

SOP 407.001

Title	Suspension or Termination of REB Approval
SOP Code	407.001
Effective Date	

Site Approvals

Name and Title	Signature	Date dd/mm/yyyy

1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures to be undertaken in determining and executing the suspension or termination of the Research Ethics Board's (REB) approval of research.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The REB is responsible for determining whether any information received throughout the course of the research requires the suspension or termination of REB approval for the research being considered.

The Researcher is responsible for notifying the REB and the organization of any suspensions or terminations of the research and for providing a detailed explanation for the action.

The REB Chair or designee is not authorized to terminate REB approval; however, the REB Chair or designee is authorized to suspend REB approval, which must be reported

to the REB at its next Full Board meeting. The REB is authorized to terminate REB approval following its review at a Full Board meeting.

The REB Chair or designee is responsible for notifying the Researcher, and the Organizational Official(s), of any suspension or termination of REB approval of the research.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

As a result of ongoing review activities, the REB may require that research be modified, or may suspend or terminate REB approval if the risks to the research participants are determined to be unreasonably high; or when there is evidence that the Researcher is not conducting the research in compliance with applicable policies and guidelines. The REB also has the authority to suspend recruitment while additional information is requested.

The REB has the authority to suspend or to terminate the REB's approval of the research. The REB Chair or designee has the authority to suspend ethics approval. Any requests to lift a suspension or to re-approve the research must be reviewed by the Full Board.

A Researcher may decide to voluntarily suspend or terminate some or all research activities; however, this is not considered a suspension or termination of REB approval.

5.1 Suspension or Terminations of Research Activities

- 5.1.1 Research may be suspended or terminated by the REB or by the researcher (?) for a variety of reasons, e.g., following results of interim analyses, in response to a safety or privacy concern, due to pre-planned stopping criteria, etc.;
- 5.1.2 The Researcher must immediately notify the REB of any suspensions or terminations of the research and the reasons for the action;
- 5.1.3 Reports of suspensions or terminations will be forwarded to the REB Chair or designee for review;

5.2 Suspension or Termination of REB Approval

- 5.2.1 If any concerns are raised during the REB's oversight of the research that are related to new information or to the conduct of the research, the REB may suspend or terminate its approval of the research as appropriate. These concerns may include but are not limited to:
- The research not being conducted in accordance with the REB-approved protocol or REB requirements,
 - The research is associated with unexpected serious harm to participants (i.e., as may be determined following REB review of reportable events
 - Failure to comply with prior conditions imposed by the REB (i.e., under a suspension or approval with modifications),
 - Repeated or deliberate failure to properly obtain or document consent from research participants,
 - Repeated or deliberate failure to obtain prior REB review and approval of amendments or modifications to the research, or
 - Repeated or deliberate failure to maintain accurate research records or submit required reportable event reports to the REB;
 - In accordance with an ongoing allegation or finding of a breach of responsible conduct of research, as determined through the Organization's policy and procedures.
- 5.2.2 The REB Chair or designee is authorized to suspend REB approval of research. If the Chair or designee suspends approval of the research, he/she must notify the REB at its next Full Board meeting;
- 5.2.3 The REB is authorized to terminate its approval of the research following a review at a Full Board meeting;
- 5.2.4 Prior to suspending or terminating REB approval, the REB must consider:
- Risks to current participants,
 - Actions to protect the safety, rights and well-being of currently enrolled participants,
 - Whether participants should be informed of the termination or suspension,
 - Whether adverse events or outcomes should be reported to the REB,
 - Identification of a time frame in which the corrective measures are to be implemented;
- 5.2.5 The REB Chair or designee will notify the Researcher of any suspensions or terminations of REB approval, and the reasons for the decision;
- 5.2.6 Unless otherwise stated by the REB, when the REB Chair or designee suspends or terminates ethics approval of the research, no further activities can take place other than the submission of an amendment or reportable events;

5.2.7 If the research is suspended or terminated, the REB Chair or designee will issue

a formal letter to the Researcher with the reason(s) for the REB action and the corrective measures proposed by the REB (if any);

- 5.2.8 Suspensions may be lifted after corrective actions are completed to the REB's satisfaction.

5.3 Reporting Suspensions or Terminations

The REB Chair or designee will report any suspension or termination of REB approval to the appropriate Organizational Official(s).

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP407.001		Original version