

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

Committee	How Does This Committee Impact Research?	When Does IRB Review Occur?	When Are IRB-Approved Documents Released?
<p>Conflict of Interest Oversight Committee (COIOC) Ms. Nadia Wong: 949-824-0012 nadiaw@uci.edu</p>	<p>COIOC review is required for new, continuing review and modifications 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.</p>	<p>Concurrent with COIOC</p>	<p>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.</p>
<p>School of Medicine (SOM) Clinical Research Acceleration and Facilitation Team (CRAFT) Ms. Erika Pitcher: 949-824-9958 Erika.pitcher@uci.edu ccrcraft@hs.uci.edu</p>	<p>(SOM) CRAFT review is required for all SOM non-cancer, clinical research. Effective November 18, 2020: CRAFT review is concurrent with IRB review.</p> <ul style="list-style-type: none"> • Sponsor-initiated research will undergo a feasibility assessment at the time of initial and continuing review. • Investigator-initiated research will undergo review for scientific merit and feasibility at the time of initial and continuing review. • 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. • Exempt and Expedited level protocols DO NOT require scientific review unless mandated by the IRB Subcommittee. 	<p>Effective Nov. 18, 2020: Concurrent with (SOM) CRAFT</p>	<p>Upon IRB approval of the protocol.</p> <p>The IRB may grant conditional approval (i.e., "M") of the protocol pending CRAFT clearance.</p> <p>The IRB Chair / Vice Chair (VC) may accept or recommend full board IRB (re)review based on the CRAFT review. If the IRB Chair / VC notes the CRAFT review has been incorporated in the IRB documentation and there are no additional concerns, IRB approval may be released</p>
<p>Clinical Research Billing (CRB) / Research Revenue Integrity (RRI) Ms. Anya C. Dang: 949-824-5925 acoultas@uci.edu</p>	<p>Obtaining coverage analysis and registration of the research protocol is required and remains the responsibility of the LR prior to initiating any clinical services. The CRB or RRI requirement (CRB may also be referred to as RRI) applies to research protocols involving both minimal risk and greater than minimal risk.</p>	<p>Concurrent with CRB / RRI</p>	<p>Upon IRB approval of the protocol.</p>
<p>Cannabis Research Review Committee (CRRC) Ms. Amy Green: 949-824-0445, acgreen1@uci.edu</p>	<p>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.</p>	<p>Concurrent with CRRC</p>	<p>Upon IRB approval of the protocol.</p>
<p>Clinical Engineering (CE) 714-456-5366</p>	<p>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.</p>	<p>Concurrent with CE</p>	<p>Upon IRB approval of the protocol.</p>
<p>Dual Use Research Committee (DURC) Ms. Amy Green: 949-824-0445, acgreen1@uci.edu</p>	<p>Securing DURC review is the responsibility of the LR and is recommended before clinical research procedures are initiated.</p>	<p>Concurrent with DURC</p>	<p>Upon IRB approval of the protocol.</p>

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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.
Epidemiology and Infection Prevention (EIP) Health Epidemiology and Infection Prevention Program: 714-456-5221	Securing EIP Committee approval is the responsibility of the LR and is required before clinical research procedures can be initiated. 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.	Concurrent with EIP	Upon IRB approval of the protocol.
Export Control Review Process (EXP CTRL) Ms. Amy Green: 949-824-0445, exportcontrol@uci.edu	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).	Concurrent with EXP CTRL	Upon IRB approval of the protocol.
Human Stem Cell Research Oversight Committee (hSCRO) Contact: 949-824-3711 or hSCRO@uci.edu	<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 * (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)	Concurrent with hSCRO	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. Upon the IRB's acceptance of the hSCRO approval and the IRB documentation includes the required statements, IRB approval may be released.
Institutional Biosafety Committee (IBC) Ms. Alice Lee: 949-824-8024, ibc@uci.edu	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.	Concurrent with IBC	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. Upon the IRB's acceptance of the IBC approval and the IRB documentation includes the required statements, IRB approval may be released.
Investigational Drug Service (IDS) Dr. Alyssa Le: alyssal@uci.edu	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 continuing reviews involving clinical investigations. Securing IDS review or consult is the responsibility of the LR and is recommended before clinical research procedures are initiated.	Concurrent with IDS	Upon IRB approval of the protocol.

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<p>Laser Safety Committee (LSC)</p> <p>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>
<p>OR/Procedural Services Committee</p> <p>Ms. Laura Bruzzone: lbruzzon@uci.edu</p>	<p>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.</p>	<p>Concurrent with OR/ Procedural Services</p>	<p>Upon IRB approval of the protocol.</p>
<p>Pathology Clearance (PATH)</p> <p>Dr. Robert Edwards redwards@uci.edu or Delia Tifrea (dtifrea@hs.uci.edu).</p>	<p>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.</p>	<p>Concurrent with PATH</p>	<p>Upon IRB approval of the protocol.</p>
<p>The Chao Family Comprehensive Cancer Center (Cancer Center) Protocol Review and Monitoring Committee (PRMC)</p> <p>Researchers should contact the PRMC at: CancerCenterCommittees@health.uci.edu for assistance in handling this requirement.</p>	<p>For cancer research that involves greater than minimal risk to subjects (i.e., requires full board review: PRMC review is required (with documentation of clearance from the PRMC) prior to IRB review of new or continuing research when the research is investigator-authored and has not received peer review for scientific merit.</p> <p>For cancer research that involves no more than minimal risk to subjects (i.e., Exempt and Expedited categories of research): PRMC review is required (with documentation of clearance from the PRMC) prior to the IRB approval of new or continuing research, including research that is:</p> <ul style="list-style-type: none"> • Industry-authored (i.e., for-profit pharmaceutical or medical device entities) and/or • Federally-sponsored or sponsored by other non-profit entities (e.g., private foundation, other academic institutions) with documentation of peer review for scientific merit. <p>Note: The UCI IRB reserves the right to require scientific merit review prior to IRB review or prior to approval for any research, including modifications.</p>	<p>Greater than minimal risk: New studies are placed on the IRB agenda upon receipt of PRMC clearance.</p> <p>Minimal risk: IRB review is concurrent with PRMC.</p>	<p>Greater than minimal risk new studies: Approval documents are released upon final IRB approval of the protocol.</p> <p>Minimal risk (new studies & continuing review) & Greater than minimal risk continuing review: The IRB will grant conditional approval (i.e., "M") of the protocol pending PRMC clearance. The IRB Chair / VC (or designee) can review the PRMC determination / clearance. Upon the IRB's acceptance of PRMC determination / clearance, IRB approval documents are released.</p>
<p>Radiation Safety Committee (RSC)</p> <p>Barbara Hamrick: 714-456-5607, bhamrick@uci.edu</p>	<p>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.</p>	<p>Concurrent with RSC</p>	<p>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.</p>

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<p>Radioactive Drug Research Committee (RDRC)</p> <p><u>Contact HRP Staff</u></p>	<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 include IND letter from FDA or IND number on Sponsor's Master Protocol, if externally sponsored.</p>	<p>N/A</p>	<p>Committee currently inactive</p>
<p>Scientific Review (Statistical Methods) (SR)</p> <p><u>Contact HRP Staff</u></p>	<p>Scientific review clearance for investigator-initiated full committee protocols is required before IRB review may proceed.</p> <p>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.</p> <p>The IRB Chair or VC may require SR review for significant study modifications.</p>	<p>Hold IRB review for Scientific Review</p> <p>If minor SR comments proceed with IRB review; 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>	<p>Upon IRB approval of the protocol.</p>