UCLA OHRPP
Office of the Human Research Protection Program

Policy and Guidance: Suspension and Termination of Research

(last updated June 24, 2011)

General Overview

A study may be suspended or terminated if there are serious concerns about the protection of the rights and welfare of human research participants. The policies described in this document are based on regulatory requirements and apply when an IRB suspends or terminates a human research study. This document also describes the responsibilities of the Principal Investigator and the procedures that the IRB will follow to suspend or terminate a study.

Definitions

Suspension: temporary cessation of some or all research activities.

Termination: permanent cessation of all research activities.

Policy

- The IRB and IRB Chair/Vice Chair have the authority to suspend the approval of research when it is suspected or determined that the following has occurred: an unanticipated problem associated with unexpected serious harm to research participants, the research is not being conducted in accordance with the IRB requirements with possible risk of harm to research participants, and/or serious or continuing noncompliance has taken place.

- Determination by the IRB to suspend the approval of research is made

    - At a convened IRB meeting or

    - By the IRB Chair/Vice Chair if an emergent situation arises and review by a convened IRB is not possible. If the IRB Chair/Vice Chair determines a suspension of research is warranted, the IRB members will be notified of and review the circumstances surrounding the suspension at a convened IRB meeting.

- The study sponsor or the Principal Investigator (PI) of the study may voluntarily decide to suspend or terminate a study due to various reasons including but not limited to the

occurrence of an unanticipated problem, evidence of noncompliance or serious and/or continuing noncompliance. If this occurs, the PI must notify the IRB in writing within three days after this suspension or termination, and describe what steps have or will be taken to protect the welfare of currently enrolled participants, and what corrective actions, if applicable, will be taken to address the cause for the research suspension or termination. This report will be reviewed at a convened IRB meeting. After reviewing the report, the IRB will decide whether or not to suspend or terminate the IRB approval as well.

- After a suspension of an IRB approval, the IRB has the authority to terminate the research if the event(s) prompting the suspension of research approval cannot be corrected in a way that serves the best interests of the research participants. The IRB may also terminate a research study if the noncompliance with the IRB requirements is serious and/or continuing and the proposed corrective action plan is not sufficient to alleviate or rectify the noncompliance.
    - Determination by the IRB to terminate the research will be made only at a convened IRB meeting.
    - The termination of research involves all research activities (enrollment, treatment and/or intervention, follow-up, and data analysis).
    - Based upon the severity of the events that resulted in the termination of research, the IRB may recommend that the Vice Chancellor for Research and/or the Department Chair review and evaluate the PI's current privileges to conduct human subjects research.

Principal Investigator Responsibilities

- The Principal Investigator is responsible for ***reporting any unanticipated problems*** (events associated with unexpected serious harm to human research subjects related to the research study) and/or study violations or incidents as described in the OHRPP Guidance and Procedure: IRB Reporting Procedures for Unanticipated Problems, Noncompliance, Suspension, or Termination.
- If the Principal Investigator voluntarily decides to suspend or terminate research activities, the PI must ***notify the IRB within three days*** of the suspension/termination, the reasons for the suspension/termination, and include a description of what measures were or will be taken to ensure the safety, rights and welfare of currently enrolled participants.
- If the study sponsor suspends or terminates research activities, the Principal Investigator must ***comply as directed by the study sponsor, notify the IRB within three days*** of the suspension/termination, ***and describe what measures will be taken*** to ensure the safety, rights and welfare of currently enrolled participants.
- The Principal Investigator must ***promptly respond to any IRB terms and condi***tions as outlined in the IRB correspondence related to any of the above occurrences.
- The Principal Investigator ***has the right to appeal*** the IRB's determination regarding the suspension or termination of research according to OHRPP Guidance and Procedure: Referral to the IRB Executive Committee.

IRB Procedures

The protection of the rights and welfare of human research participants is of primary concern when the IRB assesses whether suspension or termination of a study is warranted.

- ***Review by a convened IRB meeting (Full Committee review) will occur as follows:***
    - Review materials are distributed to all IRB members approximately one week prior to the meeting, time permitting.
    - Appropriate review materials may include but are not limited to the following: the post-approval report addressing the suspension or termination, study protocol, IRB application, current IRB approval notice, current IRB approved informed consent document, study related correspondence and other pertinent documents (i.e., audit reports, sponsor safety reports).
    - For possible suspensions, the convened IRB will determine the extent of the suspension in reference to the following:
        - Continued participant enrollment
        - Continued study treatment and/or intervention
        - Use of data for analysis
        - All research activities

      IMPORTANT NOTE: The suspension of a single aspect of the research (i.e. new participant enrollment) is not a suspension of IRB approval unless it is associated with an unanticipated problem, serious noncompliance, and/or continuing noncompliance.
- ***The IRB will consider various options and alternatives to protect research participants.*** Such options/alternatives include but are not limited to the following:
    - Additional actions to protect the rights and welfare of enrolled participants
    - Continued safety follow-up of currently enrolled participants
    - Continued study treatment/intervention by the same or different investigator
    - Withdrawal and transition of participants from research to clinical care (if applicable)
    - Notification of all current and/or former participants of the suspension of the research
    - Continued collection and reporting of any adverse events, unanticipated problems, or outcomes to the IRB and study sponsor
    - Additional training and education of investigators and research staff
- The ***corrective action(s) and stipulations necessary*** for the IRB to consider reinstatement of the research approval will be described in the written correspondence to the Principal Investigator
- ***For possible terminations,*** the IRB will consider various options and alternatives to protect research participants. Such options/alternatives include but are not limited to the following:
    - Additional actions to protect the rights and welfare of enrolled participants
    - Continued safety follow-up of currently enrolled participants
    - Withdrawal and transition of participants from research to clinical care (if applicable)
    - Notification of all current and/or former participants of the termination of the research
    - Continued collection and reporting of any adverse events, unanticipated problems, or outcomes to the IRB and study sponsor.

- The outcome and determinations made during the convened IRB meeting are documented in webIRB, in correspondence to the principal investigator and in the IRB meeting minutes.
- Written correspondence from the IRB regarding their final determination will be forwarded to the Principal Investigator within 10 working days of the IRB determination.
- The Principal Investigator will be provided an opportunity to respond in writing or in person to the IRB about the suspension or termination.

IRB Reporting Requirements

Unanticipated problems involving risks to subjects or other; any serious or continuing noncompliance; and any suspension or termination of IRB approval and the outcome of the IRB's actions will be reported to the appropriate institutional officials and the appropriate federal department or agency head(s) according to OHRPP Guidance and Procedure: IRB Reporting Procedures for Unanticipated Problems, Noncompliance, Suspension, or Termination.

References and Regulations

DHHS

- 45 CFR 46.103(b)(5)(iii)
- 45 CFR 46.113
- OHRP Guidance on Reporting Incidents to OHRP (May 27, 2005)
- OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events (January 15, 2007)
- OHRP Guidance on Written IRB Procedures (January 15, 2007)

FDA

- 21 CRF 56.108(b)(3)
- 21 CFR 56.113
- FDA Guidance for IRBs and Clinical Investigators: Continuing Review after Study Approval – Information Sheet (1998, updated October 18, 2010)

UCLA

- UCLA Policy 991: Protection of Human Subjects in Research (January 23, 2009)