



## **Policy on IRB Membership**

Effective date: 03-27-2018

### **I. Background**

The Institutional Review Board at UC Santa Cruz is charged with protecting the rights and welfare of human subjects participating in UCSC research. The IRB must have diverse backgrounds and disciplines in order to represent the general UCSC human research population. The IRB also uses alternate members with comparative background of the voting member to stand in for an absent voting member. The IRB reviews all non-exempt human subjects research.

### **II. Definitions**

a. *Affiliated member*: An IRB member who is a currently or within the past 2 years employed at UCSC, including visiting and emeritus faculty, serving on a governing board, students, volunteers, or has immediate family in one of these roles.

### **III. Composition of the IRB**

- a. The IRB is required to have at least 5 members, including a scientist, a non-scientist, a non-affiliate (member is not affiliated with UCSC nor is their immediate family), and a physician for FDA regulated research.
- b. The IRB must have diverse backgrounds, disciplines, experiences, and community attitudes necessary to evaluate human subjects research for the UCSC community.
- c. The members will be knowledgeable about federal and state regulations, guidance, and institutional policy relating to human subjects research.
- d. Research involving prisoners must be reviewed by a prisoner representative member or consultant to the IRB.
- e. Consultants may be requested to help provide expertise for specialized procedures, populations, etc. on IRB member request.
- f. Office of Research Compliance Administration provides administrative support to members.
- g. Research requiring review of a convened meeting must have a quorum present (half plus one of voting members, with at least one non-scientist member present).
- h. A physician must review any FDA regulated research.
- i. Alternates may vote in place of their voting member counterparts only when the voting member is not voting.
- j. Meetings may be convened in person, by videoconference, or audioconference.



#### **IV. Roles and Responsibilities of Members**

- a.** *Chair/Vice Chair* The Chair or Vice Chair is appointed by the Institutional Official, the Vice Chancellor of Research. They are selected based on their previous experience on the board and their expertise and commitment to the IRB. The Chair provides leadership, facilitates meetings, approves minutes, conducts expedited review, assigns other expedited reviewers, manages conflicts of interest at meetings, helps facilitate review and approval of policies and procedures, consults with investigators, and helps with review of unanticipated events and noncompliance. The Vice Chair learns the Chair roles and fills in when necessary and also reviews expedited studies. The Chair and Vice Chair will be knowledgeable about federal and state regulations, guidance, and institutional policy relating to human subjects research.
- b.** *IRB Member:* Members are appointed by the Institutional Official, the Vice Chancellor of Research. They must regularly attend and participate at meetings for review of research, policies, and procedures. They attend initial orientation and take online human research training. They must recuse themselves of any conflicts of interest following the IRB Conflict of Interest policy. The members will be knowledgeable about federal and state regulations, guidance, and institutional policy relating to human subjects research.

#### **V. References**

21 CFR 56.107, 21 CFR 56.108, 21 CFR 56.115, 45 CFR 46.103, 45 CFR 46.107, 45 CFR 46.108