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’s aims are aligned with the UCI Office of Research Strategic Plan, UCI Office of Research Administration Mission Statement, UCI Chancellor’s Strategic Pillars (research, education, service), UCOP Mission Statement, and Huron’s High Performance HRPP Matrix (Organizational Components x Operational Outcomes).
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 protections program. IRB minutes, consent forms, and protocol narratives are reviewed for adherence to the regulatory requirements. Outcomes from these reviews are shared with the HRP staff and the IRB Committee members.

Through EQUIP, HRP staff conduct periodic study monitoring, educational outreach, and other quality improvement activities in an effort to ensure that human subject research activities are conducted in accordance with regulations, laws and institutional policies regarding the protection of human subjects. This process is a requirement of UCI’s Federalwide Assurance.

Periodic study monitoring reviews conducted by EQUIP may focus on both biomedical and social-behavioral research that involves greater than minimal risk, research that includes special and/or vulnerable populations, research that is investigator initiated and sponsored and/or research that involves collection of sensitive personal information; however, all types of research (including exempt and expedited research and research conducted at non-UCI sites) are subject to EQUIP review.

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

The IRB Committee (A, B, C, Team-D, E) may make a determination to perform a for-cause review, as well.