Policy on IRB Use of Consultants

Effective date: 9/20/2019

I. Background
The UC Santa Cruz Institutional Review Board (IRB) must determine that criteria for IRB approval from 45 CFR 46 are met in order to approve non-exempt human subjects research. At times, IRB reviewers may not have the appropriate background and/or expertise to accomplish this. In these cases, reviewers may request a consultant according to this policy.

II. Definitions
a. Consultant: A person with sufficient background and expertise (e.g., education, training, occupation, research, etc.) in a given area to review proposed human research for appropriate subject protections on behalf of the IRB. This person serves on an ad hoc basis and may or may not be UCSC personnel.

III. Process
a. When the IRB lacks sufficient knowledge of a given research context in order to provide adequate review, any member of the IRB may request that ORCA invite a consultant with appropriate expertise to review the study.
b. ORCA will work with the IRB Chair and other IRB members, if appropriate, to select a qualified consultant based on their education, training, occupation, and/or research focus.
c. ORCA or the IRB Chair will reach out to the selected person and request consultation for IRB review on an unpaid basis. The consultant cannot have a conflict of interest with the research project.
d. The consultant will review the protocol application and provide any written comments back to the IRB. ORCA will provide the consultant with the expedited reviewer checklist as a guide. When eligible, the protocol will also be assigned to an IRB expedited reviewer per the Policy on Initial IRB Review. If the study requires full board review, the IRB may invite the consultant to attend via video or in person (the consultant is not required to attend the meeting in person). The consultant does not vote.

IV. References
a. 45 CFR 46