

SOP-R-006: TC IRB Standard Operation Procedures (SOP) on Suspensions, Terminations, and Investigator Holds

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 Unanticipated Problems Involving Risks to Subjects or Others SOP for a discussion of unanticipated problems and the Noncompliance SOP for a discussion of noncompliance.) The IRB's authority to suspend or terminate research applies to all research subject to IRB approval, including exempt research with limited IRB review and research for which continuing review is no longer required.

The Institutional Official has the authority to suspend or terminate the organization's approval for research. Such actions will be promptly reported to the IRB so that the IRB can review the circumstances and take any necessary actions relevant to IRB review and oversight.

Suspension of IRB approval is a directive of the convened IRB or IRB Chair to temporarily stop some or all previously approved research activities. The IRB Chair may temporarily suspend IRB approval, in part or in full, when the available information suggests that actions must be taken to protect human subjects or the integrity of the research, prior to the next convened meeting of the IRB. Temporary suspensions by the Chair will be reported to the convened IRB at the next scheduled meeting at which time the convened IRB will determine if the suspension should continue, be lifted, or be modified. Suspended research studies remain open and require continuing review. Investigators must continue to provide reports to both the IRB and sponsors just as if there had never been a suspension (i.e., all items 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 whether subjects should be notified and whether any additional actions are necessary to ensure that the rights, safety, and welfare of subjects.

The IRB will notify the investigator of suspensions in writing; a call or email may precede the written notice when appropriate. Written notices of suspensions will include a statement of the reason(s) for the IRB's action and any requirements or conditions associated with the suspension (e.g., notification of subjects). The investigator will 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 as applicable. See Reporting to Federal Agencies, Departments, and Organizational Officials SOP 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 whether any additional actions are necessary to ensure that the rights, safety, and welfare of subjects.

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The IRB will notify the investigator of terminations in writing; a call or email may precede the written notice when appropriate. Written notices of terminations will include a statement of the reasons for the IRB's action 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 as applicable. See Reporting to Federal Agencies, Departments, and Organizational Officials SOP for a detailed discussion of reporting requirements.

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.

Procedures

Investigators must submit a memo and any supporting materials via Mentor IRB to inform the IRB of the hold. The memo and materials should include:

- I. A statement that the investigator is voluntarily placing a study on hold;
 - a. The reason(s) for the hold;
 - b. A description of the research activities that will be stopped;
 - c. Proposed actions to be taken to protect current participants; and
 - d. Any actions that will be taken prior to IRB approval of proposed changes to eliminate apparent immediate risk of harm.

Upon receipt, IRB staff notify the IRB Chair or designee and place the research on the next available agenda for review;

The IRB Chair 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 Suspensions, Terminations, and Investigator Holds SOP;

The IRB Chair or designee, in consultation with the investigator, determines whether and how currently enrolled subjects will be notified of the hold;

Prior to lifting the hold, the investigator must seek approval from the IRB so that the IRB may consider whether subjects are appropriately protected and if the research remains approvable.

Protection of Currently Enrolled Participants

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

- Transferring subjects to another investigator/site
- Allowing continuation of some research activities under the supervision of an independent monitor

- Requiring or permitting follow-up of subjects for safety reasons
- Requiring adverse events or outcomes to be reported to the IRB and the sponsor
- Notification of current subjects
- Notification of former subjects

Documentation and Record-Keeping

All reports, correspondence, and relevant documentation are retained in accordance with TC's policies for research record retention. Records include copies of the initial report, any follow-up communications, and final resolutions, if applicable.