

Research Policy

Protection of Human Subjects in Research

University of California, Irvine

References

- Department of Health and Human Services (DHHS) Regulations, Policy for the Protection of Human Research Subjects, 45 CFR Part 46, Subparts A-D, published January 26, 1981 (Federal Register, Vol. 46, No. 16), effective July 27, 1981 in accordance with Public Law 93-348 and all subsequent amendments thereto.
- DHHS, Food and Drug Administration, 21 CFR Part 50 Human Subjects Protections and 21 CFR Part 56 Institutional Review Boards, published January 27, 1981 (Federal Register, Vol. 46, No. 17), effective July 27, 1981, and all subsequent amendments thereto.
- California Health and Safety Code, Sections 24170-24197.5, and other applicable state laws pertaining to the protection of human subjects in research.
- Ethical codes of conduct for research involving human subjects:
 - Belmont Report of the National Commission for the Protection of Human Subjects in Behavioral and Biomedical Research.
 - Declaration of Helsinki, amended October 2000.
 - Nuremberg Code, as amended to cover human subjects unable to give consent.
- University of California Policy on the Protection of Human Subjects in Research, issued September 2, 1981, and all subsequent amendments thereto, including the January 19, 1979, University Policy for Medical Treatment of Human Subjects for Injuries Resulting from Participation in Research.
- UC Systemwide Standards and Implementation Policies for the Health Insurance Portability and Accountability Act Privacy Rule, Standard Nine: Uses and Disclosures for Research, issued April 2003.
- UCI Federalwide Assurance of Compliance (FWA#00004071) with the DHHS Office of Human Research Protections.
- UCI Delegation of Authority, IDA130 – Human and Animal Subjects Protection, issued July 21, 1995.
- UCI Research Policy: Offsite Research Activities, issued May 19, 2003.
- UCI Research Policies: Responsibilities for Conduct and Administration of Research, issued January 31, 1998, amended December 1, 2004; May 23, 2005.

Background and Purpose

It is the purpose of this policy to enumerate the specific requirements, roles and responsibilities for the performance of human research at UCI. This policy is intended to protect the rights and welfare of human subjects and to assure that human research activities conform to the ethical codes of conduct for human experimentation, federal and state statutes, DHHS and FDA regulations, policies and guidelines; and applicable University policies and procedures that are referenced in this policy.

Applicability and Effective Date

Any human subjects research conducted by or for UCI is covered under this policy if it satisfies any of the following criteria.

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

This policy is revised effective December 1, 2004 and rescinds and supplants the policy previously issued on December 16, 1983 and revised on October 1, 1990.

Definitions

Clinical Investigation means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA, or is not subject to requirements for prior submission to the FDA under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

Derivation and Use of Human Stem Cells includes research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear transplantation. The state of California requires IRB review of all studies involving derivation and use of human stem cells.

Human Subject is (1) a living individual about whom an investigator conducting research obtains [e.g. reviews, analyzes, or records] (a) data through intervention or interaction with the individual; or (b) identifiable private information; or (2) an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

Human Subjects Research is any research or clinical investigation that involves human subjects.

Interaction includes communication or interpersonal contact between investigator and subject.

Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

IRB means an Institutional Review Board established in accord with DHHS and FDA regulations.

IRB Approval/Registration means the determination of the IRB that the human subjects research has been reviewed and may be conducted by or for UCI within the constraints set forth by the IRB and by other institutional and Federal requirements.

FDA means the DHHS Food and Drug Administration. The FDA oversees the safety of foods, drugs, devices, biologics and cosmetics for human use, and enforces DHHS regulations (21 CFR Parts 50 and 56) for the protection of human subjects and the general standards for the composition, operation, and responsibility of an Institutional Review Board (IRB) that reviews clinical investigations.

Lead Researcher means the person with primary responsibility for meeting all ethical, scientific, and regulatory requirements for conduct of a UCI study protocol, whether or not acting as the Principal Investigator for the award that funds the study.

Legally Authorized Representative means a person authorized either by California statute or by court appointment to make legal decisions on behalf of another person. In human subjects research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Offsite means occurring outside of UCI owned, operated, or leased facilities (including international sites). For purposes of research oversight, private facilities located on UCI land are considered offsite locations.

OHRP means the DHHS Office of Human Research Protections. The OHRP implements a program of compliance oversight for DHHS regulations (45 CFR Part 46, Subparts A-D) for the protection of human subjects.

Private Information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Research is any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

State Death Data Records are state of California issued death certificates and indices containing personal identifying information. The state of California requires IRB review of studies using state issued death records.

Test article means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food, Drug, and Cosmetic Act.

UCI facilities are facilities owned, operated, or leased by UCI including UCI campus, UCIMC, 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, facilities, employee time, equipment, supplies, services, and non-public information.

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

Policy Statement

In order to demonstrate appropriate oversight of human research activities and to comply with federal and state statutes, DHHS and FDA regulations, policies and guidelines; and applicable University policies and procedures, no human subjects research, derivation and use of human stem cells, or use of state death data records, as defined in this policy, shall be initiated by or for UCI prior to obtaining UCI IRB review and approval or registration.

The UCI IRBs have the authority to approve, require modifications of (to secure approval), or disapprove all human subjects research activities that are covered by this policy, or are performed at or in collaboration with offsite locations. All other applicable regulatory committee approvals (e.g., Conflict of Interest Oversight Committee, Institutional Biosafety Committee), University approvals, and completion and/or receipt of all other necessary documentation (e.g., evidence of IRB approval or permission letters from collaborating locations) are required prior to the initiation of any human research activity. No other UCI officials may approve human subjects research that has not been approved by the UCI IRB.

Studies funded by outside entities, such as drug or device companies, require an agreement between the University and the company. If UCI will receive compensation for conducting or directing a research activity, a contract must be established through UCI Office of Research Administration, Sponsored Projects. When contracts or other agreements are required, the language is to be developed and negotiated by Sponsored Projects staff to document UCI's responsibilities for the conduct of the specific project.

Authority and Responsibility

Institutional Official (IO) is responsible for:

- assuring compliance with applicable federal statutes and regulations, policies and guidelines, and applicable University policies and procedures concerning human research activities, as delegated by the UCI Chancellor;

- supporting, facilitating, and promoting ethical codes of conduct for research involving human subjects by demonstrating institutional commitment to uphold the standards set forth in the federal statutes and regulations, policies and guidelines, and applicable University policies and procedures concerning human research activities;
- establishing campus policy for the protection of human subjects;
- disapproving, suspending or terminating IRB approved protocols;
- reporting to OHRP and FDA any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with federal regulations, IRB requirements or determinations and any suspension or termination of IRB approval;
- reviewing qualifications of IRB nominees and making member appointments; and
- appointing Chairs and Vice Chairs to the IRB.

IRBs are responsible for:

- overseeing UCI's human research protections program;
- following written policies and procedures for
 - conducting initial and continuing review of research, and determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since the previous IRB review;
 - reporting its findings and actions to the investigator and institution (e.g., department chair, dean, vice chancellor, as applicable); and
 - ensuring prompt reporting of proposed changes in a research activity, and for ensuring that such changes in approved research are not initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to subjects; and
 - reporting to the IO any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with federal regulations, IRB requirements or determinations and any suspension or termination of IRB approval.
- reviewing research at convened meetings with a majority of IRB members present, except when an exempt or expedited review procedure is used;
- assuring that
 - risks to subjects are minimized;
 - risks to subjects are reasonable in relation to anticipated benefits;
 - selection of subjects is equitable;

- informed consent is sought from each prospective subject or the subject's legally authorized representative;
 - informed consent is appropriately documented;
 - adequate provisions for monitoring data collection are in place to ensure the safety of subjects;
 - when appropriate, adequate provisions are in place to protect the privacy of subjects and to maintain the confidentiality of data; and
 - additional safeguards are in place to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence.
- assuring human research activities that involve uses and disclosures of protected (personal) health information are reviewed in accord with UC privacy standards.

IRB Chairs are responsible for:

- ensuring the IRBs perform their functions as outlined in this policy and federal regulations for the protection of human subjects;
- acting as liaisons with the IO on behalf of the IRBs;
- halting any human research activity if the safety or welfare of a subjects appears to be at risk, or if the work being performed on a project is not in accordance with the approved protocol;
- addressing, in a timely fashion, any serious or repeated problems, concerns, complaints or allegations regarding the rights and welfare of human subjects; and
- reporting any subject safety or welfare issues and/or possible non-compliance to the IRBs.

Office of Research Administration is responsible for:

- serving as the office of record for the human research protections program, and
- supporting and coordinating all of the activities of the human research protection program and serving as the liaison between the IRBs and the UCI research community, specifically:
 - facilitating the protocol review process;
 - communicating to investigators in writing, on the behalf of the IRBs, all committee decisions and actions;
 - providing training, education, and consultation services on regulatory requirements;

- communicating to the IO any study-related issues that are likely to present risks or other concerns for the institution;
- communicating with other UCI administrative units and regulatory committees;
- conducting administrative audits (reviews) of alleged occurrences of regulatory noncompliance in collaboration with the IRBs in accordance with campus policy;
- assisting the IRBs in the conduct of regulatory committee reviews in accordance with campus policy;
- reporting to the IO and governmental agencies any significant problems or violations of federal regulations, IRB requirements, or suspension or termination of IRB approval.

Lead Researchers are responsible for:

- fully complying with all federal statutes and regulations, policies and guidelines, and applicable University policies and procedures, and IRB requirements concerning human research activities;
- ensuring that all co-researchers and personnel engaged in human subjects research have been educated about human subject protection requirements and have read and understand the approved protocol and all procedures to be performed;
- applying for IRB approval or registration prior to the commencement of any human research activity and initiate human research studies only after written IRB approval is provided;
- recognizing that IRB approval, in and of itself, does not necessarily constitute permission for implementation of human research projects. Accordingly, the project should not begin until all required approvals have been obtained;
- making no changes to approved studies without first having submitted those changes for review and approval by the IRB;
- providing the IRB with any information requested relative to the protection of human subjects;
- complying with an IRB decision to suspend or withdraw its approval of a human research activity;
- obtaining continuing approval prior to the expiration date approval of the study and recognizing human research activities must cease until current IRB approval is obtained;
- filing a closing report with the IRB at the conclusion of the study; and
- maintaining and make available for inspection by the IRB, authorized University officials, and federal agency inspectors all IRB protocol and study records in accordance with federal regulations.

Deans, Directors, Department Chairs, Division Chiefs, Section Heads are responsible for supervising the performance of human activities performed by investigators, including the scientific and financial management of sponsored projects.

Deans, Directors, and Chairs are responsible for reporting any failure of a faculty or staff member to carry out their human research responsibilities and recommending appropriate disciplinary action.

Deans and Chairs are responsible for recommending and encouraging faculty members from the department, unit, school, or college to serve on the IRB.