UCI ADMINISTRATIVE POLICIES & PROCEDURES

RESEARCH AND SPONSORED ACTIVITIES
Office of Research Administration
Section 480-4: Compliance with Federal Regulations 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: Resolving Regulatory Non-compliance, issued January 31, 1998; revised December 1, 2004.
- UCI Research Policy: Competency of Research Faculty, Staff and Students in the Use of Subjects in Research, issued January 31, 1998.

Background and Purpose

The University of California Irvine is committed to protecting the rights and welfare of human subjects, and accepts the responsibilities relating to the care and use of animal subjects in research activities and the use of recombinant DNA in research and teaching. These are shared responsibilities in that institutional officials, faculty, staff and students assume duties in accordance with applicable regulations and policies. This policy sets forth some of these requirements.

Applicability and Effective Date

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

Policy Statement

All UCI researchers are required to comply with government policies and regulations, and UCI policies and procedures, in doing research that requires the use of human or animal subjects and recombinant DNA activities. UCI must ensure compliance by conducting informational

sessions, by monitoring research activity, and by halting non-compliant activities. Compliance monitoring will be achieved by a number of mechanisms. These include:

1. On-site field monitoring by federally-mandated UCI regulatory committees or their designated staff.
2. Notification by faculty to the regulatory committees' staff of the results of all external audits.
3. Comparison of current protocols with experimental design sections of extramural funding applications.
4. Comparison of currently and previously approved protocols with recent publications.

UCI researchers will notify granting agency study sections of any major changes to the protocol affecting a grant or contract proposal submitted for funding. Incidents of non-compliance with federal and UCI regulations will be reviewed by the appropriate regulatory committee, and appropriate action taken as described in campus policy for addressing regulatory non-compliance.