Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 135	
CHAPTER: Institutional Review Board	ISSUED: 8/2011	REVISED/REVIEWED: 11/2013
POLICY: Suspensions and Terminations	PAGE 1 OF 5	

1. PURPOSE

The IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with Creighton University IRB, federal, state or local requirements, or has been associated with unexpected serious harm to participants.

2. DEFINITIONS

2.1. **Suspension:** An action issued by the IRB that all or some of the research activities must stop until issues have been satisfactorily resolved. Suspended projects still have IRB approval.

2.2. **Termination:** An action issued by the IRB that all or some of the research must stop permanently except for the continuation of follow-up activities necessary to protect the participants' safety.

3. PROCEDURE FOR SUSPENSION AND TERMINATION

3.1. At a convened meeting of the IRB, the IRB Chair or designee will present the facts for consideration and vote. The IRB will review a study for suspension or termination for the following types of conditions, including but not limited to:

3.1.1. Falsification of study safety data

3.1.2. Failure to comply with prior conditions imposed in writing by the IRB

3.1.3. Repeated or deliberate failure to obtain or document informed consent from human participants, which may include:

3.1.3.1. Repeated or deliberate omission of a description of serious risks of the experimental therapy when obtaining informed consent

3.1.3.2. Repeated or deliberate failure to provide informed consent in a language understandable to the subject

3.1.4. Repeated or deliberate failure to limit administration of the investigational drug or device to those participants under the Principal Investigator's supervision

3.1.5. Repeated or deliberate failure to comply with conditions placed on the study by the University, IRB, sponsor, or FDA

3.1.6. Repeated or deliberate failure to obtain prior review and approval of new protocols and ongoing human subjects research by the IRB

3.1.7. Repeated or deliberate failure to follow the signed Principal Investigator's Assurance statement or protocol (e.g., enrolling participants who should have been excluded, putting those participants at greater risk)

3.1.8. Repeated or deliberate failure to maintain accurate study records, submit required adverse event reports, report changes to the research, or report unanticipated events to the IRB

3.1.9. Repeated or deliberate falsification or concealment of study records (e.g., 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 fabricating participants)

3.2. The IRB shall decide on a course of action and establish a timeline for the completion of that action. The discussion, action and vote will be recorded in the meeting minutes. The IRB may act at any time during the investigation to modify the terms of the suspension or termination.

3.3. Until a review can be done by the convened IRB, the IRB Chair or designee may act alone to temporarily suspend or terminate previously approved human research or an investigator's privilege to conduct human subject research if the alleged serious or continuing noncompliance with the requirements or determinations of the IRB, or any incidence that has been associated with the unexpected serious harm to participants, appears to pose imminent threat to subject safety. Suspensions and terminations by the IRB Chair or designee, acting alone, are reported to and reviewed by the convened IRB.

3.4. The IRB may request an audit by the Office of Research and Compliance Services.

3.5. For suspensions, the IRB deliberates and determines the category(s) of suspension, which are:

3.5.1. Suspension to recruitment

3.5.2. Suspension to screening and enrollment

3.5.3. Suspension to interaction and intervention

3.5.4. Suspension to follow-up.

3.6. The IRB notifies the investigator in writing of its decision by letter within 5 business days. The letter will include:

3.6.1. Reason and rationale for the suspension or termination

3.6.2. IRB action plan and established timeline for response and reporting progress to the IRB

3.6.3. If appropriate, the letter will require the investigator to submit:

3.6.3.1. Procedure for the withdrawal of currently enrolled participants that considers their rights and welfare.

3.6.3.2. Letter or script notifying all currently enrolled participants that are affected by the suspension or termination.

3.6.4. A reminder that all study activities, such as reporting new information, shall still be reported to the IRB.

3.6.5. If appropriate, the letter will require the Principal Investigator to:

3.6.5.1. Complete additional training in human subjects research

3.6.5.2. Provide a plan for oversight for current and future research

3.6.5.3. Other requirements deemed appropriate by the IRB

3.6.6. Notification that an internal audit of the study will be conducted by the Office of Research and Compliance.

3.6.7. If appropriate, inform current participants of the termination or suspension.

3.7. To reinstate a project that has been suspended, the investigator must satisfactorily resolve any pending issues required by the IRB. If the issues have not been resolved after six months, the study will be terminated.

3.8. To reinstate a project that has been terminated, the investigator must submit the project to the IRB as new and past issues must be resolved to the satisfaction of the IRB.

4. SPECIAL CIRCUMSTANCES FOR CONTINUING A SUSPENDED OR TERMINATED PROJECT

If an activity for which a suspension or termination has been imposed must continue (e.g., a research-related treatment) because it is in the best interest of the subject, the investigator shall write a letter to the IRB Chair or designee. The letter shall include:

4.1. A justification as to why continuation is in the best interest of the subject

4.2. A request for approval for continuation of the specific activity either until the suspension is lifted or until alternate arrangements can be made for the subject

4.3. For terminations, confirmation that alternate arrangements are actively being sought and the anticipated time frame by which the arrangements should be finalized

4.4. Confirmation that the investigator will inform subjects that the study has been suspended or terminated but that permission for the activity has been obtained

4.5. Confirmation that the investigator will direct subjects to continue to report adverse events or unanticipated problems

4.6. Confirmation that the investigator will continue to report all activity in accordance with policy.

5. WHO MAY SUSPEND OR TERMINATE IRB APPROVAL

The IRB Chair or designee, convened IRB, Associate Vice Provost for Research and Compliance, or the Institutional Official may suspend a study. The authority to suspend studies shall not be delegated to other individual members of the IRB. The convened IRB, Associate Vice Provost for Research and Compliance, or the Institutional Official may terminate a study.

6. REPORTING SUSPENSION AND TERMINATIONS

The Associate Vice Provost for Research and Compliance, in consultation with the General Counsel's Office, shall report the noncompliance to the appropriate federal

regulatory agency and organizational officials in the time frame required by the agency or within 30 days, whichever is shorter.

7. RESPONSIBILITIES

7.1. The IRB Chair or designee is responsible for presenting the facts to the IRB at a convened IRB meeting and for sending letters to Principal Investigators.

7.2. The IRB Director is responsible for notifying the Associate Vice Provost for Research and Compliance of the IRB's determinations.

7.3. The Associate Vice Provost for Research and Compliance is responsible for notifying the appropriate individuals and agencies of the suspension or termination.

7.4. IRB members are responsible for determining whether the facts are sufficient to require suspension or termination of the research.

7.5. IRB members are responsible for determining course of action and establishing a timeline for completion of that action.