

Please note as a courtesy HRP Staff may notify the Lead Researcher (LR) / the Research Team if an ancillary partner may apply to the research.

Ancillary Partner	How Does This Ancillary Partner Impact Research?	When Does IRB Review Occur?	When Are IRB-Approved Documents Released?
Cannabis Research Review Committee (CRRC) Ms. Grace Park parkgj@uci.edu	Securing CRRC review for the use of cannabis in research is the responsibility of the LR. CRRC is recommended before clinical research procedures are initiated. CRRC review will assess the feasibility of study conduct and help to ensure compliance related to research involving cannabis.	Concurrent with CRRC	Upon IRB approval of the protocol.
Center for Clinical Research (CCR) UCclinicaltrials UCclinicaltrials@hs.uci.edu	In addition to serving those Departments that fall under the umbrella of CCR (School of Medicine), CCR review may be utilized by non-CCR, Non CFCCC, Non Alpha Stem Cell Researchers to initiate the requisite Qualified Clinical Trial (QCT) determination and subsequent Coverage Analysis (CA). <ul style="list-style-type: none"> QCT is needed for clinical trials using UCI Health items and services, as this will direct the requirement of completing a Coverage Analysis (CA) if a study is deemed qualified. Coverage Analysis is required as Medicare and most third-party payers cover the routine costs of qualifying clinical trials as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. 	Concurrent with CCR	Upon IRB approval of the protocol.
Chao Family Comprehensive Cancer Center (CFCCC) Protocol Review and Monitoring Committee (PRMC) Cancer Center: CancerCenter_Committees@hs.uci.edu	Cancer Center review is required (with documentation of clearance) if the following criteria is met: <ul style="list-style-type: none"> The research is cancer-related* and hypothesis-driven. The research involves interaction with participants, including obtaining consent. Note the following submission timing requirements: <ul style="list-style-type: none"> Investigator-initiated studies that are greater than minimal risk require Cancer Center approval prior to IRB submission. NCI National Clinical Trial Network, industry-sponsored studies, and minimal risk studies may be submitted to the Cancer Center and the IRB concurrently. <p><small>* Studies involving participants with cancer, any active intervention (e.g., behavioral or pharmacological) involving cancer or pre-cancerous participants, or participants of a study involving a specific cancer focus (e.g., program evaluations, quality-of-life survey health education, etc.).</small></p>	Concurrent with Cancer Center Review except when research meets criteria <u>in red</u>	Upon IRB approval of the protocol.
Clinical Engineering (CE) 714-456-5366	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. Securing CE approval is the responsibility of the LR and is required before clinical research procedures can be initiated.	Concurrent with CE	Upon IRB approval of the protocol.
Conflict of Interest Oversight Committee (COIOC) Ms. Nadia Wong: nadiaw@uci.edu	COIOC review is required for new, renewals and amendments when researcher/s report a disclosable financial conflict of interest. Documentation of COIOC review, including the COIOC proposed management plan and consent language (as applicable) must be provided to the IRB / IRB Chair for final review and approval.	Concurrent with COIOC	The IRB may grant conditional approval (i.e., "M") of the protocol pending COIOC clearance. After reviewing the Associate Vice Chancellor's recommendations, the IRB Chair / Vice Chair (VC) may accept or recommend full board IRB (re)review. If the IRB Chair / VC accepts the COIOC recommendations and the IRB documentation includes the required statements, IRB approval may be released.
Dual Use Research Committee (DURC) Ms. Grace Park parkgj@uci.edu	Securing DURC review is the responsibility of the LR and is recommended before clinical research procedures are initiated.	Concurrent with DURC	Upon IRB approval of the protocol.
Environmental Health and Safety (EHS) occhlth@uci.edu	When using a controlled substance on the Irvine campus, securing EHS review for the security of the substance is the responsibility of the LR and is recommended before clinical research procedures are initiated. Note: For smoking or tobacco use in research, researchers should check in with the EHS Smoke and Tobacco Free Policy Task Force to confirm the research is appropriate.	Concurrent with EHS	Upon IRB approval of the protocol.

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<p>Epidemiology and Infection Prevention (EIP) Health Epidemiology and Infection Prevention Program: 714-456-5221</p>	<p>Securing EIP Committee approval is the responsibility of the LR and is required before clinical research procedures can be initiated.</p> <p>EIP looks to identify research protocols involving humans that need further review by EIP for clearance due to trial of devices or biologic or infectious agents (e.g. live vaccine, probiotic) at UC Irvine Healthcare.</p>	<p>Concurrent with EIP</p>	<p>Upon IRB approval of the protocol.</p>
<p>Export Control Review Process (EXP CTRL) exportcontrol@uci.edu</p>	<p>Securing EXP CTRL review is the responsibility of the LR. EXP CTRL review 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).</p>	<p>Concurrent with EXP CTRL</p>	<p>Upon IRB approval of the protocol.</p>
<p>Human Stem Cell Research Oversight Committee (hSCRO) Contact: hSCRO@uci.edu</p>	<ul style="list-style-type: none"> • Use* of the following human materials: gametes, embryos, adult pluripotent cells, fetal tissue, fetal stem cells, or embryonic stem cells. • Generation of new lines of human pluripotent stem cells • Introduction of human adult pluripotent cells, human fetal tissue, fetal stem cells, or human embryonic stem cells or their neural derivatives into a non-human animal • Transplantation of neural stem cells into humans <p>* (understood as procurement under an IRB-approved research protocol or from a different source, use in purely in-vitro experiments, use as part of genome editing technologies, or for transplantation into animals or humans)</p>	<p>Concurrent with hSCRO</p>	<p>The IRB may grant conditional approval (i.e., "M") of the protocol pending hSCRO approval. The IRB Chair/ Vice-Chair can review the hSCRO determination. If additional risks or significant consent form revisions are required/suggested, or the IRB Chair / VC have concerns, full board IRB re-review is required.</p> <p>Upon the IRB's acceptance of the hSCRO approval and the IRB documentation includes the required statements, IRB approval may be released.</p>
<p>Institutional Biosafety Committee (IBC) Ms. Alice Lee: 949-824-8024, ibc@uci.edu</p>	<p>Any research involving the deliberate transfer of recombinant and synthetic nucleic acids, materials or microorganisms modified using recombinant and synthetic nucleic acids into one or more human research participants must be approved by the UCI IBC. Securing IBC approval for biosafety issues (e.g., blood draws, specimens transferred from clinic to UCI lab, etc.) is the responsibility of the LR and is required before clinical research procedures are initiated. Note: The UC-Irvine Human Gene Transfer Institutional Biosafety Committee (HGT IBC) is being administered by Clinical Biosafety Services (CBS). Researchers should still submit through the UCI IBC, who will coordinate the CBS process.</p>	<p>Concurrent with IBC</p>	<p>The IRB may grant conditional approval (i.e., "M") of the protocol pending IBC clearance. The IRB Chair / VC can review the IBC determination. If additional risks or significant consent form revisions are required/suggested, or the IRB Chair / VC have concerns, full board IRB re-review is required.</p> <p>Upon the IRB's acceptance of the IBC approval and the IRB documentation includes the required statements, IRB approval may be released.</p>
<p>Investigational Drug Service (IDS) Dr. Alyssa Le: alyssal@uci.edu</p>	<p>The IDS is a division of the 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. The HRP staff sends the IDS a report bi-monthly to provide an update on the status of pending new and renewals involving clinical investigations.</p> <p>Note the following submission timing requirements:</p> <ul style="list-style-type: none"> • Securing IDS review or consult is the responsibility of the LR and is recommended before clinical research procedures are initiated. • If an Investigator Initiated Trial (IIT), evidence of IDS clearance is required in order to release IRB approval. In order to best facilitate this in Quali Research Protocols – an "M" determination should be made. 	<p>Concurrent with IDS except when research meets criteria in red</p>	<p>The IRB may grant conditional approval (i.e., "M") of the protocol pending IDS clearance. The IRB Chair / VC can review the IDS determination. If additional risks or significant consent form revisions are required/suggested, or the IRB Chair / VC have concerns, full board IRB re-review is required.</p> <p>Upon the IRB's acceptance of the IDS approval and the IRB documentation includes the required statements, IRB approval may be released.</p>
<p>Laser Safety Committee (LSC) For more info visit: http://www.ehs.uci.edu/radsafe.html</p>	<p>Securing LSC review or consult is the responsibility of the LR and is recommended before clinical research procedures are initiated.</p>	<p>Concurrent with LSC</p>	<p>Upon IRB approval of the protocol.</p>

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OR/Procedural Services Committee Ms. Laura Bruzzone: lbuzzon@uci.edu	Notifying the OR/Procedural Services Committee is the responsibility of the LR and is required before clinical research procedures can be initiated in the surgical units.	Concurrent with OR/ Procedural Services	Upon IRB approval of the protocol.
Pathology Clearance (PATH) Dr. Robert Edwards (redwards@uci.edu) or Delia Tifrea (dtifrea@hs.uci.edu).	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.	Concurrent with PATH	Upon IRB approval of the protocol.
Radiation Safety Committee (RSC) Barbara Hamrick: 714-456-5607, bhamrick@uci.edu	All protocols involving radiation exposure to normal subjects and/or clinical human subjects when the exposure is not considered standard-of-care must be referred to the RSC. (Use the flowchart on Page 5 of the Application for Human Subject Research Involving Radiation @ https://www.ehs.uci.edu/programs/radiation/RSCReviewAppGuide.doc to determine level of RSC review.	Concurrent with RSC	If protocol requires RSC subcommittee review, approval documents will be released upon IRB approval. The IRB may grant conditional approval (i.e., "M") of the protocol pending RSC full board review/approval. The IRB Chair/VC can review the RSC determination. If additional risks or significant consent form revisions are required/suggested, or the IRB Chair/VC have concerns, full board IRB re-review is required.
Radioactive Drug Research Committee (RDRC) Contact HRP Staff	<p>When the research involves radioactive materials, documentation of RDRC review, including RDRC comments and approval is required before the IRB can grant approval.</p> <p>Alternatively, documentation of an IND from the FDA is required before final IRB approval. Sufficient documentation of an IND includes IND letter from FDA or IND number on Sponsor's Master Protocol, if externally sponsored.</p>	N/A	Committee currently inactive
Research Revenue Integrity (RRI) ResearchRevenueIntegrityCRBCRFA@hs.uci.edu	<p>RRI performs a sign-off on behalf of UC Irvine Health (study activation requirement), including review and approval of all coverage analysis. RRI is responsible for ensuring all technical and professional services provided under a clinical research study at any UC Irvine Health location are identified, coded, recharged and/or billed correctly.</p> <p>RRI maintains research rates and the research charge master.</p>	Concurrent with RRI	Upon IRB approval of the protocol.
Scientific Review (Statistical Methods) (SR) Contact HRP Staff	<p>Scientific review clearance for investigator-initiated full committee protocols is required before IRB review may proceed. Reviewer comments, including scientific review clearance must be provided to the IRB at the time of their review.</p> <p>Exempt and Expedited level protocols DO NOT require scientific review unless mandated by the IRB Subcommittee. The IRB Chair or VC may require SR review for significant study amendments.</p> <p>Patient care that does not qualify as "research" yet regulations require prospective IRB review and approval (e.g., expanded access, HUD) DO NOT require scientific review.</p>	<p>Initial hold IRB review for SR.</p> <p>If minor SR comments proceed with IRB review and include SR comments in memo to LR.</p> <p>If significant comments, LR must respond to memo and SR re-review prior to IRB review.</p>	Upon IRB approval of the protocol.