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 performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB.

b. **Principal Investigator (PI):** an individual who has primary responsibility for the design, execution, and management of a research project and who will be involved in the project in a significant manner. 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 exempted by the UCSC Institutional Review Board or Office of Research Compliance Administration (ORCA).

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

d. Investigators must follow the approved or exempted protocol as written and may not make changes without submitting and getting approval beforehand (except 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 waived the requirements. ORCA expects some informed consent process for exempt prospective studies but materials are not reviewed.
f. Investigators must disclose any financial conflicts of interest with the human research activities in the application.

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. A study may only have one PI. The PI must ensure there are adequate resources to carry out the study as approved.

c. PIs accept ultimate responsibility for all personnel on the protocol to adhere 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.

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

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

f. PIs must ensure the research team submits continuing review applications that the PI has read and signed off on. Materials must be sent ahead of protocol expiration in time to get approval before expiration; otherwise all human research activities must stop.

g. PIs have ultimate responsibility to ensure all personnel follow the approved or exempted protocol as written and may not make changes without submitting and getting approval beforehand (except when necessary to eliminate apparent immediate hazards to the human subjects).

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

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

j. 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.

k. PIs are responsible for keeping research records (e.g., approved IRB documents, signed consent forms, data collection documents, etc.) for a minimum of three years after close of the study. Note that identifiers may be removed from the data. Longer retention periods may be required, such as records pertaining to Protected Health Information under the HIPAA Privacy Rule (6 years), FDA regulated studies (2 years after FDA approval, or if not approved 2 years after the study is closed and FDA is notified), or based on sponsor contract requirements.
V. UCSC IRB Post Approval Monitoring
   a. The IRB reserves the right to monitor studies to assure 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
    45 CFR 46.111, HHS Investigator Responsibilities FAQs