UCI ADMINISTRATIVE POLICIES & PROCEDURES

RESEARCH AND SPONSORED ACTIVITIES
Research Protections
Section 480-8: Offsite Research Activities

Responsible Office: Office of Research Administration
Issued: May 19, 2003
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: Requirement to Submit Proposals and to Receive Awards for Grants and Contracts through the University, issued March 8, 1995.
- UCI Research Policy: Compliance with Federal Regulations in the Use of Subjects in Research, issued January 31, 1998.

Background and Purpose

All research activities performed by, or under the direction of, UCI personnel in the course and scope of University duties, or which use University resources, must comply with applicable UCI policies and procedures, regardless of funding and whether performed in UCI facilities or at offsite locations.

Applicability and Effective Date

This policy applies to all offsite research activities involving the use of humans, animals, recombinant DNA (rDNA), or work performed offsite by or for UCI in order to achieve the goals of a sponsored activity. This policy also applies to all employees who receive any part of their salary through the University or who use any University facilities or resources (e.g., personnel, supplies, UC-managed funds). Part-time and clinical faculty are included, unless an exception is granted as provided below. Fellowships made directly to a student, postdoctoral fellow, or faculty member will not be affected by this policy.

This policy is effective December 1, 2004 and rescinds and supplants the Offsite Research Activities policy issued on May 19, 2003.

Definitions

Offsite means activities 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.

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, pre-clinical and clinical trials, pilot testing, research development, product testing, evaluation of programs and services, fieldwork, and all care and use of animals.

UCI-affiliated institutions means offsite locations that have formal agreements in place with UCI that allow the offsite location to conduct regulatory committee (IRB, IACUC and IBC) review for research proposed solely to occur on their premises.

UCI facilities means facilities owned, operated, or leased by UCI including UCI campus, UCIMC, UCI Family Health Centers in Anaheim, Santa Ana, and Westminster.

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.

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 research activities undertaken offsite, and to comply with the requirements of study sponsors and regulatory agencies, UCI requires documentation of the nature of the collaboration and the extent of UCI's involvement in and responsibility for the offsite activity.

The documentation necessary is dependent upon the type of activity, UCI's relationship with the site, the source of funding for the research or activity, and the degree of responsibility assumed by the investigator and by UCI.

No offsite research involving humans, animals, or rDNA shall be initiated prior to obtaining applicable regulatory committee approval/registration and completion and/or receipt of all other necessary documentation.

Under certain circumstances defined in Subparts A, B and C below, UCI may defer to a duly constituted regulatory review body at an Assured institution for review, approval and oversight of research performed by, or under the direction of, UCI personnel at those sites. UCI reserves the right to limit, suspend or terminate the involvement of UCI personnel in studies approved by off-site entities.

When agreements or contracts are required, the language of the agreement is to be developed and negotiated by UCI Office of Research Administration Sponsored Projects staff in collaboration with the Principal Investigator to document the responsibilities of UCI and of the offsite location relative to the conduct of the specific project. If UCI will receive compensation

for conducting or directing the research activities as defined in subparts A-C, a contract must be established through UCI Office of Research Administration Sponsored Projects.

Authority and Responsibility

Subpart A: Human Subjects

Applicability

Any human subjects research conducted in whole or in part offsite, including research at UCI-affiliated institutions, must be reviewed and approved/registered by all applicable UCI entities prior to initiation 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 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.

Purpose

It is the purpose of this subpart to enumerate the specific requirements for reviewing the proposed human research activities to which this subpart is applicable in order to assure that the activities conform to appropriate ethical standards, federal regulations, and applicable University policies.

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.

Existing human specimens and data means biological material from or information about a living human(s), collected for a purpose other than the UCI study and "on the shelf" prior to submission of a UCI protocol application for IRB registration/approval.

Human Subjects are (1) living individuals 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 as a control. A subject may be either a healthy human or a patient.

Human Subjects Research is the systematic investigation, collection and/or use of physiologic or behavioral characteristics and responses of living humans, either through intervention, interaction with the individual(s) or from [existing] records or specimens to develop or contribute to generalizable knowledge.

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.

Offsite human subjects research activities mean any human subjects research activity that occurs offsite.

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 involving greater than minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

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.

Requirements

The UCI IRB may approve/register human subjects research, clinical investigations, derivation and use of human stem cells, or use of state death data records that is proposed to occur at or in collaboration with offsite locations when appropriate documentation demonstrating the support and collaboration of the offsite location(s) and compliance with federal requirements is provided.

The documentation necessary for UCI approval/registration of offsite human subjects research is dependent upon several factors, including but not limited to the degree of risk to subjects, UCI's relationship with the site, the source of funding for the research, and the degree of responsibility UCI personnel will assume.

The degree of risk to subjects

1. Proposed human research procedures that involve *no more than minimal risk* to research subjects (i.e., study qualifies for expedited review): a letter of

permission/collaboration from the institutional authority of the offsite location is required prior to UCI IRB approval/registration of any research activities to be initiated at the off-site location.

2. Proposed research procedures that involve *greater than minimal risk* to research subjects: a written agreement between UCI and the off-site location may be required prior to UCI IRB approval.

The relationship of the site with UCI

1. UCI-affiliated institutions:

   Three locations [Fairview Developmental Center, Kaiser Permanente Medical Care Program (Southern California component sites only), and Metropolitan State Hospital] have agreements in place with UCI that allow deferral to their IRB for review of research proposed to occur solely on their premises.

   a. A copy of the approved protocol, consent form (when applicable) and the IRB approval letter from the offsite location and a completed UCI IRB Registration Form are required for UCI IRB for registration and acknowledgment.

   b. Proposed research that is to occur at a UCI-affiliated institution and at UCI, requires UCI IRB approval *in addition to* approval from the offsite location prior to initiation of any human subjects research activity.

2. Non-affiliated institutions:

   a. UCI IRB approval/registration is required prior to initiation of any offsite human subjects research activity performed by, or under the direction of, UCI personnel.

   b. Evidence of IRB approval and a copy of the consent form (if applicable) from the offsite location is required. If the institution has no IRB, permission from the off-site location's equivalent entity may be accepted. If the off-site institution has no equivalent entity, a letter of permission or collaboration from an authorized institutional official may be accepted. In some instances, the offsite institution may be permitted to use UCI's IRB as its IRB of record.

   c. Proposed research that is to occur at a non-affiliated institution and at UCI, requires UCI IRB approval *in addition to* approval from the offsite location prior to initiation of any human subjects research activity.

   d. An appropriate agreement developed by UCI Office of Research Administration Sponsored Projects staff may be required prior to UCI IRB approval.

The source of funding for the research activity

1. DHHS-funded offsite research:

   a. Agreements must be established between UCI and the offsite institution or individual(s) cooperating with UCI personnel on DHHS-funded research projects to ensure that federal standards for the conduct of the particular research project are pledged.

b. Federal regulations require that DHHS-funded human subjects research activities be conducted only at assured institutions. A Federal Wide Assurance (FWA) number for the offsite location(s) must be provided to UCI Office of Research Administration.

2. Non-DHHS-funded, sponsored offsite research: an appropriate agreement may be required prior to UCI IRB approval and/or release of extramural funds.

3. Unfunded or intramurally funded offsite research: an appropriate agreement may be required prior to UCI IRB approval.

The degree of responsibility assumed by UCI

1. Analysis of existing human specimens/data obtained from offsite location(s):

   a. UCI IRB approval/registration is required prior to initiating the analysis.

   b. Evidence of IRB approval and a copy of the consent form (if applicable) from the offsite location may be required if the specimens originally were collected for research purposes by the offsite location.

2. Prospective collection and analysis of human research specimens/data performed by, or under the direction of, UCI personnel:

   a. UCI IRB approval/registration is required prior to initiation of the activity.

   b. Evidence of IRB approval and a copy of the consent form (if applicable) from the offsite location is required.

   c. An appropriate agreement developed by UCI Office of Research Administration Sponsored Projects staff may be required prior to UCI IRB approval.

3. Involvement of UCI personnel in research projects that is limited to activities that do not meet the federal definition of “engaged in human research” do not require approval by the UCI IRB.

Subpart B: Use of Animals

Applicability

Any use of animals for the purpose of research, testing or teaching, conducted in whole or in part offsite (including field studies), must be reviewed and approved/registered by all applicable UCI entities prior to initiation 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 activity;

3. the name of the University of California, Irvine is used in applying for funds (intra or extramural);

4. the investigator plans to use his/her University of California, Irvine association in any publication or public presentation resulting from the activity.

Purpose

It is the purpose of this subpart to enumerate the specific requirements for reviewing the proposed activities to which this subpart applies, in order to assure that any use of animals conforms to the ethical and humane standards for animal care and use, federal statutes and regulations, policies and guidelines; and applicable University policies and procedures.

Definitions

Animal means any live, vertebrate animal.

Offsite animal activities include any use of animals in a research, testing, or teaching activity that occurs offsite.

Use of animals includes animals used or intended for use in research, training, experimentation, or biological testing or for related purposes.

Requirements

The UCI IACUC may approve/register activities involving animals that are proposed to occur at or in collaboration with offsite locations when appropriate documentation demonstrating the support and collaboration of the offsite location(s) and compliance with federal requirements is provided.

The documentation necessary for UCI approval/registration of offsite animal activities is dependent upon many factors, including but not limited to the source of funding for the activity, UCI's relationship with the site, and the degree of responsibility UCI personnel will assume.

The source of funding for the animal activity

1. DHHS-funded offsite activities:

    a. Agreements must be established between UCI and the offsite institution or individual(s) cooperating with UCI personnel on DHHS-funded projects to ensure that federal standards for the conduct of the particular animal activity are pledged.

    b. Federal regulations require that DHHS-funded animal activities be conducted only at assured institutions. An Animal Welfare Assurance (domestic) or a Statement of Compliance (foreign) number for the offsite location(s) must be provided to UCI Office of Research Administration Sponsored Projects.

2. Non-DHHS-funded, sponsored offsite activities: an appropriate agreement may be required prior to UCI IACUC approval and/or release of extramural funds.

3. Unfunded or intramurally funded offsite activities: an appropriate agreement may be required prior to UCI IACUC approval.

The relationship of the site with UCI

1. Non-affiliated institutions:

    a. UCI IACUC registration is required prior to initiation of any animal activity performed by, or under the direction of, UCI personnel.

b. Evidence of IACUC approval or equivalent authorization from the offsite location is required, as applicable.

c. Proposed activities that are to occur at a non-affiliated institution and at UCI, require UCI IACUC approval *in addition to* approval from the offsite location prior to initiation of any animal activity.

d. An appropriate agreement developed by UCI Office of Research Administration Sponsored Projects staff may be required prior to UCI IACUC approval.

The degree of responsibility assumed by UCI

1. Animal activities conducted entirely at an offsite location performed by, or under the direction of, UCI personnel:

   a. A copy of the approved protocol and the IACUC approval letter from the offsite location and a completed UCI IACUC Registration Form are required for UCI IACUC registration and acknowledgment.

   b. An appropriate agreement developed by UCI Office of Research Administration Sponsored Projects staff may be required prior to UCI IACUC approval.

2. Animal activities conducted at UCI and at or in collaboration with an offsite location:

   a. UCI IACUC approval is required prior to initiation of the activity.

   b. Evidence of IACUC approval or equivalent authorization and a copy of the protocol from the offsite location are required, as applicable.

   c. An appropriate agreement developed by UCI Office of Research Administration Sponsored Projects staff may be required prior to UCI IACUC approval.

3. Analysis of existing or otherwise discardable animal specimens obtained from offsite location(s): no UCI IACUC approval is required for receipt or use of existing animal tissue specimens.

Subpart C: Use of rDNA

Applicability

Any research use of rDNA conducted in whole or in part offsite, must be reviewed and approved/registered by all applicable UCI entities prior to initiation 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 activity;

3. the name of the University of California, Irvine is used in applying for intra- or extramural funding;

4. the investigator plans to use his/her University of California, Irvine association in any publication or public presentation resulting from the research.

Purpose

It is the purpose of this subpart to enumerate the specific requirements for reviewing the proposed activities to which this subpart applies, in order to assure that any use of recombinant DNA conforms to the federal and state regulations, policies and guidelines; and applicable University policies and procedures.

Definitions

Offsite rDNA activities include any research use of rDNA that occur offsite.

Recombinant DNA (rDNA) means recombinant deoxyribonucleic acid.

Use of rDNA means any activity that involves molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; use of molecules that replicate as a result of the above.

Requirements

The UCI IBC may approve/register research uses of rDNA that are proposed to occur at or in collaboration with offsite locations when appropriate documentation demonstrating the support and collaboration of the offsite location(s) and compliance with federal requirements is provided.

The documentation necessary for UCI approval/registration of offsite rDNA activities is dependent upon many factors, including but not limited to the source of funding for the activity, UCI's relationship with the site, and the degree of responsibility UCI personnel will assume.

The source of funding for the rDNA activity

1. DHHS-funded offsite research:

    a. Agreements must be established between UCI and the offsite institution or individual(s) cooperating with UCI personnel on DHHS-funded projects to ensure that federal standards for the conduct of the particular rDNA activity are pledged.

    b. Federal guidelines require that DHHS-funded rDNA activities be conducted only at institutions that assume the responsibilities assigned in the NIH *Guidelines for the Use of Recombinant DNA Molecules*. Assurance that the NIH *Guidelines* will be followed must be provided to UCI Office of Research Administration Sponsored Projects.

2. Non-DHHS-funded, sponsored offsite research: an appropriate agreement may be required prior to UCI IBC approval and/or release of extramural funds.

3. Unfunded or intramurally funded offsite research: an appropriate agreement may be required prior to UCI IBC approval.

The relationship of the site with UCI

1. Non-affiliated institutions:

a. UCI IBC registration is required prior to initiation of any rDNA activity performed by, or under the direction of, UCI personnel.

b. Evidence of IBC approval or equivalent authorization from the offsite location is required, as applicable.

c. Proposed research that is to occur at a non-affiliated institution *and* at UCI, requires UCI IBC approval prior to initiation of any rDNA activity.

d. An appropriate agreement developed by UCI Office of Research Administration Sponsored Projects staff may be required prior to UCI IBC approval.

<u>The degree of responsibility assumed by UCI</u>

1. rDNA activities conducted entirely at an offsite location performed by, or under the direction of, UCI personnel:

   a. A copy of the approved protocol and the IBC approval letter from the offsite location and a completed UCI IBC Registration Form are required for UCI IBC registration and acknowledgment.

   b. An appropriate agreement developed by UCI Office of Research Administration Sponsored Projects staff may be required prior to UCI IBC approval.

2. rDNA activities conducted at UCI and at or in collaboration with an offsite location:

   a. UCI IBC approval is required prior to initiation of the activity.

   b. Evidence of IBC approval or equivalent authorization from the offsite location is required, as applicable.

   c. An appropriate agreement developed by UCI Office of Research Administration Sponsored Projects staff may be required prior to UCI IBC approval.

3. Shipping or receiving of recombinant DNA reagents: shipping or receiving of recombinant DNA reagents conducted in compliance with funding agency (e.g., NIH) and journal requirements for the open exchange of materials for the expressed purpose of conducting research are not covered by this subpart.