Northeastern University
Human Research

# Guidance: Protocol Suspensions & Terminations (IRB, PI, or Sponsor Initiated)

## Overview

The Northeastern University IRB has the authority to suspend or terminate IRB approval of research that is not being conducted per IRB requirements, is not being conducted per the IRB-approved protocol, or that may pose unexpected, serious harm to participants. The authority to suspend or terminate IRB approval is retained regardless of whether the research was approved by the convened IRB, through the expedited procedure, through limited IRB review, or is exempt. The IRB retains the ability to suspend or terminate research even when continuing IRB review is not required.

The IRB considers the best interests of research participants in deciding whether to temporarily or permanently halt a research study. The IRB will require that procedures for the withdrawal of enrolled participants consider their rights and welfare (e.g., planning for medical care of a research study, transfer to another researcher, and continuation of the research under independent monitoring).

During suspension or following termination of IRB approval, no new participants may be enrolled; no research drugs, devices, treatments, or procedures may be administered (unless necessary for the safety of enrolled participants); and no data to which a participant identifier is attached may be collected or analyzed. Exceptions include partial suspension and temporary continuation of research activities for safety reasons.

## Definitions

**Investigator/Sponsor-Initiated Termination or Suspension of a Research Protocol**: A determination made by the investigator or sponsor to voluntarily suspend or terminate some or all activities of an approved protocol.

**IRB-Initiated suspension of approval:** A determination made by the IRB to temporarily withdraw IRB approval for some or all activities of a currently approved research study.

**IRB-Initiated termination of approval**: A determination made by the IRB to permanently withdraw IRB approval for some or all activities of a currently approved research study.

NOTE: The terms “suspension” and “termination” do not apply to interruptions in research resulting solely from the expiration of a protocol approval period.

## Suspensions by the IRB

The convened IRB or the IRB Chair may suspend approval for some or all activities for a research project. The research may be suspended immediately following a report of a problem, during an investigation of noncompliance or an unanticipated problem involving risks to participants or others (Unanticipated Problem) or following a review of noncompliance or an Unanticipated Problem by the convened IRB. Suspensions by the IRB Chair are reported to and reviewed by the convened IRB.

The IRB Chair or designee, or the Institutional Official or designee, has the authority to suspend some or all research activities if exceptional participant safety issues are identified. This authority is only exercised if an action is required before a convened meeting and it is not feasible to assemble an emergency meeting. If exercised, this activity will be reported at the next convened IRB meeting. Correspondence is sent to the Principal Investigator as well as to all listed co-investigators and research staff. The study moves to a "suspended" state.

Suspended protocols are active studies and require continuing review by the IRB. The IRB may approve keeping a suspended research project open but with no research activities (or only specified activities) until the suspension is lifted.

## Terminations by the IRB

Only a fully convened IRB may terminate a research project, when it determines that cessation of all research activities is in the best interest of participants. Studies may be terminated during an IRB review of noncompliance or an Unanticipated Problem. Correspondence is sent to the Principal Investigator as well as to all listed co-investigators and research staff. The study moves to a "terminated" state.

## Suspension or Termination by the PI, Sponsor, or other Oversight Body

Sponsors, Principal Investigators (PI), and other oversight bodies have the authority to suspend their research any time that suspension or termination may be necessary to protect the safety and welfare of research participants or others or the integrity of a research project.

PIs or sponsors may voluntarily suspend or terminate a research project after reviewing or monitoring study data; upon recommendation from a Data and Safety Monitoring Board or Committee; or before or during an investigation of noncompliance or an Unanticipated Problem.

When a PI, sponsor, or other oversight body determines that it is in the best interest of research participants to suspend or terminate a protocol, this is to be reported as *New Information* to the IRB within ten (10) days of the PI planning for or learning of suspension or termination.

The **termination report** information should include:

- the primary reason for the termination;
- the number of participants enrolled to date;
- the plan for notifying currently enrolled participants, if necessary;
- the procedures that will be undertaken to ensure the orderly and safe withdrawal of currently enrolled participants, if necessary;
- whether there were any unanticipated problems involving risks to participants or others that were not previously reported;
- whether participants will be notified of the study results;
- whether the study had been monitored/reviewed/audited by an outside monitor, sponsor, or agency;
- whether the report has been sent to other agencies.

The **suspension report** information should include:

- the primary reason for the suspension;
- the type of suspension (intervention only; all research activities);
- the number of participants currently enrolled in the study;
- the procedure that will be undertaken to ensure the safe withdrawal of currently enrolled research participants, if necessary;
- whether permission is being requested to continue research activities during the suspension period for the safety of currently enrolled participants;
- whether participants will be notified of the study suspension;
- whether the report has been sent to other agencies;
- a description of what must occur for a request for re-initiation of study activities can be submitted.

If the PI has a contractual relationship with the sponsor, contract requirements should include notification of the sponsor of investigator-initiated suspension or termination of research. In circumstances where the IRB is notified that the investigator cannot contact the sponsor, the IRB will inform the sponsor of the suspension or termination of research.

## Partial suspension of research activities

If only some of the research activities will be suspended (e.g., suspension of enrollment), the PI must:

- specify which activities are to be suspended, and which will continue;
- justify the continuation of research activities during the suspension;
- include a timeline for eventual discontinuation of all research activities (unless the suspension is lifted); and
- describe procedures to ensure adequate oversight of research activities that will continue.

## IRB responsibilities

Regardless of who suspends or terminates, the IRB or IRB Chair/designee will:

- Consider actions to protect the rights and welfare of currently enrolled participants;
- Consider whether procedures for withdrawal of enrolled participants consider their rights and welfare (e.g., planning for medical care outside of a research study, transfer to another researcher, and continuation in the research under independent monitoring);
- Consider informing current participants of the termination or suspension: (i) what should be communicated; (ii) when should this correspondence take place; (iii) how this correspondence will take place, in-person, by phone, email, etc.
- Continue collection and reporting of unanticipated incidences, adverse events, or outcomes to the IRB and study sponsor; and,
- Identify if additional training and education is necessary for the research team.

## Removal of suspension

Following IRB confirmation that corrective actions have been satisfactorily addressed, the PI may ask for reinstatement of a suspended research project. The PI must submit a project amendment in which the study design and procedures have been revised to mitigate or correct the problem that resulted in suspension.

The convened IRB will review the amendment and may require minor changes to reinstate IRB approval, require substantive changes (to be reviewed at a subsequent IRB meeting), or reinstate IRB approval. The IRB may require more frequent continuing review (i.e., IRB approval period of less than one year; to be stated in IRB meeting minutes). The project expiration date would be updated to reflect the approval period as determined by the IRB, beginning with the date the IRB approved the reinstatement of IRB approval.