

Policy Number: 10

Title: IRB Committees' Relationship to Other University Committees, Departments and Units

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Policy:

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to work in coordination with other Committees, departments and units to provide protections to research participants. The UCI IRB functions independently, but in coordination with other UCI Committees.

- I. **Cannabis Research Review Committee (CRRC) (Office of Research)**
 - A. Proposition 64 enacted in California on November 8, 2016 allows for the use, cultivation, and sale/distribution of marijuana for non-medical purposes among people over the age of 21. However, based on federal law, marijuana is categorized as a Schedule I drug with "no currently accepted medical use" in the United States.
 - B. There is no provision for the legal use of marijuana for research at UC except as established and in compliance with the Drug Enforcement Administration (DEA), Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA) policies and regulations. Marijuana remains prohibited on all University property and at all University events, except for as used in approved academic research.
 - C. As applicable, to ensure compliance with State and Federal regulations, CRRC approval is strongly recommended before clinical research procedures involving cannabis are initiated at UCI.

- II. **Chao Family Comprehensive Cancer Center Protocol Review and Monitoring Committee (PRMC)**
 - A. The PRMC must approve all research protocols which involve cancer (e.g., research involving participants at risk for cancer, participants with cancer and program evaluations, quality of life, and health education research involving cancer).
 - B. The PRMC scientific and scholarly review assures that the research uses procedures consistent with sound research design, the study design can be reasonably expected to answer the proposed question, and the importance of the knowledge expected to result from the research is known.
 - C. PRMC review is required for new and continuing IRB review if the cancer related research is:
 1. Investigator authored research,
 2. Is biomedical/ clinical research including clinical investigations,
 3. Involves greater than minimal risk and
 4. Has not received peer review for scientific merit
 - D. For all other research, PRMC review is required prior to the release of IRB approval.
 1. The IRB will grant conditional approval (i.e., "M") of the protocol pending PRMC clearance.

- E. The UCI IRB reserves the right to require scientific merit review prior to IRB review or prior to approval for any research, including modifications.
- III. **Clinical Engineering**
- A. UCI Clinical Engineering must approve the use of medical equipment in an area that operates under the hospital's license and/or equipment used on the hospital's patients and research subjects.
 - B. Investigators conducting research which involves the use of equipment as described in above must provide written assurance to the IRB that UCI Clinical Engineering's approval will be obtained prior to the use of such equipment.
- IV. **Clinical Research Acceleration and Facilitation Team (CRAFT)**
- A. CRAFT is a scientific review committee and feasibility assessment group aimed to help facilitate the continued growth of UCI as a key site for quality clinical research.
 - B. Beginning early 2020 CRAFT will review all new and continuing investigator-initiated clinical research that has not undergone peer review except:
 1. Studies reviewed by the Cancer Center's PRMC
 2. Federally funded research (that has undergone peer review)
 3. Research that involves no more than minimal risk and falls within one of the DHHS Expedited Review categories 1-9
 4. Research that is IRB exempt
 5. Studies that rely on external IRBs
 6. Multicenter industry-sponsored studies, *unless* the research is PI-initiated by a UCI faculty member or UCI is the primary contracted site
 7. Projects *not* intended to produce generalizable knowledge (such as compassionate use / expanded access)
 - C. Studies already reviewed for scientific merit (e.g., industry-sponsored, federal grant-sponsored multi-center) will not require scientific review by CRAFT, except consortium studies where scientific review is required as a condition of consortium participation.
 - D. CRAFT review will also include new and continuing sponsor initiated research for feasibility assessment.
 - E. In addition, CRAFT will provide training and study support to researchers. CRAFT will provide recommendations (endorsement) to the IRB related to new studies as well as continuing protocol applications.
 - F. CRAFT will eventually replace Scientific Review (SR) – *see Section XIX*.
 - G. **Effective July 1, 2020:**
 1. For new protocols, CRAFT review is required prior to IRB review.
 2. For continuing review of existing protocols, either investigator initiated or sponsor-initiated, CRAFT review is concurrent with IRB review.
- V. **Clinical Research Billing (CRB)**
- A. UCI Health System has established the CRB unit in an effort to fulfill regulatory requirements from the federal Office of the Inspector General, the University of California (UC) Corporate Compliance Program and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). At UCI, CRB may also be referred to as Research Revenue Integrity (RRI).
 - B. The CRB reviews human research studies that involve UCIMC clinical services as part of research or clinical care. This includes services or resources owned/rented/ operated or provided by the UCI Health System (UCI Medical Center,

Gottschalk, Pavilions, clinic and/ or hospital visits, professional medical services, clinical treatment, diagnostics, labs, medical supplies, etc.).

- C. The CRB is responsible for ensuring proper registration and billing practices for all human subjects receiving clinical care while enrolled in clinical research studies.
- D. The IRB strongly recommends that investigators seek CRB approval prior to IRB approval. Applications received by the IRB without CRB approval will be reviewed by an IRB Committee; however, CRB approval must be in place prior to initiation of the research.

VI. **Conflict of Interest Oversight Committee (COIOC) (Office of Research)**

- A. COIOC reviews the outside financial interests of investigators as mandated by State, Federal and University requirements and recommends action to the Vice Chancellor for Research (VCR).
- B. The Committee is charged with ensuring that an investigator's personal interest in, or commitment to, entities outside the University's purview does not compromise or appear to compromise his/her objectivity in performing a research project, in mentoring students involved in a research project or in reporting the results of a research project conducted under the aegis of the UC.
- C. COIOC review and resolution is required prior to IRB review. During the IRB process, any financial interests as defined by Institutional policy must be reported to and reviewed by the COIOC. The informed consent documents must include the appropriate language regarding conflict of interest based on the COIOC's recommendations and the VCR's decision, and IRB review of the investigator's financial interest.
- D. The IRB will review the COIOC management plan including the recommended informed consent language and determine whether additional measures are necessary to protect human subjects involved in the research. For specific details of this process see IRB Policy 25.

VII. **Dual Use Research Committee (DURC) (Office of Research)**

- A. Dual Use Research of Concern (DURC), under the United States Government Policy, is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat, with broad potential consequences, to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.
- B. Securing DURC approval is the responsibility of the Lead Researcher.
- C. If applicable, DURC approval is required before clinical research procedures can be initiated.

VIII. **Epidemiology and Infection Prevention Committee (EIP)**

- A. Research protocols involving the study of devices, biologic products or infectious agent in humans on the UCIMC campus or any UCI-affiliated clinical site (including clinical sites on campus or external affiliated sites) require review by the EIP.
- B. Securing EIP approval is the responsibility of the Lead Researcher.
- C. If applicable, EIP approval is required before clinical research procedures can be initiated.

- IX. Export Control Review Process (Office of Research)**
- A. The Export Control Review Process is recommended as part of considering the feasibility of study conduct and prior to research initiated in countries subject to Office of Foreign Assets Control (OFAC) sanctions (e.g., Cuba, Iran, North Korea and Syria).
 - B. Securing review (and a license, as necessary) is the responsibility of the Lead Researcher. Research requiring a license cannot be approved by the IRB until a license is obtained
- X. Human Stem Cell Research Oversight Committee (hSCRO) (Office of Research)**
- A. hSCRO assures human stem cell activities are:
 - 1. In accord with National Academies and California DHS guidelines, the National Institutes of Health Guidelines on Human Stem Cell Research, and the ethical guidelines (e.g., Belmont Report, Declaration of Helsinki), and
 - 2. In compliance with California statute and California Institute for Regenerative Medicine (CIRM) regulations and applicable campus policies and procedures for human stem cell activities.
 - B. hSCRO considers the ethical and social issues presented by human stem cell activities and reviews the scientific/scholarly merit of human stem cell activities to assure procedures are consistent with sound research design, the study design can be reasonably expected to answer the proposed questions(s), and the importance of the knowledge expected to result is known.
 - D. hSCRO review and approval is required prior to IRB review. IRB applications received by the Office of Research (OR) without hSCRO review and approval will be held pending such approval.
 - E. The scientific/scholarly reviews performed by the hSCRO are provided to the IRB.
- XI. Institutional Biosafety Committee (IBC)**
- A. The IBC is a Committee managed by the department of Environmental Health and Safety. IBC review is required by Institutions receiving funding from the NIH for research involving recombinant DNA molecules. It is charged with reviewing and approving research conducted with microorganisms pathogenic to humans, plants, or animals.
 - B. The IBC also provides guidance on the proper acquisition, handling, transfer, and disposal of potentially hazardous or regulated biological materials.
 - C. The following types of human research protocols must receive UCI IBC review and approval:
 - 1. Any research activity involving materials potentially containing human pathogens (e.g. unfixed human specimens, human blood) must be approved by the UCI IBC before the research can be initiated.
 - 2. Any research activity involving the deliberate transfer of recombinant DNA or RNA, or DNA or RNA derived from recombinant DNA into one or more human research participants must be approved by the UCI IBC before UCI IRB review. IBC comments and approval must be provided to the UCI IRB at the time of IRB review.
 - 3. Any research activity utilizing investigational, live, recombinant, and/or attenuated microorganisms for the purposes of vaccination or infection of one or more human research participants must be approved by the UCI IBC before UCI IRB review. IBC comments and approval must be provided to the UCI IRB at the time of IRB review.

4. Any research activity utilizing a "Select Agent" as defined by the CDC in 42 CFR 72 Appendix A must be approved by the UCI IBC before UCI IRB approval may be granted. The "Select Agent" list may be found on the CDC website.
5. Investigators utilizing recombinant DNA or potentially infectious microorganisms in the course of their research, but not for direct and deliberate transfer into human participants must be approved by the UCI IBC before UCI IRB review. IBC comments and approval must be provided to the UCI IRB at the time of IRB review.

XII. Investigational Drug Service (IDS)

- A. The IDS is a division of the UCIMC Pharmacy Department that must be consulted in advance of study initiation concerning the storage, handling, and dispensing of investigational drugs, agents, and biologics to assure compliance with all IDS policies and procedures, institutional, State, Federal (FDA) and Joint Commission on Accreditation of Hospital Organizations (JCAHO) requirements.
- B. The HRP staff sends an IDS Pharmacy and Therapeutics Report twice monthly to provide an update on the status of pending new and continuing reviews involving clinical investigations.
- C. Research activities may not begin until IRB approval has been granted and IDS pharmacist has been consulted by the Lead Researcher to review the drug pharmacology, method of administration, dosage range and schedule, indication, the potential adverse effects and interactions with other drugs, as appropriate.
- D. Storage of Investigational Drugs, Agents, or Biologics
 1. It is the responsibility of the Lead Researcher to comply with all Institutional, State and Federal regulations with regard to storage of investigational drugs, agents, or biologics.
 2. Investigational drugs, agents, or biologics used in the context of research, may be stored in areas other than the IDS under the direct supervision of the Lead Researcher and in accordance with the sponsor, if applicable.
 3. Controlled substances may not be stored outside of the pharmacy department.
 4. Investigational agent storage facilities outside of the IDS must be in compliance with Institutional, State, Federal FDA and JCAHO requirements.
- E. Dispensing of Investigational Drugs, Agents, or Biologics
 1. Investigational drugs, agents, or biologics administered to inpatients or outpatients should be dispensed by a licensed physician or an IDS pharmacist.
 2. If IDS is not utilized for the dispensing of investigational drugs, agents, or biologics, it is the responsibility of the Lead Researcher to assure that dispensing is in accordance with all Institutional, State, Federal, and JCAHO requirements.
 3. Nursing staff may administer investigational drugs, agents, or biologics to inpatients at UCIMC or one of its ambulatory clinics.
 4. The Pharmacy must prepare and dispense controlled substances for all inpatients and outpatients.

- XIII. **Laser Safety Committee (LSC)**
- A. Researchers proposing use of an investigational laser or the use of an FDA approved laser off label should consult with the Laser Safety Committee to determine if review would be appropriate.
 - B. Securing LSC approval is the responsibility of the Lead Researcher.
 - C. If applicable, LSC approval is required before clinical research procedures can be initiated.
- XIV. **Office of Research Oversight (ORO)**
- A. The ORO in UCI Health Affairs conducts directed and random periodic compliance reviews of IRB-approved studies when the Lead Researcher is Health Affairs personnel (i.e., faculty, staff, or student) and/or the research is conducted at UCI Medical Center (UCIMC).
 - 1. The Health Affairs Compliance Officer provides the Director of Human Research Protections (HRP) or designee with a summary of each compliance review.
 - B. The ORO will conduct directed and random periodic compliance reviews of IRB-approved studies at the request of the IRB.
 - C. HRP staff provides the ORO quarterly reports of recently approved protocols and protocols with reported unanticipated problems involving risk to subjects or others within the past quarter.
- XV. **Operating Room (OR) / Procedural Services Committee**
- A. Any HS research studies that will be conducted in UCIMC surgical units must notify the OR/Procedural Services Committee before study procedures are initiated.
 - B. A copy of the protocol must be provided to the OR/Procedural Services Committee.
 - C. Notification should be sent via email to the Operating Room Director.
 - D. Notification is the responsibility of the Lead Researcher and is required before clinical research procedures can be initiated in the surgical units.
- XVI. **Pathology Clearance**
- A. Per HRP Policy 15 and the UCIMC Anatomical Pathology/Surgical Pathology - Procedure Number: S-23, all specimens removed from clinic or the operating room must be sent to UCI Health Pathology for review and documentation by a pathologist.
- XVII. **Radiation Safety Committee (RSC)**
- A. All human research protocols involving use of radioactive materials must be performed under a Radiation Use Authorization (RUA) approved by the Medical Center Radiation Safety Committee.
 - B. All human research protocols involving use of radiation-producing equipment must be performed or supervised by physicians holding an appropriate state-issued X-ray Supervisors and Operators Permit or Certificate. *X-ray procedures at the Medical Center that are considered "standard-of-care" do not require a specific RUA.*
 - C. To expedite radiation reviews of human research protocols at the Medical Center, the Medical Center Radiation Safety Committee has established a Subcommittee consisting of the Committee Chair, the Medical Center Radiation Safety Officer, and the Radiation Physicist.

- D. All protocols involving radiation exposure to normal subjects, and/or to clinical human subjects when the exposure is not considered standard-of-care, is referred to the Subcommittee for review. If appropriate, the Subcommittee may approve the research, or it may refer the protocol to the full Medical Center Radiation Safety Committee for more extensive review.

Examples of procedures that require RSC approval include, but are not limited to:

- Any radiation exposures to normal subjects
- Any use of an investigational radiation device
- Any use of an investigational radiopharmaceutical or investigational implant/seed
- Any use of an investigational contrast medium with radiation
- Any use of imaging where it is the subject of the investigation, such as special CT sequences to guide a new surgical procedure

Examples of procedures that do not require RSC approval include, when standard-of-care:

- Routine chest X-rays
- Routine X-rays of fractures
- Routine diagnostic nuclear medicine tests
- Radioiodine therapy for hyperthyroidism
- Radiation therapy for cancer

- E. The RSC has the authority to approve, require modification in, or disapprove all research activities that fall within its jurisdiction.
- F. UCI RSC approval is required before IRB review. RSC comments and approval must be provided to the UCI IRB at the time of IRB review.

XVIII. Radiation Drug Research Committee (RDRC)

- A. The FDA classifies all radioactive drugs as either new drugs requiring an Investigational New Drug Application (IND) for investigational use (21 CFR 312) or as generally recognized as safe and effective when administered under the conditions specified in the Radiation Drug Research Committee (RDRC) regulations (21 CFR 361.1).
- B. Protocols qualifying for RDRC review must be reviewed and approved by the RDRC before IRB review. RDRC comments and approval must be provided to the UCI IRB at the time of IRB review.

XIX. Scientific Review (SR) (Office of Research Facilitates Process)

- A. UCI's IRB assumes responsibility for scientific review in conjunction with the Biostatistics, Epidemiology, & Research Design (BERD) unit in the Institute for Clinical and Translational Science (ICTS).
- B. The IRB, in conjunction with BERD is charged with ensuring that UCI investigator authored, biomedical or clinical human subject research studies involving greater than minimal risk that have not received prior scientific or scholarly review *or as required by the IRB* will render a scientifically valid interpretation of the results as defined by the study plan and objectives.
- C. The IRB, in conjunction with BERD will assure that the research uses procedures consistent with sound research design, the study design can be reasonably

expected to answer the proposed question, and the importance of the knowledge expected to result from the research is known.

D. **Scientific Review of Human Subjects Research at UCI falls into one of five categories:**

1. **For research already subjected to full peer review** (e.g., review by a study section or grant committee): No additional internal scientific review is required. The actual protocol (which describes in detail the involvement of human subjects) being submitted to the IRB must have been reviewed in its current form. The IRB may request copies of peer review comments. Peer review of a grant that describes a clinical trial in general terms does not satisfy this criterion. In addition, an industry-sponsored, clinical trial authored by a UCI investigator does not satisfy this criterion for independent peer-review.
2. **For research that involves cancer:** Patients with cancer, individuals at risk for cancer, or individuals in a study involving a specific cancer focus (e.g., program evaluations, quality of life, and health education) require scientific review by the PRMC. No additional scientific review is required. PRMC clearance is not required for cooperative group studies and protocols which have received prior PRMC exemption from review.
3. **For non-cancer research that is UCI investigator-authored and has not been subject to full peer review:**
 - i. **For biomedical/clinical research involving greater than minimal risk (full board review):** UCI HRP staff will directly coordinate with the BERD unit. If the IRB submission including the methodological or statistical information provided in Appendix F is incomplete, researchers will be required to revise their submission prior to IRB review. An incomplete submission may delay IRB review. Lead Researchers proposing investigator-authored studies are strongly encouraged to seek the consultation of a biostatistician prior to submission of an IRB application. This review will help assure the quality of the IRB submission and reduce the turnaround time for IRB review and approval.
 - ii. **For biomedical/clinical research involving minimal risk (Exempt and Expedited level of review):** Scientific review takes place at the school or departmental level. The Department Chair or Institute Director signs the IRB application attesting that the research is appropriate in design (i.e., the research uses procedures consistent with sound research design, the study design can be reasonably expected to answer the proposed question, and the importance of the knowledge expected to result from the research is known). The IRB reserves the right to require scientific review on a study-by study basis.
 - iii. **For social, behavioral, and educational research (all levels of review):** An appropriate scientific review takes place at the school or departmental level. The Department Chair or Institute Director signs the IRB application attesting that the research is appropriate in design (i.e., the research uses procedures consistent with sound research design, the study design can be reasonably expected to answer the proposed question, and the importance of the knowledge expected to result from the research is known). The IRB

reserves the right to require scientific review on a study-by study basis.

XX. Sponsored Projects Administration (SPA) (Office of Research)

- A. SPA is responsible for reviewing, endorsing and submitting proposals to extramural sponsors for research, training and public service projects.
- B. SPA's institutional responsibilities also include the following:
 - 1. Negotiating and accepting awards on behalf of The UC Regents;
 - 2. Drafting, negotiating and executing subcontracts;
 - 3. Ensuring institutional compliance with Federal and State regulations, sponsor policy and University policy;
 - 4. Representing the campus and The UC Regents when interacting with sponsors; coordinating pre-award and post-award actions that require either institutional or sponsor prior approval;
 - 5. Resolving problems related to sponsored projects; and
 - 6. Reviewing UCI consultant agreements.
- C. Funding for human subjects research (e.g., grant, contract) is not finalized without prior IRB approval.

XXI. Other Approvals Not Required Prior to IRB Approval

- A. At times, research may be subject to review and approval of other University Committees (e.g., another Scientific Review Committee) or External Review Committees (e.g., Research Cooperative Group).
- B. The IRB approval letter indicates that UCI IRB approval has been granted, but it is the Lead Researcher's responsibility to obtain approval from any other required committee before initiating the research.

References:

21 CFR 50
21 CFR 56
21 CFR 312
21 CFR 361
21 CFR 812
42 CFR 72, Appendix A
FDA Information Sheets
California Health & Safety Code, Section 125300 (hSCRO)
UCOP – Policy DURC