Policy on IRB Member Conflict of Interest

Effective date: 9/20/2019

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 for IRB Members
An IRB member is said to have a conflict of interest (COI) whenever that IRB member, or his/her spouse, domestic partner or first degree relative (e.g. child, sibling, or parent) is or acts as a/an:
- investigator or key personnel on the protocol under consideration;
- officer or a director of the sponsor or an agent of the sponsor;
- coordinator, protocol consultant and/or primary advisor to the research; or
- has or has received any of the following with respect to 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) over the last 12 months;
  - Positions of management (e.g., board member, scientific advisor, director, officer, partner, trustee, employee, consultant)
  - Equity interest (e.g., stock, stock options, investment, or other ownership)
  - Rights to a pending patent application or issued patent to any invention(s), or license rights or copyright for software that has a direct relationship to the project proposed.

An IRB member may also identify themselves as having a COI for any reason (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 themselves 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 who disclose a COI with a given protocol may not be present during IRB voting on that protocol.
IV. Process Overview
   a. IRB members are reminded at each IRB meeting to disclose relevant COIs prior to review and vote on the corresponding protocol.
   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. ORCA staff documents disclosed COIs and recusals in the IRB meeting minutes. The IRB Chair and ORCA staff ensure that IRB members with a COI do not participate in IRB voting on protocols with which they have a COI.

V. References
   a. 45 CFR 46.107
   b. 21 CFR 56.107
   c. OHRP's "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection"