Policy on IRB Membership

Effective date: 9/20/2019

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. It does so by reviewing all non-exempt human subjects research and exempt research requiring limited IRB review. IRB members, including alternate members, must be from diverse backgrounds and disciplines in order to represent the general UCSC human research population.

II. **Definitions**

a. **Affiliated member:** An IRB member who is (or has an immediate family member who is) currently, or was within the past 2 years, an employee of UCSC, including visiting and emeritus faculty, a member of a UCSC governing board, a UCSC student, or a UCSC volunteer.

b. **Non-scientist member:** An IRB member whose primary concerns are not in scientific areas and who are not human subjects research investigators.

c. **Alternate member:** An individual designated to stand in for a regular voting member when the voting member is not able to fulfill their duties due, for example, to absence or recusal. Alternates may also conduct expedited review if designated by the Chair.

III. **Composition of the IRB**

a. The IRB is required to have at least 5 members, including a scientist, a non-scientist, and a non-affiliate.

b. The IRB membership must reflect diverse backgrounds, disciplines, experiences, and attitudes. Both genders must be represented per federal regulations.

c. The members must 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. Subject matter experts may be consulted at the request of any IRB member to provide their expertise on specialized procedures, populations, etc.

f. **Office of Research Compliance Administration provides administrative support to members.**

g. A quorum must be present in order to discuss or vote on any research protocol requiring full board review. A quorum consists of one half of the total number of regular voting members plus one, with at least one non-scientist member present.
h. Alternates are appointed to stand in for specific regular members and may only vote in place of a regular member when the regular member is not voting.

i. 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 reviews expedited studies, learns the Chair’s roles, and fills in when necessary. The Chair and Vice Chair must be knowledgeable about federal and state regulations, guidance, and institutional policy relating to human subjects research. The length of service is open-ended, renewed yearly.

b. IRB Member: Members are appointed by the Institutional Official, the Vice Chancellor of Research. Scientists are selected based on their human subjects research expertise, with an effort to recruit members from those departments that submit the most IRB applications. They must regularly attend and participate at meetings for review of research, policies, and procedures. They must attend initial orientation and take online human research training. They must recuse themselves from participating in the discussion or vote related to any studies with which they have any conflicts of interest as per the IRB Member Conflict of Interest policy. The members must be knowledgeable about federal and state regulations, guidance, and institutional policy relating to human subjects research. The length of service is open-ended, renewed yearly.

c. The Institutional Official may remove a member who is not regularly engaged (not responding to requests for expedited review or providing feedback on full board agenda items, either not at all or not in a timely manner), who does not support UCSC policies as a whole (critical feedback on specific policies is encouraged), or who is chronically absent.

V. References

a. 45 CFR 46.103, 45 CFR 46.107

b. 45 CFR 46.108