8 Study Suspension, Termination and Investigator Hold

8.1 Suspension/Termination

IRB approval may be suspended or terminated if research is not being conducted in accordance with IRB or regulatory requirements or has been associated with unexpected problems or serious harm to subjects. (See Section 15 for a discussion of unanticipated problems and Section 16 for a discussion of non-compliance.)

Suspension of IRB approval is a directive of the convened IRB, IRB Chair or IO/IO designee to temporarily stop some or all previously approved research activities. Suspensions made by the IRB Chair or IO/IO designee must be reported to a meeting of the convened IRB. Suspended research studies remain open and require continuing review. Investigators must continue to provide reports on adverse events and unanticipated problems to both the IRB and sponsors just as if there had never been a suspension (i.e., all events that need to be reported during a study need to continue to be reported during the suspension period).

When approval of some or all research activities is suspended by the IRB, the IRB will consider notification of subjects and any actions necessary to ensure that the rights, safety, and welfare of subjects are appropriately protected.

The IRB shall notify the investigator in writing of suspensions and shall include a statement of the reasons for the IRB's actions and any requirements or conditions associated with the suspension (e.g., notification of subjects). The investigator shall be provided with an opportunity to respond in person or in writing.

Suspensions of IRB approval must be reported promptly to the IO, sponsors including federal department or agency heads, and federal oversight agencies according to applicable federal and organizational requirements. See Section 14 for a detailed discussion of reporting requirements.

Termination of IRB approval is a directive of the convened IRB to permanently stop all activities in a previously approved research study. Terminated research studies are closed and no longer require continuing review. Terminations of IRB approval of research studies must be made by the convened IRB.

When study approval is terminated by the IRB, in addition to stopping all research activities, the IRB will consider notification of subjects and any actions necessary to ensure that the rights, safety, and welfare of subjects are appropriately protected.

The IRB shall notify the investigator in writing of a study termination and shall include a statement of the reasons for the IRB's actions and any requirements associated with the termination (e.g., notification of subjects). The investigator shall be provided with an opportunity to respond in person or in writing.

Terminations of IRB approval must be reported promptly to the IO, sponsors including federal department or agency heads, and federal oversight agencies according to applicable federal

and organizational requirements. See Section 14 for a detailed discussion of reporting requirements.

Note: Suspension or termination of research studies approved by the IRB can also be issued by Organization officials acting outside of and unrelated to the interests of the IRB (i.e., not necessarily related to protecting the rights and welfare of study participants). Such Organization actions can be made by, for example, the IO, the Provost, Department Chairs or School Deans. The investigator must report any suspension or termination of the conduct of research to the IRB. The IRB determines if suspension or termination of IRB approval is warranted and notifies the Investigator.

8.2 Investigator Hold

An investigator may request an investigator hold when the investigator wishes to temporarily or permanently stop some or all approved research activities. Such a hold is initiated by an investigator, but must be immediately reported to the IRB so that the IRB can consider whether any additional actions are necessary to protect subjects. Investigator holds are not equivalent to IRB suspensions or terminations.

8.2.1 Procedures

1. Investigators must notify the IRB in writing that:
    a. They are voluntarily placing a study on hold
    b. A description of the research activities that will be stopped
    c. Proposed actions to be taken to protect current participants
    d. Actions that will be taken prior to IRB approval of proposed changes in order to eliminate apparent immediate risk of harm
2. Upon receipt of written notification from the investigator the IRB Director or designee places the research on the next available agenda for review.
3. The IRB Chair and/or Director or designee, in consultation with the investigator, determines whether any additional procedures need to be followed to protect the rights and welfare of current participants as described in “Protection of currently enrolled participants”(see Section 8.3).
4. The IRB Chair and/or Director or designee, in consultation with the investigators, determine how and when currently enrolled participants will be notified of the hold.
5. Investigators may request a modification of the research on hold by submitting a request for a modification to previously approved research.

8.3 Protection of Currently Enrolled Participants

Before a study hold, termination, or suspension, is put into effect the IRB Chair, Director, or IRB considers whether any additional procedures need to be followed to protect the rights and welfare of current participants. Such procedures might include:

- Transferring participants to another investigator/site
- Making arrangements for clinical care outside the research
- Allowing continuation of some research activities under the supervision of an independent monitor
- Requiring or permitting follow-up of participants for safety reasons
- Requiring adverse events or outcomes to be reported to the IRB and the sponsor
- Notification of current participants
- Notification of former participants