Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: II.B
Section: HRPP Compliance
Review Responsibility: HRPP Policy and Procedure Committee
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Subject: Suspension, or Termination of IRB Approval

Definitions:
1. **Sponsor-Imposed Suspension:** A determination from the sponsor of the study to place specific research activities on hold. This determination may be made for interim data analysis; inadequate drug availability; response to a DSMB report/recommendation; or a preplanned stopping point.
2. **Expired Study:** When continuing review of the research does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. The study expires on the date specified on the approval letter and the informed consent document. No activities can occur after the expiration date.
3. **Suspension for Cause:** An action initiated by the IRB to stop temporarily some or all research procedures pending future action by the IRB or by the Investigator or his/her study personnel.
4. **Termination for Cause:** An action initiated by the IRB to stop permanently some or all research procedures.

Policy:
It is the policy of the HRPP that all currently approved research is subject to modification or change in approval status, as deemed necessary by the IRB. The IRB may suspend or terminate research due to cause for the research not being conducted in accordance with the IRB’s requirements or the federal regulations or if it has been associated with unexpected serious harm to participants, prior to any investigation.

I. Sponsor-Imposed Suspensions.
   A. Notification of suspension by a sponsor unrelated to risk is submitted to the IRB for review and approval as a modification to previously approved research. Such modifications are considered minor and may be reviewed by the expedited procedure (See HRPP Policy III.J).
   B. Notification of suspension by a sponsor possibly related to risk is submitted to the IRB for review by the full Committee for evaluation as a potential unanticipated problems involving risk to participants or others (See HRPP Policy III.J), and as a review of a modification to previously approved research.

II. Study Expiration.
   A. If an Investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the specified continuing review expiration date, the study expires. Enrollment of new participants cannot occur after the expiration of IRB approval and all research activities must stop.
   B. Once notified of the expiration, the Investigator must immediately submit to the IRB Chair, a list of research participants for whom cessation of the research would cause...
harm if the expiration impacts ongoing research activities. The full IRB Committee reviews this list and allows individual participants to continue participating in the research interventions or interactions only when the IRB determines that it is in their best interests.

C. The IRB notifies the Investigator in writing of the Study Expiration.
   1. The letter indicates that after the expiration date:
      a) Enrollment of new participants must stop;
      b) All research activities must stop; and
      c) Any continuation research activity is a violation of federal regulations.
   2. The letter also indicates that the Investigator must immediately submit to the IRB, a list of research participants for whom cessation of the research would cause harm.

D. Research studies not reviewed and approved within ninety (90) days of the notification of Expiration are administratively closed by the IRB. Reinstatement of the research requires submission of a research protocol for initial review.

III. Suspensions and Terminations Due to Cause.

A. The IRB reports in writing, all suspensions due to cause, promptly to the Investigator. The letter:
   1. Includes a statement of the reasons for the IRB's action;
   2. Requires the Investigator to submit to the IRB proposed procedures for withdrawal of currently enrolled subjects that considers their rights and welfare. The IRB Committee reviews the proposed procedures. The IRB may mandate oversight or transfer responsibility to another Investigator to assure implementation of these procedures;
   3. Requires the Investigator to submit to the IRB a proposed script or letter notifying all currently enrolled participants that are affected by the suspension, if applicable. The IRB Committee reviews the proposed script or letter. If follow-up of subjects for safety reasons is permitted/required by the IRB, participants should be so informed. The IRB may directly contact participants to fulfill this notification; and
   4. Requires the Investigator to report any events to the IRB or sponsor that would have required reporting had the former participants continued to be enrolled in the research. The IRB may mandate oversight or transfer responsibility to another Investigator to ensure implementation of these procedures.

B. Investigators receiving repetitive suspensions or terminations due to cause may necessitate institutional actions for serious and continuing non-compliance (See HRPP Policy III.L).

C. All suspensions and terminations will be reported according to IRB Policy (See HRPP Policy II.D).

References:
45 CFR 46.113
42 CFR 50 Subpart A
HRPP II.B.1 - Procedure for Suspension, or Termination of IRB Approval
HRPP II.C - Investigating Any Non-Compliance, Serious, or Continuing Non-Compliance
HRPP III.K - IRB Continuing Review