Policy on Subject Rights and Concerns

Effective date: 9/20/2019

I. **Background**
The Office of Human Research Protections (ORCA) requires as part of the informed consent process that subjects must be given an explanation of whom to contact for answers to questions about subjects’ rights. This policy outlines the process for handling incoming questions, concerns and complaints related to subjects’ rights on a human subjects research protocol carried out by a UCSC affiliate.

II. **Process**
The ORCA general phone number and email address are required on all informed consent documents. Anyone may contact ORCA with a human subjects research question, concern or complaint. The person answering the inquiry will take down the name and contact information and general question/concern/complaint. Except in the case of straightforward procedural or other questions, this information will be forwarded to the ORCA Director or designee for evaluation and to follow up with person as necessary for more details. The level of investigation required is dependent on the potential risk to subjects or others.

ORCA will forward the question/concern/complaint, dependent on evaluation outcome, to the Chair or designee for review of next steps, and the Chair may make any alterations to the plan. If warranted, the concern may be forwarded to the convened IRB for recommendations. ORCA shall keep identities confidential. The investigation response to complainant should occur in a timely manner. ORCA will retain a record of the concern or complaint and outcome.

III. **References**
a. 45 CFR 46.116
b. UC Irvine policy and procedure for Concerns and Complaints Regarding Human Subjects Research