The following roadmap outlines the various institutional approvals needed to initiate your research at UC Irvine.

Your research activity requires review and approval by the following Research Protections regulatory committee(s):

- **Human Stem Cell Research Oversight (hSCRO)**
  All research or clinical investigations that involve the use of pluripotent human stem cells shall be reviewed and approved by the UCI hSCRO before such activities are initiated by or for UCI. This review requirement applies to the use of human gametes and embryos (e.g., blastocysts), the derivation and/or use of human embryonic (hESCs) or fetal 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.

  It is not necessary to obtain hSCRO approval for adult tissue-specific stem cells such as hematopoietic cells or mesenchymal cells unless such cells have been shown to, or are being induced to differentiate into the three major germ lines.

  **NOTE: hSCRO review and approval is required prior to IRB or IACUC review.**

- **Institutional Review Board (IRB)**
  Human research activities, regardless of sponsorship, must be reviewed and approved by the UCI IRB, or registered as exempt by the HRP Staff in the Office of Research prior to initiation. This includes research activities that involve interventions and interactions with human subjects, or access to identifiable private information about human subjects. Securing IRB approval or exempt registration is the responsibility of the Lead Researcher.

- **Institutional Animal Care and Use Committee (IACUC)**
  IACUC is charged to assure that the use of live, vertebrate animals in research, testing, teaching or related activities is scientifically justified; that all animals intended for use in those activities are provided humane care and treatment, including appropriate veterinary medical care; that
procedures are designed to minimize or avoid pain, distress and discomfort; and that all personnel involved in the use of animals have received appropriate training to conduct the procedures and care for the animals.

The IACUC also works closely with Environmental Health and Safety to ensure the safety of research personnel involved with the use of live animals, including the use of hazardous agents.

Approval or other requirement is necessary before Research Protections committee review (e.g., IACUC, IRB).

**IRB - Required Education for Human Subject Researchers:**

UCI Researchers must complete mandatory training in human subject education prior to IRB review. For individuals engaged in human subjects research completion of the following web-based tutorials is required:

- Collaborative Institutional Training Initiative (CITI) Human Research Protections Training
- HIPAA Research Tutorial - (required only if research involves protected health information (PHI))

Be sure that all research team members complete the required tutorials.

**IACUC - Required Education for Animal Researchers:**

UCI Researchers must complete mandatory training in the ethical and humane use of live animals in research prior to IACUC submission.

**IRB - Investigator-Authored Human Subjects Research:**

Biomedical and Clinical Research Studies require scientific merit review if the research:

- is investigator-authored;
- involves greater than minimal risk to subjects (i.e., full board review); and
- has not been previously peer reviewed; or does not require PRMC review (i.e., not cancer-related).

Lead researchers should submit their completed application to the IRB. The UCI IRB will work directly with the Biostatistics, Epidemiology and Research Design (BERD) unit in the Institute for Clinical and Translational Sciences (ICTS) to secure scientific review.

NOTE: Minimal risk research is subject to scientific review at the discretion of the IRB. The requirement for scientific merit review could lengthen the time to IRB approval.
IRB - Radiation Safety Committee (RSC):

All protocols involving human use of radioactive materials and/or radiation-producing equipment are subject to Radiation Safety Committee (RSC) review. The Medical Center RSC is currently responsible for reviewing all human research studies involving radiation. The IRB will review the results of the RSC before granting approval.

Approval or other requirement may be secured concurrent with Research Protections committee review (e.g., IACUC, IRB). Exceptions are noted below.

IRB - Clinical Research Billing (CRB):

UC Irvine Health has established the CRB process to assure appropriate billing of clinical services delivered in a research study. The functions of the CRFA (Clinical Research Finance Assessment) office are now a component of CRB. CRB processes include correctly identifying, coding, and recharging and/or billing all technical and professional services provided; ensuring regulatory/contractual documents are consistent with the Medicare National Coverage Determination (NCD); advising on appropriate cost language in informed consent; and providing quotes for research rates to be included in proposed budgets. Obtaining a coverage analysis for your protocol and registration of your protocol with CRFA/CRB is required and remains the responsibility of the Lead Researcher prior to any clinical services being initiated for the purposes of the research study.

IRB - Conflict of Interest Oversight Committee (COIOC):

COIOC review is concurrent with IRB review of new protocols.

All study team members, their spouses/registered domestic partners, and/or dependent children must disclose their financial interests as part of the Application for IRB Review. The COIOC reviews all human subjects research studies where a financial interest related to research has been disclosed. The IRB reviews the COIOC management plan accepted by the Institutional Official to determine whether additional human subjects protections are necessary.

IACUC - Institutional Biosafety Committee (IBC):

The charge of the Institutional Biosafety Committee (IBC) is to assure the safe acquisition, use, and disposal of all biological agents at UCI. IBC approval is required prior to the release of IACUC approval documents.

IACUC - Radiation Safety Committee (RSC):

Research involving radioactive materials, radiation-producing equipment or lasers require RSC approval prior to the release of IACUC approval documents.
IRB - Chao Family Comprehensive Cancer Center Protocol Review and Monitoring Committee (PRMC):

The PRMC reviews all human studies that involve patients with cancer, participants at risk for cancer, or participants of a study involving a specific cancer focus (e.g., program evaluations, quality of life, and health education). The PRMC has overall responsibility for evaluating scientific merit, statistical design as applicable to the study, and accrual. The PRMC has ongoing oversight of all cancer-related human research protocols except cooperative group studies.

**PRMC approval is required 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.

**PRMC review prior to IRB review is NOT required for:**

- 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.

IRB - Institutional Biosafety Committee (IBC):

The charge of the Institutional Biosafety Committee (IBC) is to assure the safe acquisition, use, and disposal of all biological agents at UCI. Research activities involving rDNA research activities or activities involving the introduction of genetically engineered micro-organisms or infectious agents into human subjects must obtain IBC approval.

IBC review is concurrent with IRB review of new protocols. 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's (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

Approval or other requirement is necessary before initiation of research activities.

IRB - Laser Safety Committee:

Laser Safety Committee review or consultation may be appropriate for research that involves the use of an investigational laser or the use of an FDA approved laser off label. For lasers with a biomedical, clinical or therapeutic focus, contact John Gratzle. For other research use of lasers on campus contact Bryan Ruiz.
Points to Remember:

- The Research Protections Roadmap has been developed based on your responses. It is designed to guide researchers through the process of securing the applicable institutional approval.
- The Lead Researcher is responsible for securing all applicable institutional approvals.
- This Research Protections Roadmap does not represent institutional review and approval.
- Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the University and the entity. Such agreements must be executed in Sponsored Projects Administration prior to the initiation of research.
- For research that involves outside sites, additional approval(s) may be necessary.
- For more information on the Research Protections Committees, visit the Office of Research webpage, Regulatory Compliance.