I. Background
   (a) The Federalwide assurance between the Department of Health and Human Services (DHHS) and the University of California Santa Cruz (UCSC) states that investigators conducting study activities involving human subjects, IRB members, and Office or Research Compliance Administration (ORCA) staff have appropriate education and training about human subject protections. This policy describes training requirements for the human research community at UCSC.

II. Applicability
   (a) Human subjects research training is required before engaging in research activities involving human subjects on behalf of UCSC.
   (b) Human subjects research training is required of all UCSC investigators (faculty, staff, and students) who will be engaged in human subjects research or collaborative research for which UCSC has entered into a reliance agreement regardless of whether the UCSC IRB/ORCA staff are reviewing the research or relying on another IRB/institution for review.
   (c) All non-UCSC study team members engaged in research activities involving human subjects reviewed by the UCSC IRB/ORCA staff must complete an appropriate UCSC required CITI Program course. At ORCA’s discretion, such investigators may complete their own institution’s training requirements.
   (d) Modified human subjects research training is required of all faculty advisors who are not engaged in human subjects research but who supervise students engaged in research activities involving human subjects on behalf of UCSC.
   (e) Modified human subjects research training is required of all student interns engaged in research activities involving human subjects on behalf of UCSC.
   (f) Modified human subjects research training is required of all IRB members who review human subjects research studies on behalf of UCSC.
   (g) All required human subjects research training (see below) must be completed before a study is approved and research activities involving human subjects can begin.
   (h) CITI Program courses must be retaken, or an appropriate refresher course completed, every five years to ensure UCSC investigators maintain knowledge of ethical considerations and current regulations regarding human research protections.

III. Available Training
   (a) Social, Behavioral, and Economic Research Human Subjects Training:
      (1) For most study investigators involved in social, behavioral and Economic Research (SBER) studies, ORCA requires completion of the online Collaborative Institutional Training Initiative (CITI) Program course Group 1: Human Subjects Researchers-Social, Behavioral, and Economic (ID: 96465).
(2) Human subjects research modules taken in CITI for another institution may be used to fulfill this requirement via an affiliation with UCSC in CITI.

(3) Other human subjects research courses taken in CITI may be used to fulfill this requirement at ORCA’s discretion.

(b) Biomedical Research Human Subjects Training:

(1) For most study investigators involved in research studies involving biomedical procedures, ORCA requires completion of the online CITI Program course, Group 2: Human Subjects Researchers – Biomedical (ID: 96466).

(2) Other CITI Program human subjects research courses with a biomedical emphasis may be used to fulfill this requirement at ORCA’s discretion.

(c) Non-engaged Faculty Advisor Training:

(1) For all faculty advisors who are not engaged in human subjects research, but supervise UCSC students who are engaged in human subjects research on behalf of UCSC, ORCA requires completion of the online CITI course Group 3: Faculty Advisors Not Engaged in Human Subjects Research Activities (ID: 207497).

(2) Other CITI Program human subjects research courses may be used to fulfill this requirement at ORCA’s discretion.

(d) Student Intern Training:

(1) For all student-interns engaged in human subjects research activities on a UCSC study, ORCA requires completion of the online CITI Program course, Students in Research (ID: 1321).

(2) ORCA defines “student intern” as a non-UCSC student performing a supervised research internship offered by an organization (not only UCSC) for a limited period of time. For example, the UCSC Science Internship Program (SIP) or a non-UCSC undergraduate or graduate visiting for a short, defined period to work on an already established research study.

(3) Other CITI Program human subjects research courses may be used to fulfill this requirement at ORCA’s discretion.

(e) Human Subjects Research Ethics Training Equivalency Letter:

(1) For foreign engaged investigators for whom CITI training is not available in their language, but their institution has its own training.

(f) Local Community Research Assistant Field Training Pamphlet:

(1) For foreign engaged investigators for whom CITI training is not available in their language, and they are not affiliated with an institution that has its own training.

(g) Research Activity Specific Training:

(1) Additional training is required for all study investigators conducting specific types of human subjects research activity. This training is required in addition to the Group 1 or Group 2 training requirements noted above.

(i) For all study investigators accessing or receiving Protected Health Information (PHI) from a HIPAA covered entity, ORCA requires completion of the online CITI Program HIPAA course Health Privacy
Issues for Researchers (ID: 215959). Other CITI Program human subjects research courses related to HIPAA may be used to fulfill this requirement at ORCA’s discretion.

(ii) For all study investigators involved in research related to subjects’ illegal activities or undocumented status, ORCA requires completion of the online CITI Program course Illegal Activities or Undocumented Status in Human Research (ID: 16656).

(iii) For all study investigators conducting international research, ORCA requires completion of the online CITI Program course International Research - SBE (ID: 509).

(iv) For all study investigators involved in internet-based research, ORCA requires completion of the online CITI Program course Internet-Based Research - SBE (ID: 510).

(v) For all study investigators involved in research with decisionally impaired subjects, ORCA requires completion of the online CITI Program course Research with Decisionally Impaired Subjects (ID: 16610).

(vi) For all study investigators involved in research in which pregnant women, fetuses, or neonates are subjects or in which placental or fetal materials are involved, ORCA requires completion of the online CITI Program course Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)

(vii) For all study investigators involved in research in which prisoners are subjects, ORCA requires completion of the online CITI Program course Research with Prisoners - SBE (ID: 506) or Research Involving Prisoners (ID: 8).

(viii) For all study investigators who will handle, as part of study activities, subject education records where FERPA applies ORCA requires completion of the online CITI Program course Research involving Family Educational Rights and Privacy Act (FERPA) which includes the following modules:

(A) FERPA: An Introduction (ID: 17407),
(B) FERPA for Researchers (ID: 17410), and
(C) Research in Public Elementary and Secondary Schools - SBE (ID: 508).

(ix) For all study investigators involved in research with pregnant women, fetuses, or neonates ORCA requires completion of the online CITI Program course Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10).

(x) For all study investigators involved in research with child subjects, ORCA requires completion of the online CITI Program course Research with Children - SBE (ID: 507) or Research Involving Children
Good Clinical Practices Training: For any investigators conducting a NIH-sponsored clinical trial or FDA-regulated clinical trial, ORCA requires completion of one of the following online CITI Program Good Clinical Practices courses corresponding to the type of research being conducted (contact ORCA for assistance in determining the appropriate course to take):

(B) Good Clinical Practice Course (US FDA focus) (ID: 75054).
(C) GCP Course for Clinical Trials Involving Investigational Medical Devices (international focus) (ID: 75053).
(D) GCP Course for Clinical Trials Involving Investigational Drugs (international / ICH focus) (ID: 75052).

For any investigators who conduct, review, approve, oversee, support, or manage Department of Defense (DoD) human subject research activities, ORCA also requires that the DoD requirements for research ethics training are met. The requirements are outlined in the UCSC IRB Policy on Studies Involving the DoD.

The UCSC Human Research Protections Program (HRPP) website is a great resource to investigators, providing guidance and information on policies and regulations related to human subjects research activities.

ORCA provides relevant human research news on the HRPP website, via bulk email announcements and in the Office of Research newsletter.

IV. ORCA Staff
(a) ORCA staff involved in the HRPP must complete the online CITI Program course, Group 1: Human Subjects Researchers-Social, Behavioral, and Economic (ID: 96465).

V. IRB Members
(a) All UCSC IRB members must complete the online CITI Program course IRB Members (ID: 9945).
(b) ORCA provides members with periodic educational emails and updates at meetings.
(c) The UCSC Human Research Protections Program (HRPP) website can be utilized by members to help in their role, providing guidance and information on policies and regulations related to human subjects research activities.
(d) Potential new members shall observe a convened committee meeting as a guest before proceeding with an appointment to ensure they have a clear understanding of the role of an IRB member.
(e) New members attend an orientation with the ORCA Director, or ORCA staff member designee, and the IRB Chair describing ethical principles, human subjects regulations,
the Belmont Report, IRB functions, IRB actions, review of research, levels of review, and informed consent requirements and waivers.

(f) New members receive reviewer checklists and links to the applicable federal regulations in 45 CFR 46, the Belmont Report, and UCSC IRB policies.

(g) New members shall observe an additional convened committee meeting before being assigned as a reviewer.

(h) New members are typically assigned to perform “co-reviews” of 3-5 studies along with an experienced IRB member over the first 6 months of their appointment in order to gain familiarity with the review process.

VI. References

(a) UC Irvine Policies Education and Training of Lead Researchers and Research Personnel, and IRB Members