

Procedures: Human Research Ethics

SOP 407 Suspension or Termination of REB Approval

Associated Policy	Human Research Ethics Policy AR-03
Procedure Holder	Associate Vice President Research
Executive Lead	Research Services
Approval Authority	President
Original Date	Replaces AR-03 procedures (May 2009, Oct. 2014)
Effective Date	July 2022

1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures associated with the suspension or termination of the Research Ethics Board's (REB) approval of research.

2.0 SCOPE

This SOP pertains to all research submitted to the YukonU REB for the review of human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

All REB members and Research Ethics Coordinator 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 Co-Chairs or designee are/is not authorized to terminate REB approval; however, the REB Co-Chairs 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 Co-Chairs or designee shall notify the Researcher, and the appropriate YukonU Official(s), of any suspension or termination of REB approval of the research and has the authority to notify the regulatory authorities (as applicable) and the Sponsor.

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; for example, cases in which there are high numbers of unexpected serious adverse events, or when there is evidence that the Researcher is not conducting the research in compliance with applicable regulations and guidelines. The REB also has the authority to suspend new enrollment while additional information is requested.

A decision to suspend or to terminate the REB's approval of the research must include consideration of the safety, rights and well-being of the participants already enrolled in the research; specifically, how to continue the care of enrolled participants, and how and when the notification to participants of the suspension or termination of the research will take place.

The REB has the authority to suspend or to terminate the REB's approval of the research. The REB Co-Chairs or designee have/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 by the Sponsor

- 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 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 of the research by the sponsor will be forwarded to the REB Co-Chairs or designee for review;
- 5.1.4 If the REB Co-Chairs or designee decide(s) to suspend REB approval of the research, they must notify the REB at its next Full Board meeting;
- 5.1.5 If REB approval is suspended, a subsequent review must be conducted and the REB suspension must be lifted prior to resumption of the research following the sponsor's

lifting of a suspension.

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:

- 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),
- Falsification of research records or data,
- 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 comply with conditions placed on the research by the REB, by the sponsor, or by regulatory agencies,
- 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.
- Any other non-conformity which the REB or the University considers to have serious implications to the safety of the participants or the integrity of the study

5.2.2 The REB Co-Chairs or designee are authorized to suspend REB approval of research. If the Chair or designee suspends approval of the research, they must notify the REB at its next Full Board meeting;

5.2.3 If a Yukon University official suspends approval of research they must notify the REB as per applicable requirements;

5.2.4 If a YukonU official suspends approval of the research, the Principal Investigator shall be notified of the requirement to suspend the study, the reasons for the suspension and the requirement that the REB be notified immediately

5.2.5 The REB is authorized to terminate its approval of the research following a review at a Full Board meeting;

5.2.6 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,
- The appropriate care and monitoring of research participants,
- Whether withdrawal of enrolled participants is warranted and the specific procedures for their safe withdrawal,
- 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;

5.2.7 The REB Co-Chairs or designee will notify the Researcher of any suspensions or terminations of REB approval, and the reasons for the decision;

5.2.8 Unless otherwise stated by the REB, when the REB Co-Chairs 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;

5.2.9 If the research is suspended or terminated, the REB Co-Chairs or designee will issue a formal letter to the Researcher with the reason(s) for the REB action and will enter into a dialogue with the Researcher concerning corrective measures proposed by the REB;

5.2.10 If REB approval of a research or if the conduct of the research has been suspended, the suspension may be lifted after corrective actions are completed to the REB's satisfaction.

5.2.11 In the event of such a suspension or termination, the REB will take appropriate actions to protect the rights and welfare of the currently enrolled participants in suspended or terminated research.

5.3 Reporting Suspensions or Terminations

The REB Co-Chair or designee will report any suspension or termination of REB approval to the Associate Vice-President Research.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 407	July 2022	YukonU version adapted from N2/CAREB SOP 407.003 (October 8, 2019) and CAREB SOP407.001 (2021)