

Interim Policy on Upholding Research Integrity and Responding to the Allegations of Research Misconduct

Sources:

42 CFR Parts 50 and 93 (2005)

NIH Guide to the Handling of Research Misconduct Allegations

OMB 78 FR 78589

Integrity in research, scholarly, and creative activities is a University's paramount value.

Responsible Conduct of Research and the fundamental principles of Research Integrity – honesty, fairness, responsibility and accountability are at the very essence of the Academic Research enterprise and crucial to society's trust in science.

The National Institutes of Health identifies the following tenants of Research Integrity:

- the use of honest and verifiable methods in proposing, performing, and evaluating research
- reporting research results with particular attention to adherence to rules, regulations, guidelines, and
- following commonly accepted professional codes or norms.

A framework of Responsible Conduct of Research developed by the HHS Office of Research Integrity includes training topics on research misconduct, protection of human and animal subjects in research, conflict of interest, data management, mentor and trainee responsibilities, collaborative research, authorship and publications, peer review, biosafety, and whistleblowing.

California State University San Bernardino (CSUSB) requires training to ensure the highest ethical and professional standards for conducting research. Responsible Conduct of Research training is intended to promote awareness of principles and practices that facilitate ethical and professional conduct across all research disciplines.

All CSUSB employees, students and the individuals affiliated with CSUSB by a contract or agreement who engage in research and/or scholarly activities under the CSUSB's or an affiliated Auxiliary's auspices are subject to Responsible Conduct of Research and shall uphold the highest level of research integrity.

Thus, allegations of misconduct in scholarship and research must be treated with the utmost seriousness and examined carefully and responsibly.

It is the shared responsibility of all members of our academic community to ensure that misconduct in scholarship and research is dealt with in a timely and effective manner and all employees or individuals associated with CSUSB are required to report to Associate Provost for Research, observed, suspected, or apparent misconduct including, but not limited to plagiarism, falsification, and fabrication of data, misuse of funds and equipment, and violations of the policies of the Institutional Review Board (IRB) and the Institutional Animal Care and Use Committee.

Section 1. Definitions

Abuse of confidentiality: releasing the ideas or data of others that were shared with the legitimate expectation of confidentiality (e.g., disclosing ideas from others' grant proposals, award applications, or manuscripts for publication when one is a reviewer for granting agencies or journals or is an internal destroying property of others, such as experiments, research papers, supplies, equipment, or products of research or scholarship).

Allegation: a disclosure of possible research misconduct through any means of communication. The disclosure may be by a written or oral statement or other communication.

Complainant: A person who in good faith makes an allegation of research misconduct. They may also make an allegation of inadequate institutional response to such an allegation of research misconduct. The role of the complainant is limited. Once the complainant has made an allegation of research misconduct, that person does not participate in the proceeding other than as a witness. (A complainant is not the equivalent of a "party" in a private dispute.) The University must pursue allegations of research misconduct independent of the complainant's role.

Conflict of Interest: financial, personal, or professional relationships that may compromise, or appear to compromise a person's decisions.

Deciding Official (DO): The person who shall make the final determination as to whether research misconduct has taken place, and shall initiate administrative action against those found to have committed research misconduct, ordinarily the President or Provost, or a designee. 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.

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

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

Failure to report observed research misconduct: covering up or otherwise failing to report observed, suspected, or apparent research misconduct by others.

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.

Inquiry: Preliminary information gathering and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

Investigation: The formal examination and evaluation of all relevant facts to determine misconduct has occurred, and if so, the responsible person and the seriousness of the misconduct.

Misuse of funds: stealing or expending research funds on goods or services which violate allowability and/or reasonability and/or allocability of costs as defined in the Cost Principles section of OMB 78 FR 78589.

ORI: Office of Research Integrity, an independent entity within the U.S. Department of Health and Human Services reporting to the Secretary of the Department of Health and Human Services. ORI is responsible for protecting the integrity of PHS extramural and intramural research programs.

Plagiarism is 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 or specific knowledge by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, the matters of study.

Research Integrity Officer (RIO): The person who has lead responsibility for ensuring that the institution takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct, ordinarily Associate Provost for Research or a designee.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results.
Research misconduct does not include honest error(s) or differences of opinion.

Research record: the record of data or results that embody the facts resulting from scientific inquiry or other scholarly endeavors, including but not limited to research proposals, laboratory records (physical and electronic), progress reports, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, correspondence, and any documents and materials provided to an institutional official in the course of a research misconduct proceeding.

Respondent: The person against whom an allegation of research misconduct is directed, or the person who is the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

Retaliation: An intentional act of reprisal, threat or intimidation by a CSUSB employee that has a material and substantial adverse effect on the terms and conditions of employment or other status of a complainant who, in good faith, has made an allegation of research misconduct or inadequate institutional response thereto, or who has cooperated in good faith with an investigation of such allegations.

Sabotage or other property violations: stealing, tampering with, or destroying property of others, such as experiments, research papers, supplies, equipment, or products of research or scholarship.

Section 2. Scope

This Policy is intended to comply with institutional responsibilities under the **Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93**. Other federal agencies have published their research misconduct regulations; to the extent those regulations apply to an allegation of research misconduct and are inconsistent with this Policy, CSUSB employees and students shall comply with the applicable regulatory requirements.

This Policy applies to allegations of research misconduct (as defined by this Policy) involving any person who, at the time of the alleged research misconduct, was employed by, or was affiliated by contract or agreement with CSUSB or UEC at CSUSB, including without limitation officials, tenured and non-tenured faculty, teaching and support staff, researchers, technicians, post-doctoral and other fellows, students and volunteers.

This Policy also applies to other research-related misconduct including defined in this Policy: abuse of confidentiality, failure to report observed research misconduct, misuse of funds, retaliation and sabotage or other property violations and directing or encouraging others to engage in any of the above offenses.

This Policy also applies to research that is not federally funded.

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 CSUSB or an affiliated Auxiliary or the U.S. Department of Health and Human Services (HHS) received the allegation subject to the subsequent use, health or safety of the public, and grandfather exceptions articulated in 42 C.F.R. § 93.105(b).

Concerning students involved in allegations of research misconduct that involve federal funding, the Office of Student Conduct and Ethical Development and the Office of Undergraduate Studies or the Office Graduate Studies will be notified of the initiation of any inquiries and/or investigations and will be informed of the findings of any such inquiries and/or investigations, including receiving copies of all inquiry and/or investigation reports. Allegations of research misconduct against students that do not involve federal funding will ordinarily be referred to the Office of Student Conduct and Ethical Development.

Section 3. Upholding Research Integrity; Research Misconduct Prohibited; Standard of Proof.

All CSUSB employees, students and the individuals affiliated with CSUSB by a contract or agreement who engage in research and/or scholarly activities under the CSUSB's or an affiliated Auxiliary's auspices are subject to Responsible Conduct of Research and shall uphold the highest level of research integrity.

CSUSB prohibits research misconduct and investigates and responds to allegations of research misconduct in accordance with this Policy.

A finding of research misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community;
- The respondent committed the research misconduct intentionally, knowingly, or recklessly; and
- The allegation be proven by a preponderance of the evidence.

The destruction of research records, absence of research records, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the institution establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them.

CSUSB bears the burden of proof for making a finding of research misconduct. A respondent has the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised (such as an honest error).

Section 4. Responsibility to Report Research Misconduct

All employees or individuals associated with CSUSB are required to report observed, suspected, or apparent misconduct in research to the RIO. If an individual is unsure whether a suspected incident of misconduct falls within the definition, the individual may meet or contact the RIO to discuss the suspected misconduct informally and confidentially. The RIO contact information is available in the Office of Associate Provost for Research.

If the circumstances described by the individual do not meet the definition of research misconduct or research-related misconduct, the RIO will refer the individual or allegation to other appropriate offices or officials with responsibility for resolving the problem.

Section 5. Cooperation with Inquiries and Investigations

All CSUSB employees shall cooperate with the RIO and/or other University designated officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the RIO on research misconduct allegations.

Section 6. Confidentiality

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.

Section 7. Protecting Complainants, Witnesses, and Committee Members

CSUSB employees shall not retaliate in any way against complainants, witnesses, or others involved in the review process. Employees should immediately report any alleged or apparent retaliation to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to stop and remedy any potential or actual retaliation.

Section 8. Protecting Respondent

If requested to do so and as appropriate, the RIO and other University 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. During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in applicable federal regulations and CSU policies and procedures.

Section 9. Appointment of Personnel

Deciding Official (DO)

The Provost shall serve as Deciding Official (DO) shall make the final determination as to whether research misconduct has taken place, and shall initiate administrative action against those found to have committed research misconduct in accordance with the relevant Collective Bargaining Agreement.

Research Integrity Officer (RIO)

The Associate Provost for Research shall serve as RIO.

If upon receipt of the allegation, it appears that the RIO has any unresolved personal, professional, or financial conflicts of interest with those involved in the allegations, then the DO shall appoint another qualified individual to serve as Interim RIO with respect to reviewing the allegation and conducting any research misconduct proceeding.

The RIO shall appoint the Inquiry Committee and Investigation Committees in consultation with the Provost and the Chair of the Faculty Senate.

Inquiry and Investigation Committees

The Inquiry Committee shall consist of the following individuals:

- a. One faculty member from the same College but not from the same department as the respondent.
- b. One faculty member from an outside College with expertise in the research area of the project under inquiry or with expertise in research misconduct matters. If no person is available with these qualifications from within the University, expertise may be sought from outside the University.
- c. One Associate Dean who is not from the respondent's College.
- d. One faculty member appointed by Faculty Senate.
- e. One member of the Committee on Responsible Conduct of Research appointed by the committee's chair.

The Investigation Committee will be constituted in the same manner as the Inquiry Committee. Every effort shall be made to appoint Investigation Committee members who have no prior involvement with the case at hand. Inquiry Committee members may serve on the Investigation Committee only under extraordinary circumstances.

If, upon an inquiry or investigation committee member appointment, it appears that the appointee has any unresolved personal, professional, or financial conflicts of interest with those involved in the allegations, then the RIO shall appoint another qualified individual to serve on the corresponding committee.

Section 10. Process and Timeline

Sequestration of Research Records

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.

Those engaged in administering this Policy have all rights necessary to access research records created or maintained by individuals subject to this Policy.

As to timing, 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. The RIO also shall sequester any additional research records that become pertinent to an inquiry or investigation after the initial sequestration.

The RIO is responsible for inventorying the records and evidence.

Notice to Respondent

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 inquiry subsequently identifies additional respondents, they must be notified in writing.

There are three phases of the process: assessment of allegations, inquiry, and investigation.

Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO immediately will assess it to determine whether the allegation:

- Falls within the definition of research misconduct, and
- Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

An inquiry must be conducted if these criteria are met.

The assessment period should be brief, preferably concluded within a week - seven (7) calendar days. 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 preliminary assessment shall be documented and all records pertaining to the review of allegations will be retained by the RIO for seven (7) years following the completion of the proceeding.

Inquiry

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.

Inquiry Process

The inquiry committee shall examine relevant research records and materials as well as normally interview the complainant, the respondent and key witnesses. Then the inquiry committee shall evaluate the evidence, including the testimony obtained during the inquiry. After consultation with the RIO, the committee members shall decide whether an investigation is warranted. 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, the institution shall promptly consult with ORI to determine the next steps that should be taken.

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 60 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 60-day period.

Investigation

The investigation shall begin within 30 calendar days after the determination by the DO 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 shall also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation must be reported in an investigation report.

Investigation Process

The investigation committee and the RIO shall:

- a. Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes an examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;
- b. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
- c. 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
- d. 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.

Time for Completion

The investigation shall be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment to the respondent, and, as appropriate, sending the final report to ORI or other applicable federal agency or office. However, if the RIO determines that the investigation will not be completed within this 120-day period, they shall submit to University officials and, as appropriate, to ORI or other applicable federal agency or office a written request for an extension, setting forth the reasons for the delay. If the request for an extension is granted and periodic progress reports are requested, the RIO shall ensure that periodic progress reports are filed with University officials and, as appropriate, ORI or other applicable federal agency or office.

Section 11. Appeals

The decision of the DO is final and cannot be appealed.

Section 12: Sanctions and Administrative Actions

If the DO determines that research misconduct is substantiated by findings, they shall decide on the appropriate actions to be taken after consultations with the RIO. These may include removal from project, reimbursement of funds, withdrawal of manuscripts or articles pending or published, and/or disciplinary action.

Section 13. Interim Institutional Actions and Notifying Federal Agencies 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 research process. In the event of such a threat, the RIO will, in consultation with the DO, Faculty Senate, other institutional officials, and ORI, as necessary, take appropriate interim actions 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 the responsibility for the handling of federal funds and equipment;
- additional review of research data and results; or delaying publication.

RIO shall, at any time during a research misconduct proceeding, notify ORI (or the relevant federal agency) immediately if there is 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;
- Federal resources or interests are threatened;
- Research activities should be suspended;
- 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;
- The research misconduct proceeding may be made public prematurely and federal action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

Section 14. Other Research-related Misconduct Not Included in this Policy

The following types of research-related misconduct are governed by the following policies:

- Financial Conflict of Interest (FCOI) by the FCOI policy.
- Deviations from or violations of the approved IRB protocol by the IRB policy.
- Deviations from or violations of the approved IACUC protocol by the IACUC policy.