Policy on Human Research Training and Education

Effective date: 9/20/2019

I. Background
The Federalwide assurance between the Department of Health and Human Services and UC Santa Cruz states that research investigators, IRB members, and ORCA staff have appropriate education and training about human subject protections. This policy describes training requirements for the human research community at UCSC.

II. Research Faculty, Staff, and Students Engaged in Human Subjects Research
a. Social-Behavioral-Economic (SBE) Human Subjects Training:
   1. Applicability: Human subjects training is required of the following individuals before engaging in human subjects research on behalf of UCSC:
      a. Non-tenure track faculty
      b. Staff
      c. Students
      d. All research personnel on research funded by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html)
      e. All UCSC researchers who will be engaged in human subjects research on collaborative projects for which UCSC has entered into a reliance agreement, regardless of whether the UCSC IRB is reviewing or relying.
      f. Non-UCSC personnel engaged in research reviewed by UCSC IRB must either complete their institutional training requirements, or complete the UCSC required course.

b. Required Course: For most social-behavioral studies, the Office of Research Compliance and Administration (ORCA) will accept training taken online either through the Collaborative Institutional Training Initiative (CITI) program or through NIH. The CITI course accepted by ORCA is “Group 1: Human Subjects Researchers-Social, Behavioral, and Economic.” Human subjects research courses taken in CITI under a different name may be accepted at ORCA’s discretion.

b. Biomedical Human Subjects Training: For studies involving biomedical procedures, ORCA requires CITI course, “Group 2: Human subjects researchers-biomedical.” Human subjects research courses with a biomedical
emphasis taken in CITI under a different name may be accepted at ORCA’s discretion.

c. HIPAA Training: Any UCSC researchers accessing or receiving Protected Health Information from a HIPAA covered entity must complete the UC San Diego Human Subjects Protection Program Online Tutorial Assessment on Research Aspects of HIPAA

d. Clinical Practices Training: Any researchers (including tenure-track faculty) conducting a NIH-sponsored clinical trial (study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes) must complete the online CITI “Good Clinical Practices” course corresponding to the type of research being conducted. Contact ORCA for the appropriate course. This training is required in addition to the SBE or biomedical human subjects training requirement, as applicable.

e. DOD Training: Any personnel who conduct, review, approve, oversee, support, or manage Department of Defense (DoD) human participant research must also meet DoD requirements for research ethics training as outlined in the UCSC DOD policy.

f. All relevant courses must be completed before the study can be approved and human research activities begin.

g. The UCSC IRB website also has policy and guidance on human subjects research and is a great resource to investigators.

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

III. ORCA Staff

ORCA human research staff must complete the online CITI course, “Group 1: Human Subjects Researchers-Social, Behavioral, and Economic.”

IV. IRB Members

a. All IRB members must complete the online course, “IRB Members”

b. New members attend an orientation with the ORCA Director and the IRB Chair describing ethical principles, human subjects regulations, the Belmont Report, IRB functions, IRB actions, review of research, levels of review, informed consent requirements and waivers.

c. New members shall observe a full committee meeting before being assigned as a reviewer.

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

e. ORCA provides educational emails and updates at meetings to members periodically.
f. The UCSC IRB website has policy and guidance on human subjects research and can be utilized by members to help in their role.

V. References
   a. UC Irvine Policies Education and Training of Lead Researchers and Research Personnel, and IRB Members