UCI ADMINISTRATIVE POLICIES & PROCEDURES

RESEARCH AND SPONSORED ACTIVITIES

Office of Research Administration

Section 480-3: Competency of Research Faculty, Staff, and Students in the Use of Subjects

in Research

Responsible Office: Office of Research Administration

Issued: January 1, 1998 **Revised:** December 1, 2004

References

• UCI Research Policy: Protection of Human Subjects in Research, issued December 16, 1983; amended December 1, 2004.

- UCI Research Policy: Use of Vertebrate Animals in Research and Teaching, issued August 1, 1985; amended June 11, 2002.
- UCI Research Policy: Use of Recombinant DNA With or Without Etiologic Agents, issued July 2, 1999; amended January 5, 2000.
- UCI Research Policy: Compliance with Federal Regulations in the Use of Subjects in Research, issued January 31, 1998.

Background and Purpose

Government policies and regulations, as well as UC and UCI policies, require Principal Investigators to possess specific knowledge regarding the preparation of research protocols and the conduct of approved research. Evidence of basic certification will be required for all protocol participants at the time of protocol submission to the regulatory committees. Continuing education is an essential component of this process.

Applicability and Effective Date

This policy was issued on January 1, 1998 and amended December 1, 2004.

Policy Statement

Researchers shall maintain documentation of their own competency certification (e.g., completion of a UCI electronic research tutorial). The units within the Office of Research (Research Administration, Research Development and University Laboratory Animal Resources) shall maintain documentation of education in order to support the committee review process and assist researchers in maintaining valid certification. Required educational resources will be available at UCI in a variety of media. Review of required educational materials and retesting must be completed at least every five years or sooner if so determined by the regulatory committees.

Authority and Responsibility

Principal Investigator and Lead Researcher are responsible for acquiring and maintaining the required knowledge for themselves and other individuals listed on their proposals and protocols.

Regulatory Committees are responsible for assessing the qualifications and training of study team members and confirming the adequacy of completed education for proposed research activities.

Regulatory Committees and Vice Chancellor for Research (VCR) are responsible for setting standards and acceptable methods of demonstrating required knowledge.

Regulatory Committees, Vice Chancellor for Research (VCR), and Chairs, Deans, and Directors are responsible for overseeing and ensuring competency of researchers and staff (UCI personnel) using subjects in research and performing regulated activities.