Policy on IRB Suspension and Termination

Effective date: 9/20/2019
Updated: 1/24/2020 (reporting timeline)

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 research funded by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html) to report IRB suspensions and terminations to the funding agency. These problems must also be reported to the Institutional Review Board (IRB) and the Institutional Official (IO) per this policy. 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 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. Procedures for determination of suspension or termination
a. Either the IRB at a convened meeting, the Principal Investigator (PI), or the Institutional Official (IO) may suspend or terminate some or all human 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 notice of suspension/termination will be created stating the action and reason for the action, along with the study title, protocol number, PI name,
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and any corrective action or continued monitoring plans required of the PI. This notice will be delivered by the ORC Director or their designee within 1-week of the determination to suspend or terminate to the:

a. IRB
b. PI
c. IO
d. PI’s Department Chair
e. Sponsor, if applicable
f. Office of Human Research Protections (OHRP), if the research is funded by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html)
g. Other federal agencies, if required
h. Other officials as necessary (Office of Sponsored Projects, etc.)

V. Researcher Expectations

Upon receipt of the IRB’s notice of suspension or termination, investigators must halt some or all human subjects research activities, as directed in the notice. If a corrective action plan is required, the PI should promptly confirm how they will comply with the IRB’s requirements and report back once all required actions have been completed, if so directed in the notice. The PI may be required by the IRB/IO to notify current subjects of the suspension/termination.

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 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.).

IX. 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