Institutional Review Board

Policy on Human Subjects Research

Effective Date: 9/20/2019

I. Background
As an institution that receives federal funding, UCSC personnel engaged in human subjects research must submit their activities for UC Santa Cruz IRB review or exemption and receive IRB approval or exempt determination before initiating human research activities. This policy outlines what activities fall under human subjects research review.

II. Definitions
Some HHS Common Rule definitions have been paraphrased below. Wherever the following definitions differ from the HHS definition, the HHS definition shall prevail.

a. Human Subject (HHS): a living individual about whom an investigator (whether professional or student) conducting research:
(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

b. Identifiable private information: private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

c. Identifiable biospecimen: a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

d. Intervention (HHS): Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

e. Private Information (HHS): Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

f. Research (HHS): A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under
a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

III. Determining Whether UCSC is Engaged in Human Subjects Research
The UC Santa Cruz Human Research Protection Program is responsible for ensuring IRB oversight (whether by conducting its own IRB review or by formally relying on another IRB’s review) of activities that constitute “research” and involve “human subjects” according to the HHS definition (see above definitions); when one of the following is also true:
   a. UCSC faculty, staff, and/or students interact or intervene with human subjects or analyze identifiable private data for research purposes, including but not limited to recruiting, consenting, conducting study procedures, and analyzing identifiable data;
   b. UCSC is the prime awardee of a grant supporting the research from 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).

IV. Human Subjects Research Review
When UCSC is engaged in human subjects research, UCSC must either conduct its own IRB review, formally rely on another IRB’s review, or ensure adequate review by a commercial IRB.
   a. If the study is FDA-regulated (e.g., investigational drug, biologic, device, etc.), the research must be reviewed by a commercial IRB or, in the case of multi-site research, by a collaborator’s IRB (see Policy on IRB Reliance).
   b. If the study appears (to the researcher) to be eligible for exemption and the UCSC IRB is reviewing, the Principal Investigator (PI) will apply using an Exemption Request form. ORCA will verify whether exemption criteria are met and either proceed with exempt review or recommend non-exempt review. Exempt research must uphold the ethical principles of the Belmont Report. (See Policy on Exempt Review)
   c. If the study does not appear to be eligible for exemption and the UCSC IRB is reviewing, the PI will apply using a Full Protocol Application. ORCA will confirm that the research is not eligible for exemption and forward to an experienced IRB reviewer designated by the Chair or to the full board, as appropriate. Non-exempt research must satisfy the criteria for IRB approval outlined in 45 CFR 46, or else the applicable UCSC criteria under the UCSC Policy on Regulatory Flexibility.
   a. UCSC may rely on another IRB’s review if reliance criteria are met and both institutions formally agree (see Policy on IRB Reliance).
V. Researcher Responsibilities
Activity that does not meet the definition of human subjects research does not require UCSC IRB review and PIs may independently make this determination. PIs are encouraged to contact ORCA with questions or to obtain an official determination of “not human subjects research.” ORCA bases such determinations on a description of the research provided by the PI by email.

Researchers may not begin human subjects research activities until they receive IRB approval or an exempt determination.

VI. References
a. 45 CFR 46.102, OHRP Engagement Guidance 2008