UNIVERSITY OF CALIFORNIA
SANTA CRUZ
Institutional Review Board

Policy on IRB Suspension and Termination

Effective date: 04-26-2018

I. Background

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 research regulations and policies. OHRP requires all PHS funded research to report IRB suspensions and terminations to the funding agency. These problems must also be reported to the Institutional Review Board and the Institutional Official per this policy. The IRB 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 on a study are halted for a limited period of time.
b. Termination: All human subjects research activities on a study are halted permanently.

III. Determination of suspension or termination

Either the IRB at a convened meeting, the PI, or the Institutional Official (if an urgent situation presents itself) may suspend or terminate some or all human research activities on a study if potential/actual harm is present due to unanticipated problems involving risks to subjects or others or serious noncompliance.

IV. Procedures

Materials supporting consideration for a suspension or termination will be given to the IRB for review at a convened meeting (or if urgent, the IO may review for a suspension). The IRB/IO must determine if a suspension or termination is warranted and the length of time for a suspension if applicable. During review, corrective actions may be voted on to send to the PI. The PI will receive any corrective actions and a notice of suspension or termination along with reason(s). The PI must stop all noted activities as the notice outlines. The PI must respond promptly to the IRB notice.

A convened IRB may revoke the suspension based on determination of a complete response to corrective actions to alleviate the issue(s).

V. Reporting

A suspension/termination letter will be created stating the action and reason for the suspension/termination, along with title, protocol number, and Principal Investigator, and any corrective action plans or plans for continued monitoring. This letter will promptly be delivered to the:
a. IRB
b. Principal Investigator
c. Institutional Official
d. the FDA (if study is FDA regulated)
e. PI department chair
f. Sponsor if applicable
g. Office of Human Research Protections if study is supported by a federal agency that follows 45 CFR 46 (e.g., NIH, etc.)
h. to other federal agencies when required
i. Other officials as necessary (Office of Sponsored Programs, etc.)

VI. Researcher Expectations

Upon receipt of the IRB's decision to suspend or terminate some or all of the research, the investigators must halt all research activities, or activities outlined in the letter if only some activities are affected. If a corrective action plan is required, the Principal Investigator should promptly report back to the IRB their action plan, and report once all items have been completed.

VII. Lifting Suspension

Once the PI has addressed the concerns in the corrective action plan, the convened IRB will review to ensure that all issues have been corrected (e.g., potential harms to subjects alleviated, noncompliance issues resolved, etc.). If the IRB agrees the issues are resolved they may vote to lift the suspension.

VIII. References

21 CFR 56.108, 21 CFR 56.113, 45 CFR 46.103, 45 CFR 46.113, OHRP "Guidance on Reporting Incidents to OHRP" (06/20/11)