Research Integrity Policy

Responsible Executive: Vice President for Finance and Business Affairs/ Chief Financial Officer

Responsible Office(s): Office of the Vice President for Finance and Business Affairs

Originally Issued: December 28, 2015

Current Version Approved: August 8, 2022

Last Updated: December 28, 2015

Table of Contents

1. Policy Statement and Requirements

1.1 Policy Statement

In accordance with 42 CFR Part §93, it is the policy of Southern California University of Health Sciences to have an established administrative process for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research, biomedical or behavioral research training, or activities related to that research or research training share responsibility for the integrity of the research process. The goal of this policy is to provide a

framework to resolve allegations of research misconduct as rapidly and fairly as possible and to protect the rights and integrity of all individuals involved.

In accordance with § 93.103, Southern California University of Health Sciences defines research misconduct as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(a) Fabrication is making up data or results and recording or reporting them.

(b) 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.

(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion."[1]

Southern California University of Health Sciences strongly denounces violations of federal and institutional rules and regulations governing the conduct of research involving human research participants that are serious or continuing.

A finding of research misconduct made under this part requires that:

(a) There be a significant departure from accepted practices of the relevant research community; and

(b) The misconduct be committed intentionally, knowingly, or recklessly; and

(c) The allegation be proven by a preponderance of the evidence.

1.2 Scope

This Policy sets forth the policies and procedures to be followed in reporting, assessing, inquiring into, and investigating allegations of research misconduct. This Policy is intended to comply with the regulatory requirements of federal funding agencies related to research misconduct[2]. All employees or individuals associated with the university ought to report observed, suspected, or apparent misconduct. When allegations of misconduct are made, the university is committed to a thorough investigation of such allegations, while protecting the rights of all involved to the maximum extent feasible.

This policy applies to all allegations of misconduct that occur within 6 years prior to the date of the allegation. Exceptions to the general 6-year timeframe will extend the reach of this policy and procedures (a) if the respondent (as defined herein) perpetuates potential misconduct through citation, republication, or other use within 6 years; (b) where the university determines that the alleged

[1] eCFR :: 42 CFR Part 93 -- Public Health Service Policies on Research Misconduct
[2] eCFR :: 42 CFR Part 93 -- Public Health Service Policies on Research Misconduct

misconduct, if it occurred, could have a substantially adverse effect on the health or safety of the public; (c) as required by federal regulations or a relevant federal oversight agency; or (d) under certain grandfather exceptions set forth under relevant laws.

1.3 Policy Requirements

(1) Informing the scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures.

(2) Taking immediate and appropriate action as soon as misconduct on the part of employees or persons within the organization's control is suspected or alleged.

(3) Informing and cooperating with the Office of Research Integrity (ORI) with regard to each investigation of possible misconduct.

(4) Inquiring immediately into an allegation or other evidence of possible misconduct. An inquiry must be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. A written report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry. The individual(s) against whom the allegation was made shall be given a copy of the report of inquiry. If they comment on that report, their comments may be made part of the record. If the inquiry takes longer than 60 days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period.

(5) All individuals are expected to act in good faith when making allegations of research misconduct and while cooperating with research misconduct proceedings. Protecting, to the maximum extent possible, the privacy of those who in good faith report apparent misconduct.

(6) Affording the affected individual(s) confidential treatment to the maximum extent possible, a prompt and thorough investigation, and an opportunity to comment on allegations and findings of the inquiry and/or the investigation.

(7) Notifying the Director, ORI, in accordance with 42 CFR Part §50.104(a) when, based on the initial inquiry, the institution determines that an investigation is warranted, or prior to the decision to initiate an investigation if the conditions listed in § 50.104(b) exist.

(8) Notifying the ORI within 24 hours of obtaining any reasonable indication of possible criminal violations, so that the ORI may then immediately notify the Department's Office of Inspector General.

(9) Maintaining sufficiently detailed documentation of inquiries to permit a later assessment of the reasons for determining that an investigation was not warranted, if necessary. Such records shall be maintained in a secure manner for a period of at least three years after the termination of the inquiry, and shall, upon request, be provided to authorized HHS personnel.

(10) Undertaking an investigation within 30 days of the completion of the inquiry if findings from that inquiry provide sufficient basis for conducting an investigation. The investigation normally will include examination of all documentation, including but not necessarily limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls.

(11) Whenever possible, interviews should be conducted of all individuals involved either in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegations; complete summaries of these interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

(12) Securing necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence in any inquiry or investigation.

(13) Taking precautions against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation.

(14) Preparing and maintaining the documentation to substantiate the investigation's findings. This documentation is to be made available to the Director, ORI, who will decide whether that Office will either proceed with its own investigation or will act on the institution's findings.

(15) Taking interim administrative actions, as appropriate, to protect Federal funds and ensure that the purpose of the Federal financial assistance is carried out.

(16) Keeping the ORI apprised of any developments during the course of the investigation which disclose facts that may affect current or potential Department of Health and Human Services funding for the individual(s) under investigation or that the PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

(17) Undertaking diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed, and also undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

(18) Imposing appropriate sanctions on individuals when the allegation of misconduct has been substantiated.

(19) Notifying the ORI of the final outcome of the investigation

Southern California University of Health Sciences shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations to the ORI.

1.4 Protection from Retaliation

Southern California University of Health Sciences is committed to and strongly believes in the importance of protecting all individuals from retaliation for his/her activities in cooperation with, or initiation of, research misconduct proceedings, provided, such activities were not undertaken in bad faith. SCU will

not tolerate acts of retaliation, actual or perceived, against individuals participating in research misconduct proceedings. If any person involved in a research misconduct proceeding feels s/he has been adversely affected by retaliation, they should notify the appropriate officers immediately.

2. Policy Applicability

This policy is applicable to any individual involved in research under the auspices of Southern California University of Health Sciences and to allegations of research misconduct in all areas of research regardless of the funding source.

3. Exceptions/Exclusions

This Policy does not apply to allegations or complaints that do not fall within the definition of research misconduct as set forth in this document or to matters that fall exclusively under other policies, including violations of conflict of interest policies, violations of Institutional Review Board or Institutional Animal Care and Use Committee policies, or violations of fiscal or other University policies, which shall be directed to the offices responsible for such matters.

4. Definitions

Allegation: a disclosure of possible research misconduct through any means of communication.

Conflict of interest: financial, personal, or professional relationships which may compromise, or appear to compromise an individual's decisions.

Evidence: any document, tangible item, or testimony offered or obtained during a research misconduct proceeding, including the research record, which tends to prove or disprove the existence of an alleged fact.

Fabrication: making up data or results and recording or reporting them.

Falsification: manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Good faith: having a belief in the truth of one's statements such that a reasonable person in the same position could have, based on the information known to one at the time. Examples include: (i) An allegation is not made in good faith if made with knowing or reckless disregard or willful ignorance of certain facts that would disprove said allegation; (ii) Good faith as applied to a committee member means cooperating with the purpose of helping the institution meet its responsibilities regarding investigation of allegations of research misconduct.

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

Preponderance of the evidence: proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Research: a systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research).

Research misconduct: see introduction section

Research record: the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to primary research material, research proposals, laboratory records (physical and electronic), research animals, images, machines and equipment, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, correspondence.

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

Retaliation: an adverse action taken against an individual involved in a research misconduct proceeding, including but not limited to, complainant, witness, or committee member, by a member of the SCU community in response to a good faith allegation of research misconduct or good faith cooperation with a research misconduct investigation.