Policy on IRB Member Conflict of Interest

Effective date: 3/27/2018

I. Background
In the environment of research, openness and honesty are indicators of integrity and responsibility that promote quality research and strengthen the research process. Therefore, conflicts of interest should be eliminated when possible and effectively managed and disclosed when they cannot be eliminated.

II. Conflict of Interest (COI) for IRB Members
An IRB member is said to have a conflicting interest whenever that IRB member, or his/her spouse, domestic partner or first degree relative (e.g. child, sibling, or parent):

- is an investigator or key personnel on the protocol under consideration;
- acts as an officer or a director of the sponsor or an agent of the sponsor;
- is involved in the research as a coordinator, protocol consultant and/or primary advisor;
- has received any of the following from an entity whose financial interests would reasonably appear to be affected by the outcome of the research:
  - non-university salary or other payments for services (e.g., consulting fees or honoraria) exceeding $10,000 over a 12-month period;
  - equity interests (e.g., stocks, stock options or other ownership interests) exceeding $10,000 or 5% of the equity of the entity; or
  - intellectual property rights (e.g., patents, copyrights, royalties from such rights); or
  - has a management position (e.g., director, officer, partner, or trustee) with the interested entity.
- has identified him/her self for any other reason as having a conflicting interest (e.g., having a close personal or professional association with the submitting investigator, serving as co-investigator and/or the primary mentor for a student or post doc investigator).

III. Disclosure and Documentation of Financial Interest and COI
It is the responsibility of each member of the IRB to disclose any COI in a study submitted to the IRB and recuse him/herself from the review of that protocol. No member may participate in the discussion for initial or continuing review of any research project in which the member has a conflict of interest, except to provide information or answer questions from the IRB as requested. Members with a COI for a protocol may not be present during IRB voting on that protocol.

IV. Process Overview
   a. The IRB Chair is responsible for identifying COI disclosures at IRB meetings before each protocol review and discussion. The Director serves as the liaison between UCSC’s COI Committee Chair and/or COI Coordinator and the IRB.
   b. IRB members will recuse themselves from voting where a COI exists or may appear to exist. They may be present for the discussion to answer questions if the IRB determines that they may have information that is beneficial to the deliberations.
   c. The ORCA staff documents COI and recusal in IRB meeting minutes. The IRB Chair and ORCA staff ensure that IRB members with a COI do not participate in the IRB voting subject to their COI disclosure.

V. References
45 CFR 46.107