Research

Research Compliance

Sec. 480-7 Resolving Regulatory Noncompliance

Responsible Administrator: Vice Chancellor for Research
Issued: January 31, 1998
Revised: December 1, 2004, July 11, 2007, and May 23, 2025

References / Resources:

- UC Office of the President
  - Standards of Ethical Conduct
  - UC Research Policy Library
  - Research Policy Analysis Coordination Guidance Memos
  - UC Contract and Grant Manual
  - Presidential Policies on Research Administration
  - Compendium of Conflict of Interest and Related Policies - Guidance
- UCI Policies
  - UCI Research Policy Library
- UCI Resources
  - Office of Research website
  - Whistleblower Office

Contact: Associate Vice Chancellor for Research Administration

Contents

A. Purpose and Scope

The purpose of this policy is to:

- Establish UCI's principled commitment to regulatory compliance in Research.
- Implement a general framework for addressing and resolving instances of Regulatory Non-compliance and to establish a guide for UCI's Compliance Areas in creating their own policy for resolving Regulatory Non-compliance.
- Foster and promote UCI researchers' compliance with applicable rules and regulations.

This policy applies to all UCI Community Members who conduct or perform UCI Research, regardless of location, or who use or plan to use their UCI association or affiliation in disseminating, publishing, or publicly presenting Research.

B. Definitions

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1. **Compliance Areas** – All Office of Research compliance functions, including Sponsored Projects Administration, as well as research regulatory committees administered by other central administrative offices for which the Vice Chancellor for Research is the institutional official.
2. **Lead Researcher:** The leader responsible and accountable for Research conducted under protocols reviewed and approved by UCI's regulatory oversight committees.
3. **Principal Investigator:** See the definition and applicable policy in 480-5 Principal Investigator Eligibility and Project Leadership.
4. **Non-compliance Case**: The alleged or discovered incident, actions, and/or inactions involving one or more UCI Community Members that appear to be Regulatory Non-compliance.
5. **Research:** Activities undertaken to develop or contribute to generalizable (i.e., scholarly) knowledge or to devise new applications for such knowledge, including, but not limited to, preclinical and clinical trials, pilot testing, research development, product testing, evaluation of programs and services, fieldwork, and all care and use of animals.
6. **Research Misconduct**: See the definition in the Responding to Allegations of Research Misconduct policy.

7. **Regulatory Non-compliance:** Failure to comply with applicable governmental (domestic and foreign) laws, rules, regulations, statutes, and policies, sponsored award terms and conditions, and/or with the requirements or determinations of a UCI or external regulatory committee, and University of California and UCI policies.
8. **UCI Community Members:** All individuals associated or affiliated with UCI, including employees, appointees, students, volunteers, contractors, agents, and others associated with the university, including visitors who use or utilize UCI resources.
9. **UCI Research:** Any Research that is designed, performed, conducted, or reported on by UCI Community Members on behalf of UCI. This includes UCI Research performed offsite as defined in 480-8: Offsite Research Activities.

C. Responsibilities / Authority

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1. **Office of Research Compliance Areas**
    a. Uphold UCI's commitment to compliance by following this policy.
    b. Report Non-compliance Cases to the Whistleblower Office, as applicable.
    c. Communicate and collaborate with other central administrative units when Non-compliance Cases involve potential compliance concerns within their area of responsibility.
2. **Vice Chancellor for Research**
    a. Uphold UCI's commitment to compliance by following this policy.
    b. Oversee the appeal process and make final decisions in response to appeals.
    c. Impose sanctions reserved to the Vice Chancellor for Research (see F.5.b).
3. **Principal Investigators/Lead Researchers**
    a. Fully cooperate with Compliance Areas in their review of Non-compliance Cases, including participating in interviews and providing complete information and documentation requested by Compliance Areas.
4. **UCI Community Members**
    a. Fully cooperate with Compliance Areas in their review of Non-compliance Cases.

D. Policy

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1. **Commitment to Compliance**

    a. Compliance is a keystone principle that upholds UCI's reputation for ethically and responsibly conducting Research. Upholding public trust is a principle underpinning UCI's fiduciary responsibility to the people of California and the Nation. As part of supporting UCI's mission and strategic vision, it is imperative that UCI remain eligible to receive external funding to support UCI Research. Accordingly, UCI is committed to complying with all applicable laws, regulations, statutes, rules, policies, and guidelines governing, regulating, managing, administering, or otherwise overseeing Research.

    b. As part of UCI's compliance commitment, all UCI Community Members engaged in Research are expected to and must comply with the University of California Standards of Ethical Conduct.

    c. UCI is committed to reviewing and resolving Non-compliance Cases reported to it or discovered through other means.

2. **Regulatory Non-compliance**

    a. Any alleged or discovered Regulatory Non-compliance will be addressed and resolved through this policy by following the general review and resolution framework outlined in Section F, unless the exception in Section E applies.

3. **Research Misconduct**

    a. If a Non-compliance Case includes a Research Misconduct allegation, then the Research Misconduct allegation must be separately addressed and resolved through the Responding to Allegations of Research Misconduct policy.

E. Exceptions

If a Compliance Area has established and published its own policy for addressing and resolving Regulatory Non-compliance, it shall follow its policy. However, if a Compliance Area's policy does not include an appeal process, then section D.4. of this policy applies and will supplement the Compliance Area's policy.

F. Procedures

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1. **Responsibility**

    a. Each Compliance Area is responsible for reviewing and resolving Non-compliance Cases within their purview. Compliance Areas that include regulatory oversight committees may conduct their reviews using either the full committee or a subcommittee.

    b. Non-compliance Cases involving more than one Compliance Area may be separately or jointly reviewed and resolved by the applicable Compliance Areas. The decision to review separately or jointly will be made through consultation between the Compliance Areas. If the Compliance Areas do not agree, the Vice Chancellor for Research, or their designee, shall decide.

2. **Notification**

    a. A Compliance Area must promptly notify the Principal Investigator/Lead Researcher that it has received or discovered a Non-compliance Case, with a copy to the applicable department chair or organized research unit (ORU) director and the Associate Vice Chancellor for Research Administration. When a Compliance Area determines that prompt notification must be delayed (for example, to secure documents, files, and records needed for the Compliance Area's review), it must provide notification as promptly as possible considering the specific facts and circumstances.

3. **Review**

    a. Compliance Areas must thoroughly review available information and documentation to determine if a Non-compliance Case rises to the level of Regulatory Non-compliance. Reviews may include interviews with individuals who have direct knowledge of matters relevant to the Non-Compliance Case, as well as internal or external experts who can provide objective, unbiased insights, advice, and/or recommendations. It is expected that reviews commence promptly and be completed as expeditiously as possible given the circumstances and relevant facts.

b. A Compliance Area may temporarily halt or suspend a Research protocol during the review process in compliance with, or in accordance with its authority under, external regulatory oversight agency/entity polices, rules, or regulations. Where such authority resides with the Vice Chancellor for Research as UCI's designated institutional official, the Compliance Area may recommend halting or suspending a research protocol, and the Vice Chancellor for Research shall make the final decision.

4. Notice of Review Outcomes

a. Once the Compliance Area completes its review, it must promptly notify the Principal Investigator/Lead Researcher, the applicable department chair/ORU director, the chair of any applicable UCI regulatory committee, and the Associate Vice Chancellor for Research of the review outcome (including, but not limited to findings, whether the Non-Compliance Case rises to the level of Regulatory Non-compliance, steps to achieve compliance, and reporting to external oversight agencies/entities). If the review outcome includes reporting to an external oversight agency/entity or sanctions (see 5.b., below), the Compliance Area must copy the school dean in which the Research took place and the Vice Chancellor for Research on the notice of review outcome.

5. Resolution

a. If a Non-compliance Case does not rise to the level of Regulatory Non-compliance, but the findings include concerns about Research compliance quality, the Compliance Area will discuss them with the Principal Investigator/Lead Researcher with the goal of using informal means such as, but not limited to, on-going discussions, outreach efforts, alternative approaches, and improved procedures to promote, advocate, and achieve quality compliance.

b. If a Compliance Area determines that a Non-compliance Case rises to the level of Regulatory Non-compliance, the Compliance Area may use a combination of informal and formal means to resolve the Research Non-compliance and to achieve compliance going forward. Formal means may include, but are not limited to, re-education regarding compliance requirements, responsibilities, and/or obligations, changing compliance procedures, requiring additional or more frequent oversight by or on behalf of an applicable UCI regulatory oversight committee for a specified time period, reporting Regulatory Non-compliance to external oversight agencies/entities when required by agency/entity policy, imposing sanctions within the Compliance Area's authority (such as suspending Research protocols or rescinding regulatory committee approval), and referring the case to other administrative units for review under

other applicable policies.

c. If a Compliance Area does not have the authority to implement sanctions, it may recommend sanctions to the Vice Chancellor for Research.

d. Compliance Areas may also recommend additional sanctions, the implementation authority for which is reserved to the Vice Chancellor for Research. These include, but are not limited to, Research privilege probation, suspending Research privileges, terminating Research privileges, terminating/relinquishing a sponsored award, and/or embargoing publication(s).

e. Only the review outcomes noted in 6.a., below may be appealed. All other review outcomes are final. All appealable review outcomes become final if an appeal is not received within the period noted in 6.a.

6. Appeal

a. A Principal Investigator/Lead Research may submit an appeal to the Vice Chancellor for Research within fifteen (15) calendar days of the date that a Compliance Area issues a notice of review outcome if the review outcome includes any of the following:
   i. Suspending, or recommending suspension of, a Research protocol.
   ii. Rescinding, or recommending rescission of, a UCI regulatory oversight committee's protocol approval.
   iii. Recommending any sanctions reserved to the Vice Chancellor for Research.

b. An appeal must be submitted via e-mail as instructed in the notice of review outcome, and the Principal Investigator/Lead Researcher may provide the Vice Chancellor for Research with:
   i. Any relevant new information not provided to the Compliance Area for conducting its review, including new facts and circumstances relevant to the Non-compliance Case, and
   ii. A brief statement (one page limit) regarding why they believe that this new information should be considered with regard the Compliance Area's actions or recommendations.

c. The Vice Chancellor for Research will promptly acknowledge receipt of an appeal to the Principal Investigator/Lead Researcher, with a copy to the department chair or ORU director, school dean, applicable UCI regulatory committee chair, and the Associate Vice Chancellor for Research Administration.

d. The Vice Chancellor for Research will promptly notify the Principal Investigator/Lead Research of their final decision on any appeal. The Vice

Chancellor's final decision will also be communicated to the department chair or ORU director, school dean, applicable UCI regulatory committee chair, the Associate Vice Chancellor for Research Administration, and the Provost and Executive Vice Chancellor.