## COIOC review is required for new, continuing review and modifications when researcher's report a plausible 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.

**COIOC Leakage Date:**

1. **Effective July 1, 2020:** For new studies only: CRAFT Reviewer comments must be provided to the IRB at the time of their review.
1. **Effective July 1, 2020:** Concurrent with CRRC review except in red: Hold IRB Review

**Concurrent with COIOC Review**

Upon IRB approval of the protocol.

**Effective Immediately:**

For continuing review of existing protocols, either investigator initiated or sponsor-initiated, the IRB may grant conditional approval (i.e., "M") of the protocol pending CRAFT review.

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.

### Clinical Research Acceleration and Facilitation Team (CRAFT)

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</tr>
</thead>
<tbody>
<tr>
<td>Environmental Health and Safety (EHS)</td>
<td>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.</td>
<td>Concurrent with EHS</td>
<td>Upon IRB approval of the protocol.</td>
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<tr>
<td>Epidemiology and Infection Prevention (EIP)</td>
<td>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.</td>
<td>Concurrent with EIP</td>
<td>Upon IRB approval of the protocol.</td>
</tr>
<tr>
<td>Export Control Review Process (EXP CTRL)</td>
<td>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).</td>
<td>Concurrent with EXP CTRL</td>
<td>Upon IRB approval of the protocol.</td>
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</table>
| Human Stem Cell Research Oversight Committee (hSCRO)          | • 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)                       | 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. | 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)                            | 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.       |

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 Impact on Research

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<td><strong>Laser Safety Committee (LSC)</strong></td>
<td>Securing LSC review or consult is the responsibility of the LR and is recommended before clinical research procedures are initiated.</td>
<td>Concurrent with LSC</td>
<td>Upon IRB approval of the protocol.</td>
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<td><strong>OR/Procedural Services Committee</strong></td>
<td>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.</td>
<td>Concurrent with OR/Procedural Services</td>
<td>Upon IRB approval of the protocol.</td>
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</table>
| **The Chao Family Comprehensive Cancer Center (Cancer Center) Protocol Review and Monitoring Committee (PRMC)** | PRMC review is required (with documentation of clearance from the PRMC) prior to new and continuing 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 new and continuing 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 | The IRB may 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 may be released. |
| **Radiation Safety Committee (RSC)** | 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 Subjed 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)** | 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 |

*For more info visit: [http://www.ehs.uci.edu/radsafe.htm](http://www.ehs.uci.edu/radsafe.htm)*

*Note: The UCI IRB reserves the right to require scientific merit review prior to IRB review or prior to approval for any research.*
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| Scientific Review (Statistical Methods) (SR) | **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.**
**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 modifications.** | **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.** |

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.

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**Institutional Review Board**

Version 03-30-2020