Institutional Review Board

Policy on Investigator Responsibilities

Effective date: 9/20/2019

I. Background
UCSC Investigators are expected to conduct human subjects research in an ethical manner adhering to federal regulations, institutional policy, and the approved protocol. This policy outlines the responsibilities of investigators engaged in human subjects research.

II. Definitions
a. Investigator: an individual engaged in conducting human subjects research or with intentions to conduct human subjects research as defined in 45 CFR 46 (see Policy on Human Subjects Research), including obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB about an IRB proposal.

b. Principal Investigator (PI): an individual who has primary responsibility for the design, execution, and management of a research project and who will be sufficiently involved in the project to oversee the protection of human subjects and compliance with applicable human subjects policies and standards. The PI must be eligible to serve in such capacity by UCSC position (see ETP Determination Chart by Appointment Type matrix), or request exception to PI policy (see ETP Form).

III. General Requirements for Investigators
a. Investigators must be trained (e.g., by education, profession, PI, etc.) for their respective human research activities, and also trained in the protection of human subjects in research according to UCSC Training Requirements.

b. Investigators must not begin any human research activity (including recruitment and accessing identifiable private information) until such activity has been reviewed and approved or determined exempt by the UCSC IRB or Office of Research Compliance Administration (ORCA).

c. Investigators must ensure Confidentiality of Electronic Research Data and store non-electronic research data in a secure manner approved by the IRB.

d. Investigators must follow the approved or exempt protocol as written and obtain IRB approval for all changes by way of an amendment request prior to being implemented (except to correct typographical errors or when necessary to eliminate apparent immediate hazards to the human subjects).

e. Investigators must obtain and document informed consent of subjects or their legally authorized representatives before their participation for non exempt research unless the IRB has approved a waiver or alteration of consent requirements. ORCA’s expectation for obtaining informed consent on exempt
studies is outlined in the Policy on Exempt Review; consent materials are not reviewed at exempt level.

f. Investigators must disclose any financial conflicts of interest with the human research activities with the application (see IRB Financial Interest Disclosure form).

IV. Additional Requirements for Principal Investigators
a. A PI must have appropriate expertise and training to oversee human research protocols. The PI must be eligible to serve in such capacity by UCSC position (see ETP Determination Chart by Appointment Type matrix), or request exception to PI policy (see ETP Form).

b. Only 1 individual may serve as the PI. When more than one individual shares responsibility for a study, one individual must be selected to serve as PI and the others may be listed as co-investigators (Co-Is). Note that the designation of PI for IRB purposes does not affect scholarly credit for the work.

c. The PI must ensure there are adequate resources to carry out the study as approved.

d. PIs accept ultimate responsibility on behalf of all personnel on the protocol for adherence to federal and state regulations and UCSC policies regarding the rights and welfare of human participants, and the protection of human participants in this study.

e. PIs must ensure the research team has sufficient expertise and training to conduct human research activities.

f. For studies involving greater than minimal risk, the PI must monitor research data to ensure subject safety and describe their plan for doing so in the application.

g. PIs are responsible for the content of continuing review applications and ensuring that they are submitted well in advance of protocol expiration; if the research is not approved to continue beyond its expiration date, all human research activities must stop (see Policy on Continuing Review).

h. PIs have ultimate responsibility to ensure all personnel follow the approved or exempt protocol as written and obtain IRB approval for all changes by way of an amendment request prior to being implemented (except to correct typographical errors or when necessary to eliminate apparent immediate hazards to the human subjects).

i. PIs must promptly report any unanticipated problems involving risks to subjects or others.

j. PIs must promptly report any serious or continuing non-compliance with the regulations or the IRB approved protocol.

k. If the PI leaves UCSC, the PI must amend the study to add another eligible PI to take over oversight of the study, or close out the study.
I. PIs are responsible for keeping administrative records and study data, including approved IRB documents, signed consent forms, data collection documents, etc., for a minimum of three years after close of the study (see Policy on Records Retention). Note that identifiers may be removed from the data. In some cases, records may need to be retained for longer than three years – e.g., records pertaining to Protected Health Information under the HIPAA Privacy Rule (must be retained 6 years) or records subject to sponsor-specific contract requirements.

V. UCSC IRB Post Approval Monitoring
The IRB reserves the right to monitor studies to ensure adherence to regulations, policies, and the approved human research protocol. This may be for-cause based on non-compliance, or the IRB may choose to conduct random not-for-cause audits.

VI. References
a. 45 CFR 46.111
b. DHHS Investigator Responsibilities FAQs