UCI ADMINISTRATIVE POLICIES & PROCEDURES

RESEARCH AND SPONSORED ACTIVITIES
Office of Research Administration
Section 480-7: Resolving Regulatory Noncompliance

Responsible Office: Office of Research Administration
Issued: January 31, 1998
Revised: December 1, 2004; July 11, 2007

Background and Purpose

UCI has four regulatory oversight committees that are responsible for University compliance with the regulations, policies and procedures that apply to the conduct of research: the Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC), the Human Stem Cell Research Oversight Committee (hSCRO), and the Conflict of Interest Oversight Committee (COIOC). The staff of these committees are within the Office of Research Administration (ORA). Where potential occurrences of noncompliance are identified, the procedures described in this policy will be followed.

Applicability

This policy applies to all research activities conducted by or for UCI that require oversight by the UCI IRB, IACUC, hSCRO or COIOC. This policy applies to activities that satisfy any of the following criteria:

A. It is conducted by UCI personnel or under the direction of UCI personnel in connection with his or her UCI responsibilities.
B. It uses UCI property, facilities, or resources to support or carry out the activity.
C. The name of the University of California, Irvine is used in applying for funds (intra or extramural).
D. The investigator plans to use his/her University of California, Irvine association in any dissemination, publication or public presentation resulting from the activity.
E. The name of the University of California, Irvine is used in explanations and/or representations to subjects.
F. UCI's non-public information will be used to identify or contact human research subjects or prospective subjects.

Definitions

Regulatory Noncompliance is all other violations and deviations are not research misconduct.

Research means activities undertaken to develop or contribute to generalizeable (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.

Research (Scientific) Misconduct means fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the

academic community for proposing, performing, or reviewing research, or reporting research results. Misconduct does not include honest error or honest differences in interpretations or judgments of data.

University Duties are responsibilities assigned by the University or tasks performed to meet expectations of one's employment, affiliation, appointment, or academic program.

UCI Facilities means facilities owned, operated, or leased by UCI including UCI campus, UCIMC, UCI Family Health Centers in Anaheim and Santa Ana, Westminster, and any space rented to the University.

UCI Personnel are UCI students, staff, and faculty (including part-time, emeritus, and volunteer faculty), or any other agents of UCI.

UCI Resources are funds (including contract, grant and gift funds), facilities, paid employee time, UCI owned or leased equipment, supplies, services, and non-public information.

Policy Statement

In order to demonstrate appropriate oversight of research activities and to comply with federal and state statutes, regulations, policies and guidelines; and applicable University policies and procedures, the University will investigate and resolve allegations of regulatory noncompliance through the ORA with involvement of the chairs from the appropriate regulatory oversight committees (i.e., IRB, IACUC, hSCRO, COIOC). The ORA and regulatory oversight committees strive to achieve informal resolution of noncompliance issues with the cooperation of the Investigator, when appropriate.

When an allegation of noncompliance cannot be resolved informally, the regulatory oversight committees have the authority to impose sanctions and recommend additional sanctions to the Vice Chancellor for Research. Regulatory oversight committees may temporarily halt or suspend approval of research at any time during the review process.

Distinguishing Regulatory Noncompliance from Scientific Misconduct

When an allegation of inappropriate conduct of research or scholarship is made, it is the responsibility of the Vice Chancellor for Research or designee(s) to determine whether to pursue the matter as an incident of regulatory noncompliance and/or scientific misconduct. Through the process of investigating and attempting to resolve an incident originally regarded as regulatory noncompliance, new information may be revealed that suggests additional classification as possible scientific misconduct. Examples of regulatory noncompliance and research (scientific) misconduct are provided below. In the event a clear determination cannot be made, the Vice Chancellor for Research will be consulted.

Regulatory Noncompliance includes:

- failure to obtain/maintain approval for research;
- failure to obtain informed consent when required;
- failure to file adverse event reports;
- coercion or undue influence of human subjects;
- performance of an unapproved procedure;

- performance of research at an unapproved site;
- failure to file protocol modifications;
- failure to adhere to an approved protocol; and
- any other failure to adhere to regulations, policies, procedures or special conditions related to research.

Scientific Misconduct includes:

- plagiarism, such as misrepresentation of authorship and/or misappropriation of data;
- fabrication and/or falsification of data;
- other serious deviations from accepted scientific practices, such as obstruction of another's research; violation of confidentiality; and willful deception or omission.

Procedures for Resolving Allegations of Regulatory Noncompliance

Step 1 - Administrative Review

The purpose of an Administrative Review is to determine whether the allegation of regulatory noncompliance can be substantiated and whether it requires further review by a regulatory oversight committee. An Administrative Review is initiated when an allegation is received from an individual; it is deemed by the Office of the Vice Chancellor for Research or the chair of a regulatory oversight committee that a review is necessary, or when informal or formal monitoring activities reveal potential regulatory noncompliance.

Administrative Reviews are conducted by the ORA staff person responsible for compliance in a specific regulatory area (humans, animals, human stem cells, and conflict of interest). An Administrative Review may include: review of files, literature, and documents from the Investigator and others, which could serve to validate or dismiss the allegation.

When an Administrative Review reveals information that appears to substantiate an allegation of noncompliance with policies or regulations, the chair of the appropriate regulatory oversight committee is consulted for further action. All efforts will be made to resolve the matter informally.

Possible outcomes of an Administrative Audit are:

- dismiss the allegation,
- achieve compliance with the cooperation of the Investigator (and report to the appropriate regulatory oversight committee and/or federal Agency when required),
- recommend review by the appropriate regulatory committee (Step 2 - Regulatory Committee Review), or
- recommend reclassification as possible scientific misconduct.

The results of an Administrative Review will be communicated by the ORA staff in writing to the Investigator (with a copy to the chair of the appropriate regulatory oversight committee) within 30 days of the commencement of the review. This communication will either: notify the Investigator that the allegation was dismissed, confirm that compliance was achieved, inform the Investigator that a Regulatory Committee Review was

recommended, or apprise the Investigator that the incident may be investigated as a matter of scientific misconduct.

In cases where the result of an Administrative Review suggests that an Investigator has demonstrated an apparent pattern of disregard for research regulations, policies, or procedures, a Regulatory Committee Review may be recommended even when the specific finding of noncompliance is resolved informally.

Step 2 - Regulatory Committee Review

A Regulatory Committee (IRB, IACUC, hSCRO, or COIOC) Review is initiated after a completed Administrative Review suggests that an incident of noncompliance appears to have occurred and when informal resolution was not achieved or when informal resolution is achieved but the Investigator has been determined to have engaged in a pattern of disregard for research regulations, policies or procedures. Regulatory Committee Reviews may be conducted by full committees or by subcommittees charged by the committee chairs. Whenever possible, the result of a Regulatory Committee Review will be informal resolution. Such reviews may include: review of files, literature, and other documents; requests for additional information from and/or interviews with the Investigator, complainant or others; and review of other documents which could serve to validate or dismiss the allegation.

Possible outcomes of a Regulatory Committee Review are:

- dismiss the allegation,
- achieve compliance with the cooperation of the Investigator (and report to the appropriate federal Agency when required),
- impose sanctions to achieve compliance (and report to the appropriate federal Agency when required), or
- recommend reclassification as possible scientific misconduct.

The results of a Regulatory Committee Review will be communicated by the committee chair in writing to the Investigator (with a copy to the appropriate protocol file) within 60 days of commencement of the review. This communication will either: notify the Investigator that the allegation was dismissed; confirm that compliance was achieved; inform the Investigator of recommended sanctions; or apprise the Investigator that the incident may be investigated as a matter of scientific misconduct.

If sanctions are recommended or if a report to an external agency is required, a copy of the results of the review will also be sent to the Vice Chancellor for Research, the Department Chair, Unit Director and the Dean of the school within which the research activity took place.

Step 3 - Sanctions for Regulatory Noncompliance

Whenever possible, ORA staff will be available to assist Investigators with resolving noncompliance issues. In cases where cooperation does not occur or when it is determined that subjects or the institution has been placed at risk, sanctions may be imposed by Institutional Review Boards, the Institutional Biosafety Committee, and the Institutional Animal Care and Use Committee. Possible sanctions include:

- requiring more frequent review an investigator’s research activities;

- suspending research activities until compliance is achieved; or
- terminating committee approval for research activities.

Other Sanctions by the Vice Chancellor for Research

In addition, the regulatory oversight committees may recommend additional sanctions to the Vice Chancellor for Research. Possible sanction recommendations include:

- research privilege probation,
- suspension of research privileges,
- termination of research privileges, or
- embargo of publications.

The hSCRO and COIOC do not have regulatory authority to impose sanctions, but may recommend sanctions to the Vice Chancellor for Research.

The Vice Chancellor's decision will be communicated in writing to the Investigator (with a copy to the regulatory oversight committee chair, the department chair, the director or dean of the school within which the research activity took place, and the Provost and Executive Vice Chancellor).

References

A. UCI Research Policies 480-2: Responsibilities for Conduct & Administration of Research

B. UCI Research Policy 480-3: Competency of Research Faculty, Staff and Students in the Use of Subjects

C. UCI Research Policy 480-4: Compliance with Federal Regulations in the Use of Research Subjects

D. UCI Research Policy 480-8: Offsite Research Activities

E. UCI Research Policy 481-1: Disclosure & Review of Principal Investigator's Financial Interests in Non-governmental Sponsors (State policy)

F. UCI Research Policy 481-2: Disclosure & Review of Financial Interests in Federal Awards

G. UCI Research Policy 481-3: Disclosure & Review of Financial Interests in Human Subjects Research

H. UCI Research Policy 484-1: Review of Human Stem Cell Activities

I. UCI Research Policy 485-1: Protection of Human Subjects in Research

J. UCI Research Policy 486-1: Use of Vertebrate Animals in Research and Teaching

K. UCI Research Policy 489-1: Integrity in Research, Irvine Policy and Procedure Manual