Subject: Procedure for Suspension, or Termination of IRB Approval

Procedure:
This procedure outlines the circumstances and methods in which a study’s approval status may be changed and subsequently reinstated.

I. Investigator Responsibilities.
   A. Sponsor-Imposed Suspension Unrelated to Potential Risk.
      1. The notice of suspension or removal of suspension is forwarded to the IRB as soon as possible, but no later than 10 working days after the Investigator first learns of the notice of suspension or its removal.
      2. Research activities cease as specified in the sponsor’s suspension until notified by the sponsor that the study is re-opened and the IRB acknowledges this notification.
      3. Adverse events or unanticipated problems involving risk to participants or others are still reported to the IRB.

   B. Sponsor-Imposed Suspension for Potential Risk.
      1. Investigators forward any correspondence from the sponsor, indicating suspension or removal of suspension imposed for potential risk, to the IRB as soon as possible, but no later than 7 calendar days after the Investigator first learns of the notice of suspension or its removal for full Committee review and approval.
      2. Research activities cease as specified in the suspension imposed by the sponsor until the study is re-opened by the sponsor and the full IRB Committee has reviewed and approved the study. Also, the IRB may determine additional criteria for suspension or for re-opening the study.
      3. Adverse events or unanticipated problems involving risk to participants or others are still reported to the IRB.

   C. Study Expiration.
      1. The Investigator completes all continuing review requirements promptly.
      2. Research activities cease until the IRB has determined continuing review requirements are met and approval is granted.
      3. Enrollment of new participants and interaction of already enrolled participants cannot occur after the expiration of IRB approval.
      4. The Investigator may provide justification in writing to the IRB Committee for continuing treatment of participants to avoid additional risk or if the drug is available outside the research study.
      5. Adverse events or unanticipated problems involving risk to participants or
others are still reported to the IRB.

D. Suspension Due to Cause.
1. Research activities cease, as specified in the suspension criteria, until the Investigator is notified that the full IRB Committee has granted approval of the study to resume. However, it is also within the authority of the IRB to terminate the study.
2. The Investigator cooperates with the IRB in complying with all corrective actions as designated by the IRB Committee.
3. The Investigator notifies the sponsor of the IRB imposed suspension/reinstatement.
4. The Investigator is responsible for notifying all affected participants of the suspension as deemed appropriate by the Committee. The Investigator submits the script or letter to the IRB for approval prior to notification to participants.
5. Adverse events or unanticipated problems involving risk to participants or others are still reported to the IRB.

E. Termination for Cause.
1. The Investigator ceases all study related activities and notifies the sponsor of the termination of IRB approval.
2. The Investigator is responsible for notifying all affected participants of the termination. The Investigator submits the script or letter to the IRB for approval prior to notification to participants.
3. Adverse events or unanticipated problems involving risk to participants or others are still reported to the IRB.

II. IRB Committee Responsibilities.
A. Sponsor-Imposed Suspension Unrelated to Potential Risk.
1. Notification of suspension and the reinstatement of research by the sponsor for issues unrelated to risks are reviewed by expedited procedures and approved by the IRB Chairperson or his/her designee.

B. Sponsor-Imposed Suspension for Potential Risk.
1. Notification and re-instatement of a suspension imposed by the Sponsor possibly related to risk is reviewed and approved by the full IRB Committee.
2. The full IRB Committee suspends the research study as determined by the sponsor. However, the IRB Committee may impose additional restrictions upon research conducted under its jurisdiction.
3. The IRB notifies the Investigator in writing of its determinations.

C. Expiration of Approval.
1. The IRB Chair or his or her designated Committee Member notifies the Investigator in writing of the pending Expiration.
2. Expired studies may be granted approval after the continuing review requirements are completed and approved at the appropriate level of review for which the study currently qualifies.
3. The IRB Chair or designated Committee Member may review the submitted justification for continuing treatment of participants to avoid additional risk or if the drug is available outside the research study.
D. Suspension Due to Cause.

1. The IRB reviews a study for Suspension for Cause at a full IRB Committee meeting. Examples of these types of circumstances include:
   a) Falsification of study safety data;
   b) Failure to comply with prior conditions imposed in writing by the IRB under a Suspension;
   c) Repeated or deliberate failure to obtain or document informed consent from human participants, which may include:
      (1) Repeated or deliberate omission of a description of serious risks of the experimental therapy when obtaining informed consent; and/or
      (2) Repeated or deliberate failure to provide informed consent in a language understandable to the subject;
   d) Repeated or deliberate failure to limit administration of the investigational drug or device to those participants under the Investigator’s supervision;
   e) Repeated or deliberate failure to comply with conditions placed on the study by the University or Institution, IRB, Sponsor, or FDA;
   f) Repeated or deliberate failure to obtain prior review and approval of new protocols and on-going human subjects research by the IRB;
   g) Repeated or deliberate failure to follow the signed Investigator statement or protocol, e.g., by enrolling participants who should have been excluded because of concomitant illnesses that put those participants at greater risk;
   h) Repeated or deliberate failure to maintain accurate study records or submit required adverse event reports to the IRB;
   i) Repeated or deliberate falsification or concealment of study records, e.g., by substituting in study records the results of biological samples from participants who met the inclusion criteria for samples of participants who did not meet the inclusion criteria, or by fabricating participants.

2. Prior to presentation at full Committee, the IRB Chairperson or his/her designee is encouraged to present the details at the HRPP Optimization Committee meeting for an open discussion and dialogue to assist the Committee Chairperson in organizing and prioritizing a presentation of the facts for consideration and vote at the next IRB Committee meeting. This promotes consistency and compliance across all IRB Committees.

3. In addition, the Committee may request an ad hoc review from an independent source with expertise in the type of research being conducted or in the specific area of concern.

4. The Criteria for suspension are:
   a) Suspension to recruitment;
   b) Suspension to screening/enrollment;
   c) Suspension to interaction/intervention; and/or
   d) Suspension to follow-up.

5. The IRB notifies the Investigator in writing of its decision to suspend the study for cause and provide a rationale for its actions. This letter includes an opportunity for the PI to respond to the Committee’s determinations and to attend an IRB Committee meeting to discuss the suspension and provide clarification of the issues.

6. The Committee may request the development of an education plan and/or the completion of a directed audit by an RCA on the appropriate team.
7. Suspensions for cause are reinstated for approval after corrective actions are completed to the IRB Committee’s satisfaction. The Committee may approve the study with or without additional restrictions (e.g., mandating a data and safety monitoring committee to oversee the research at designated intervals, increase in the frequency of IRB Committee review, observation of the consent process, etc.).

E. Termination for Cause.
1. The IRB reviews a study for Termination for Cause at a full IRB Committee meeting.
2. Prior to presentation at full Committee, the IRB Chairperson or his/her designee is encouraged to present the details at the HRPP Optimization Committee meeting for an open discussion and dialogue to assist the Committee Chairperson in organizing and prioritizing a presentation of the facts for consideration and vote at the next IRB Committee meeting. This promotes consistency and compliance across all IRB Committees.
3. In addition, the Committee may request an ad hoc review from an independent source with expertise in the type of research being conducted or in the specific area of concern.
4. The IRB notifies the Investigator in writing of the decision to terminate the study for cause and provide a rationale for its actions. This letter includes an opportunity for the PI to respond to the Committee’s determinations and to attend an IRB Committee meeting to discuss the termination and provide clarification of the issues.

F. Reporting of Suspensions for Cause or Terminations for Cause.
1. All Suspensions or Terminations for Cause are promptly reported per HRPP Policy and Procedure II.D and II.D.1.
2. The institution may determine that suspensions or terminations associated with a particular study or an Investigator are repetitive and warrant action for issues of serious and continuing non-compliance.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
A. Sponsor-Imposed Suspension Unrelated to Potential Risk.
1. The RCA processes the notification from a sponsor of a suspension unrelated to risk for administrative acknowledgement requiring a signature of the Chairperson or his/her designee. This may occur via expedited review.
2. The RCA updates the HRPP database accordingly with the current status of the research.

B. Sponsor-Imposed Suspension for Potential Risk.
1. The RCA processes the notification from a sponsor of a suspension due to possible risk for full Committee review.
2. The RCA notifies the PI in writing of the IRB Committee’s determinations. This letter requires a signature of the Chairperson or his/her designee.
3. The RCA assists the Committee in obtaining any additional information needed for the Chairperson or his/her designee to determine if a change in the risk-potential benefit profile has occurred.
4. The RCA updates the HRPP database accordingly with the current status of the research.

C. Expiration of Approval.
1. Prior to the study expiration date, the PA assigns the study for review to determine the date of IRB Expiration. Reviews may be conducted in accordance with the level of review for which the study qualifies.

2. The RCA notifies the PI in writing of the IRB Committee’s determinations. This letter requires a signature of the Chairperson or his/her designee.

3. The RCA assists the Committee in obtaining the additional information required to conduct continuing review of the research.

D. Suspensions Due to Cause.

1. The RCA notifies the PI in writing of IRB determinations. The letter requires a signature of the Chairperson or his/her designee.

2. The RCA assists the Committee in obtaining information from the Investigator. The RCAs keep each other informed of all corrective actions to be taken by the Investigator and their status.

3. The HRPP staff completes a directed audit and/or develops an education plan as deemed appropriate by the IRB Committee. The HRPP staff is available as a resource to the Investigator.

4. The RCA notifies the HRPP Director within 1 working day of any Suspensions for Cause.

5. The RCA updates the HRPP database accordingly with the current status of the research.

E. Terminations for Cause.

1. The RCA notifies the PI in writing of IRB determinations. The letter requires a signature of the Chairperson or his/her designee.

2. The RCA promptly notifies the HRPP Director within 1 working day of any Terminations for Cause.

3. The RCA updates the HRPP database accordingly with the current status of the research.

References

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