Policy on Study Suspension or Termination  
Date of Last Revision: 9/20/2019; 4/7/2021

I. Background
   (a) UC Santa Cruz has a Federalwide Assurance with the Office for Human Research Protections (OHRP) within the Department of Health and Human Services to comply with and enforce human subjects research regulations and policies. OHRP requires all research funded by any Common Rule department or agency to report IRB suspensions and terminations to the funding agency. To find funding agencies to which the regulations apply see Common Rule Departments and Agencies and HHS Agencies & Offices.
   (b) These problems must also be reported to the Institutional Review Board (IRB) and the Institutional Official (IO) per this policy.
   (c) The IRB/IO is charged with determining whether any suspension or termination of human subjects research is necessary (e.g., due to serious non-compliance, unanticipated problems involving risks to subjects or others, etc.).

II. Definitions
   (a) Suspension: Some or all human subjects research activities are halted for a limited period of time.
   (b) Termination: All human subjects research activities are halted permanently.

III. Procedures for determination of suspension or termination
   (a) Either the IRB at a convened meeting, the PI, or the IO may suspend or terminate some or all human subject research activities on a study.
   (b) Reasons for suspension or termination include unanticipated problems involving risks to subjects or others, serious noncompliance, or other reasons determined by the convened IRB or IO.
   (c) Relevant information related to the possible suspension or termination will be provided to the IRB/IO.
   (d) The IRB/IO must determine if a suspension or termination is warranted, the length of suspension if applicable, and whether the PI must notify currently enrolled subjects of the action. In making this determination, the IRB/IO will consider the effect of the action on current subjects.
   (e) The IRB may vote to require corrective actions by the PI.
   (f) The PI will be notified in writing of the suspension or termination, the reason for the action, and any corrective actions required by the IRB.
   (g) The determination and required actions will be documented in the notice to the PI, and in the IRB meeting minutes if applicable.
IV. Reporting
(a) A notice of suspension/termination will be created stating the action and reason for the action, along with the study title, study number, PI name, and any corrective action or continued monitoring plans required of the PI.
(b) This notice will be delivered by the ORCA Director, or their designee, within 30 days of the determination to suspend or terminate to the:
   (1) IRB,
   (2) Principal Investigator (PI),
   (3) IO,
   (4) PI’s Department Chair,
   (5) sponsor, if applicable,
   (6) OHRP, if the research is funded by any Common Rule department or agency,
   (7) other federal agencies, if required, and
   (8) other officials as necessary (UCSC Office of Sponsored Projects, etc.).

V. Researcher Expectations
(a) Upon receipt of the IRB’s notice of suspension or termination, the PI must halt some or all human subjects research activities, as directed in the notice and promptly confirm that all human subjects research activities have ceased, as directed in the notice of suspension/termination.
(b) If a corrective action plan is required, the PI should submit a Cayuse Human Ethics Modification Submission to address how study investigators will comply with the IRB’s requirements and report back once all required actions have been completed, if so directed, in the notice. This may include notification to current subjects of the suspension/termination as required by the IRB/IO and outlined in the notice of suspension/termination.
(c) If the study is terminated, the PI must submit a plan for the withdrawal of current subjects in such a way that protects subject rights and wellbeing. The PI may propose to transfer a study to a different eligible PI.

VI. Lifting Suspension
(a) A suspension may be lifted once the IRB determines at a convened meeting that all relevant concerns have been addressed (e.g., potential harms to subjects alleviated, noncompliance issues resolved, etc.).

VII. References
(a) 21 CFR 56.108
(b) 21 CFR 56.113
(c) 45 CFR 46.103
(d) 45 CFR 46.113
(e) OHRP “Guidance on Reporting Incidents to OHRP” (06/20/11)
(f) UC Irvine policy Hold, Suspension, and Termination of IRB Approval