The University of California, Irvine (UCI) Institutional Review Board (IRB) is responsible for ensuring that all human subjects research conducted by faculty, staff, and students at UCI approved sites or using UCI’s name is conducted in compliance with federal regulations, state and local law as well as UCI IRB policies, procedures, and UCI’s Federalwide Assurance with OHRP, in order to preserve the rights and safety of research subjects, the quality of scholarly work and the integrity of the institution. In an effort to promote accountability and excellence, UCI HRP has developed the Education and Quality Improvement Program (EQUIP).

EQUIP monitors and measures the effectiveness, efficiency and quality of UCI’s human research protection program. The primary purpose of the EQUIP is to provide education, training and post-approval monitoring, to assure that all human research protection operations support UCI’s mandate to protect the rights and welfare of research participants. This includes compliance with institutional policies and procedures, and applicable federal, state and local laws pertaining to the protection of human subjects in research.

EQUIP staff are available to provide educational workshops to undergraduate and graduate courses, and for departmental and academic units. Newsletters are also published quarterly, to ensure the research community are informed on new policies and processes. CITI Training modules are regularly updated to align with regulatory requirements.

EQUIP: Subject complaints and New Information Reports are initially assessed by EQUIP staff, through the appropriate IRB (A, B, C, Team-D) subcommittee. Cases/activities that may potentially meet the definition of an UP, SNC, and/or CNC, are reviewed by the IRB-E Committee.

Federal Award-to-Protocol Congruence
ClinicalTrials.Gov Registration/QA

The Office of Research (OR) is responsible for certifying that research procedures and activities supported by federal agencies and departments are authorized by the applicable regulatory committee/s (e.g., IRB and IACUC). This certification process is done to protect both the institution and the investigator from inadvertently spending award dollars to perform unauthorized research procedures or to perform activities in violation of funding agreements and/or regulatory requirements. Because UCI is subject to unannounced audits by federal regulatory and granting agencies, it is very important that the research supported by federal departments and agencies be approved by the applicable regulatory committee/s.

The HRP-EQUIP Unit also has oversight for the registration process of applicable clinical trials (ACTs), as well as the monitoring (QA) of the registered ACTs that occur at UC Irvine.

Office of Research
141 Innovation Dr, Suite 250
Irvine, CA 92697-7600

Phone: (949) 824-4704
Fax: (949) 824-3400

Web: http://www.research.uci.edu/compliance/human-research-protections/researchers/equip.html
In accordance with its charge, the IRB has procedures for observation of the informed consent process in ongoing research, when appropriate. As part of IRB oversight, the IRB may require an IRB Committee Member and/or EQUIP staff member observe the consenting of research participants to determine whether:

- The informed consent process has been appropriately completed and documented;
- The participant has had sufficient time to consider study participation;
- No coercion has been used by the consenting staff; and
- The information presented to the participant reflects the content of the consent form and is conveyed in understandable language.

Outcomes from these monitoring activities are shared with the HRP staff and the IRB Committee members.

Within the EQUIP program, a Post-Approval Investigator Responsibilities (PAIR) initiative was developed to facilitate regulatory compliance by educating randomly selected investigator-initiated protocols on post-approval responsibilities, either at the beginning of a new study or at the time of continuing submission.

- Investigator-initiated greater than minimal risk studies with less experienced lead researchers will be offered training on record-keeping requirements and regulatory submissions such as modification submissions, adverse event/unanticipated problems submissions, and continuing protocol submissions.
- Investigator-initiated minimal risk studies with less experienced lead researchers will be offered an opportunity to complete a self-evaluation of their record-keeping requirements and post-approval responsibilities at the time of their continuing application submission.

The EQUIP monitors and measures the effectiveness, efficiency and quality of UCI’s human research protection program.

- One component of this program is the ongoing internal quality assurance review of the IRB minutes, both for individual internal reviews of a specific protocol, as well as an entire set of IRB meeting minutes.

- Another component of this program is the ongoing internal quality assurance review of approved consent forms.

Outcomes from these reviews are shared with the HRP staff and the IRB Committee members.