - A Respondent shall submit a request to replace an Investigation committee member to the RIO in writing and shall described the reason the Respondent would like to have the committee member replaced.
  - b. The RIO shall determine whether a committee member identified by the Respondent has an unresolved personal, professional, or financial Conflict of Interest with the Complainant, Respondent, or witnesses, and if so, appoint an alternate committee member to replace the member to which the Respondent raises an objection.
  - c. The RIO shall communicate the name and department affiliation of the alternate committee member to the Respondent and the Respondent may request a replacement for the alternate member as described in this section.

- d. The Investigation committee begins <u>5 business five calendar</u> days after the day on which the last committee member has been appointed without the Respondent requesting a replacement.
- 7. The members of the Investigation committee shall sign non-disclosure agreements prior to beginning the Investigation process.
- The Investigation committee may take up to 120 <u>businesscalendar</u> days to complete the Investigation and issue the final written report described in this policy.
- 9. The Investigation committee shall review all pertinent documents and data related to the Allegation.
- 10. The Investigation committee shall conduct interviews with the Complainant(s), the Respondent, and other individuals who have been reasonably identified as having information regarding any relevant aspect of the Investigation, including those identified by the Respondent.
  - a. All University faculty, staff, affiliates, and students shall cooperate with the Investigation committee. If an individual with whom the Investigation committee requests an interview refuses to participate in the investigation:
    - i. the RIO may address this refusal through existing University disciplinary processes for faculty and staff; and
    - ii. the Investigation committee may proceed in the absence of an interview with an individual who refuses to participate in the Investigation.
- 11. The Investigation committee may obtain expert consultation and secure any necessary documentation or data.
- 12. The Investigation committee shall pursue diligently all significant issues and leads discovered that are determined to be relevant to the Investigation

including any Evidence of additional instances of possible Research Misconduct.

- 13. The Investigation committee shall issue a final formal written report and provide it to the RIO, the vice president for research, the Respondent, and administrative leadership of the Respondent's department that includes:
  - a. a list of the Investigation committee members;
  - b. a description of the specific Allegations of Research Misconduct considered in the Investigation, including identification of the Respondent;
  - c. a description of how and from whom information was obtained;
  - d. a list the individuals interviewed by the Investigation committee;
  - e. a description of the related external research support related to the Allegation, including, for example, grant numbers, grant applications, contracts, and publications listing sponsored support;
  - f. a copy of the University policy and procedures under which the Investigation was conducted;
  - g. identification and summary of the Research Records and Evidence reviewed during the Investigation; and
  - h. for each separate Allegation of Research Misconduct identified during the Investigation, a finding as to whether or not the conduct was a significant departure from accepted practices of the relevant Research community, and if the conduct was, the report shall also:
    - i. identify whether the alleged Research Misconduct was Falsification, Fabrication, or Plagiarism;
    - ii. if the alleged Research Misconduct was Falsification, Fabrication, or Plagiarism, identify whether the Respondent engaged in the Research Misconduct Intentionally, Knowingly, or in reckless disregard;

- iii. summarize the Evidence supporting the finding and discuss the merits of any explanation by the Respondent as to why the alleged conduct was not Research Misconduct and any Evidence that rebuts the Respondent's explanations;
- iv. identify any publications, known at the time of the Investigation report, which need to be corrected or retracted;
- v. identify the person(s) responsible for the Research Misconduct; and
- vi. indicate whether the Allegation was proven by a Preponderance of Evidence.
- 14. The Investigation committee shall provide the respondent the final report and notify the Respondent that they have five <u>businesscalendar</u> days to provide a response to the report. A Respondent shall provide this response in writing to the RIO.
  - a. The Investigation committee may provide the final report to the Complainant.
  - b. The RIO shall include the written responses with the final report.
- 15. The factual findings of the Investigation committee are conclusive and binding on any later proceeding related to the Allegation convened for other purposes, such as a respondent appeal filed with the Senate Consolidated Hearing Committee or sanctions imposed for Research Misconduct.
- 16. If, on the basis of the Investigation, an individual is found to have engaged in Research Misconduct, the Investigation committee may make recommendations to the RIO on appropriate follow-up, such as recommended sanctions, and steps to ensure that the University meets obligations to affected third parties, including funding sources, journals, the scientific community, Research subjects, and referral sources.
- 17. The vice president for research, in consultation with the cognizant senior vice president, shall make the final determination about follow-up with and

sanctions for the Respondent and shall communicate the determination in writing to the RIO, the Office of General Counsel, and the Respondent.

- a. The RIO shall inform the Complainant(s) that the Investigation committee has issued a report and that the Investigation stage is complete.
- b. As to student and staff respondents, the decision of the vice president for research is final.
- c. As to faculty respondents, the decision regarding any finding of Research Misconduct is final, but the faculty member may appeal the sanctions imposed by the vice president for research as described in Section III.G.<u>H</u>.
- 18. In addition to any sanctions imposed by the University for Research Misconduct involving Public Health Service funds, the federal Office of Research Integrity may also impose sanctions upon a Respondent(s) who engaged in Research Misconduct or on the University if such action is appropriate.
- H. G. Faculty Appeal to Senate Consolidated Hearing Committee
  - A Respondent who is a faculty member may appeal and request a formal hearing on sanctions imposed by the University within 10 <u>calendar</u> days of receipt of the <u>Investigation committee's final reportwritten notification of</u> <u>sanctions from the vice president for research</u> by filing a request for a hearing with the Senate Consolidated Hearing Committee (SCHC) through the Office of the Academic Senate.
  - If the Office of the Academic Senate receives a request described in Section III.GH.1, the SCHC shall conduct a hearing on sanctions according to the process described in Policy 6-011.
    - a. The Investigation committee findings regarding Research Misconduct are final, and the SCHC may only consider appeals of sanctions as described in Policy 6-011.

- L H. Protection of Affected Parties
  - The confidentiality and privacy of all parties involved, including whistleblowers, in a Research Misconduct Inquiry or Investigation shall be respected insofar as it does not interfere with the University's legal obligation to investigate Allegations of Misconduct and to take corrective action.
    - a. To the extent permitted by law and University regulations, the University shall protect the identities of Respondents.
    - b. To the extent permitted by law and University regulations, the University shall protect the identity and privacy of individuals who, in Good Faith, report apparent Research Misconduct or provide information regarding alleged Research Misconduct. Retaliation of any kind against an individual who, in Good Faith, alleges Research Misconduct or cooperates with an Inquiry or Investigation, is prohibited and the retaliator may be subject to discipline under University regulations.
    - c. To the extent permitted by law and University regulations, the documents, records, and other information gathered by the RIO, the vice president for research, the Inquiry committee, the Investigation committee, or the Senate Consolidated Hearing Committee, shall be kept confidential.
  - The University shall undertake diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in Research Misconduct when such Allegations are not confirmed and to protect the positions and reputations of those persons who, in Good Faith, report apparent Misconduct.
- <u>J.</u> Reporting Possible Research Misconduct Related to Federally Funded Research
  - If the Research described in an Allegation is funded by the Public Health Service (PHS), the RIO shall follow the reporting and notification process described in Section III. JK.

- 2. If the Research described in an Allegation is funded by a federal agency other than the PHS, the RIO shall follow reporting and notification processes required by the federal funder.
- K. J. Reporting Possible Research Misconduct Related to PHS funded research to the Federal Office of Research Integrity
  - If the Research described in an Allegation is funded by the PHS, the RIO shall, within 30 <u>calendar</u> days of the determination that an Investigation is warranted, notify the director of the federal Office of Research Integrity that the Investigation will begin. The notification shall include: (1) the name of the Respondent against whom the Allegation has been made; (2) the general nature of the Allegation; (3) the PHS application or grant number involved; (4) the basis for recommending that the alleged actions warrant an Investigation; and (5) any comments on the report by the Respondent or the Complainant.
  - The University shall notify the federal Office for Research Integrity immediately if at any stage of the Inquiry or Investigation of Research funded by the PHS, any of the following conditions exist:
    - a. an immediate health hazard exists;
    - b. an immediate need to protect federal funds or equipment purchased with federal funds exists;
    - c. an immediate need exists to protect the interests of the person making the Allegations or of the Respondent and their co-investigators and associates, if any;
    - d. the alleged incident is likely to be reported publicly; or
    - e. there is a reasonable indication that the alleged Research Misconduct is a criminal violation.

- 3. In the event of a reasonable indication of a criminal violation related to PHSfunded research, the federal Office of Research Integrity must be notified within 24 hours of obtaining that information.
- L. K. Interim Institutional Actions
  - Protection of Public Health, Federal Funds and Research Integrity. After an Allegation of Research Misconduct is made and before the completion of the Investigation, the vice president for research may take one or more of the following actions that the vice president for research deems necessary to protect public health, federal funds and/or Research integrity:
    - a. freeze Research funds, or otherwise suspend Research project(s);
    - temporarily remove a respondent from participating in the Research project at issue and other Research projects pending the results of the Investigation;
    - c. prohibit submission of new applications to the Institutional Review Board and/or the Office of Sponsored Projects by the Respondent pending the results of the Investigation; or
    - d. other actions that the vice president for research deems necessary.
  - 2. Interim Suspension or Paid Administrative Leave
    - a. The president of the University may impose an interim suspension on a faculty member related to Research Misconduct in accordance with the process and requirements described in Policy 6-316.
    - b. The University may place a respondent who is a staff member on a paid administrative leave during an Inquiry or Investigation.
- M. L. Educating Staff, Faculty Members, and Students Involved in Research
  - 1. Deans and department chairs should, on an ongoing basis, inform their Research and administrative staff, faculty, and students of the University's

policies and procedures for addressing alleged or apparent Misconduct in Research.

2. This policy shall be printed in the Principal Investigator's Handbook and any other appropriate publication.

Sections IV- VII are for user information and are not subject to the approval of the Academic Senate or the Board of Trustees. The Institutional Policy Committee, the Policy Owner, or the Policy Officer may update these sections at any time.

# IV. Policies/ Rules, Procedures, Guidelines, Forms and other Related Resources

- A. Policies/ Rules. [ reserved ]
- B. Procedures, Guidelines, and Forms. [reserved]
- C. Other Related Resources. [ reserved ]

# V. References

A. [reserved]

# VI. Contacts

The designated contact officials for this Regulation are

- A. Policy Owners (primary contact person for questions and advice): Associated Vice President for Research Integrity & Compliance
- B. Policy Officers: Vice President for Research

See University Rule 1-001 for information about the roles and authority of policy owners and policy officers.

# VII. History

Revision History.

A. Current version. Revision <u>34</u>

- Approved by -- Academic Senate March 14, 2022 February 6, 2023, and Board of Trustees, April 12, 2022 February 14, 2023, with effective date of April 12, 2022 February 14, 2023.
- 2. Legislative History for Revision <u>34</u>.
- 3. Editorial Revisions:

a. Editorially revised September 26, 2022 to add the word "on" in Section III.F.18 to clarify that the Federal Officer of Research Integrity may impose sanctions on the University.

- B. Past versions.
  - 1. Revision 23. Effective April 22, 2022
    - a. Legislative History
  - 2. Revision 42
  - 3. Revision 1
  - 4. 3. Revision 0
- C. Renumbering
  - 1. Renumbering: Renumbered from Policies and Procedure Manual 6-1.1