



## Policy on Human Subjects Research

Effective Date: 08/23/2018

### 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

- a. *Clinical investigation (FDA): Any experiment that involves a test article (drug, device, biologic) and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.*
- b. *Engagement: Personnel 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.*
- c. *Human Subject (DHHS): A living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.*
- d. *Human Subject (FDA): An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.*
- e. *Intervention (DHHS): 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.*
- f. *Private Information (DHHS): 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). Private information must be individually identifiable (i.e., the*



*identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.*

- g. Research (DHHS): 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.*
- h. Test Article (FDA): Any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354-360F of the Public Health Service Act.*

### **III. Determining Whether Activity is Human Subjects Research under UCSC Jurisdiction**

The UC Santa Cruz Human Research Protection Program reviews human subjects research activities when:

- a. The activities meet either the DHHS or FDA definitions of 'human subjects' and 'research' or 'clinical investigation', respectively (see above definitions);
- b. UCSC faculty, staff, and/or students are 'engaged' (see above definition) in the research;
- c. The activities are conducted at a UCSC research site;
- d. The activities are covered under a prime sponsored award to UCSC.

### **IV. Human Subjects Research Review**

When an activity is human subjects research involving UCSC, review is required. If the study falls under one or more exempt categories, the Principal Investigator (PI) will submit an Exempt application. If the study does not meet exempt criteria, one of the following will occur:

- a. PI will request that another institution be the IRB of record for the study if collaborating (if study meets the criteria from the IRB Reliance policy, and both institutions are in agreement and sign an Institutional Authorization Agreement); or
- b. PI will submit a Non-Exempt application and the IRB expedited reviewer will determine whether it receives expedited (if qualifying) or full board review.

### **V. Researcher Responsibilities**



If the Principal Investigator determines that the study does not meet the definitions of human subjects research or clinical investigation, no submission is required; however, they may contact the Office of Research Compliance Administration for confirmation. If an official determination of “not human subjects research is needed,” a description of activities will need to be emailed to ORCA.

Researchers may not begin human subjects research activities until exempt determination or IRB approval is received.

**VI. References**

- a. 45 CFR 46.102, OHRP Engagement Guidance 2008
- b. 21 CFR 56.102