UCI Office of Research

Institutional Review Board

REFERENCE: UCI IRB REVIEW AND APPROVAL TIMEFRAME WITH OTHER COMMITTEES

Version 09.01.2017

Please note as a courtesy Human Research Protections (HRP) Staff will notify the Lead Researcher if an ancillary committee may apply to the research.

Committee	How Does This Committee Impact Research?	When Does IRB Review Occur?	When Are IRB-Approved Documents Released?
Clinical Research Finance Assessment **(CRFA)** Ms. Anya Dang: 714-456-7618, acoultas@uci.edu	*Obtaining coverage analysis and registration of the research protocol is required and remains the responsibility of the Lead Researcher prior to initiating any clinical services. The CRFA/CRB requirement applies to research protocols involving both minimal risk and greater than minimal risk.*	**Concurrent with CRFA**	Upon IRB approval of the protocol.
Conflict of Interest Oversight Committee **(COIOC)** Ms. Nadia Wong: 949-824-0012, nadiaw@uci.edu Ms. Amy Green: 949-824-9015, acgreen1@uci.edu	*Documentation of COIOC review, including the COIOC report and suggested consent language must be provided to the 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. The IRB Chair/VC can review the Associate VC's recommendation. After reviewing the recommendations, the IRB Chair/VC can 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. Amy Green: 949-824-9015, acgreen1@uci.edu	*Securing DURC review or consult is the responsibility of the LR and is recommended before clinical research procedures are initiated.*	**Concurrent with DURC**	Upon IRB approval of the protocol.
Epidemiology and Infection Prevention Committee **(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.*	**Concurrent with EIP**	Upon IRB approval of the protocol.

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Human Stem Cell Research Oversight Committee **(hSCRO)** **Administrator: 949-824-3711**	*Research protocols involving **the derivation or use of the following** require review by the hSCRO Committee:* • *human gametes and embryos (e.g., blastocysts),* • *human embryonic stem cells,* • *induced pluripotent stem cells (iPS) derived from adult cells,* • *any cells which can differentiate into a gamete, and any other human pluripotent stem cells, fetal-tissue origin multipotent stem cells* *It is not necessary to obtain hSCRO approval for adult tissue-derived stem cells such as hematopoietic cells, bone-marrow stromal or mesenchymal cells unless such cells have been shown to, or are being induced to differentiate into the three major germ lines.*	**Concurrent with hSCRO**	The IRB may grant conditional approval (i.e., "M") of the protocol pending hSCRO approval. The IRB Chair/VC 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 activity 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. IRB approval will be granted upon receipt of the IBC approval letter. If, however, substantive changes to the IRB protocol are required based on IBC determination or NIH Recombinant DNA Advisory Committee (RAC) review, additional IRB review will be required to confirm that changes meet requirements for IRB approval under 45 CFR 46.111 and 21 CFR 56.111.* *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.*	**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.

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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.
Laser Safety Committee **(LSC)** For more info visit: http://www.ehs.uci.edu/radsafe.html	*Securing LSC review or consult is the responsibility of the LR and is recommended before clinical research procedures are initiated.*	**Concurrent with LSC**	Upon IRB approval of the protocol.
OR/Procedural Services Committee Ms. Laura Bruzzone: (lbruzzon@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.

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The Chao Family Comprehensive Cancer Center (Cancer Center) Protocol Review and Monitoring Committee **(PRMC)** **Researchers should contact the PRMC at: CancerCenter_Committees@health.uci.edu or (714) 456-6550 for assistance in handling this requirement.** **Researchers may obtain the required PRMC forms and detailed information about the PRMC review process at the internal PRMC website.**	*PRMC review is required (with documentation of clearance from the PRMC) prior to IRB review if the research meets the following criteria:* • *Investigator-authored research;* • *Involves biomedical/clinical research including clinical investigations;* • *Involves greater than minimal risk to subjects (i.e., requires full board review); and* • *Has not received peer review for scientific merit.* *Concurrent with IRB review:* • *Research involving no more than minimal risk to subjects (i.e., Exempt and Expedited categories of research).* • *Research that is industry-authored (i.e., for-profit pharmaceutical or medical device entities)* • *Research that is federally-sponsored or sponsored by other non-profit entities (e.g., private foundation, other academic institutions) with documentation of peer review for scientific merit.* *Note: The UCI IRB reserves the right to require scientific merit review prior to IRB review or prior to approval for any research.*	**Concurrent with PRMC *except* when research meets criteria in red**	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/RSC ReviewAppGuide.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.

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Radioactive Drug Research Committee **(RDRC)** Contact HRP Staff	***When the research involves radioactive materials, documentation of RDRC review, including RDRC comments and approval is required before the IRB can grant approval.*** *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.*	N/A	Committee currently inactive
Scientific Review Contact HRP Staff	***Scientific review clearance for full committee protocols is required before IRB review. Reviewer comments, including scientific review clearance must be provided to the IRB at the time of their review.*** ***Exempt and Expedited level protocols DO NOT require scientific review unless mandated by the IRB Subcommittee.***	**Hold IRB review for Scientific Review** If minor SR comments proceed with IRB review; include SR comments in memo to LR. If significant comments, LR must respond to memo and SR re-review prior to IRB review.	Upon IRB approval of the protocol.