TITLE	**407: Suspensions, Terminations and Cancellations of Approval**
SCOPE	All health research submitted to the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	April 2024

1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures associated with the suspension, termination or cancellation of the HREB's approval of research (including the suspension, termination or cancellation of approval).

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 RESPONSIBILITIES

HREB members and Research Ethics Office (REO) Personnel are responsible for ensuring that the requirements of this SOP are met.

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

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

The HREB Chairperson or designee is not authorized to cancel HREB approval; however, the HREB Chairperson or designee is authorized to suspend HREB approval, which must be reported to the HREB at its next Full Board meeting. The HREB is authorized to cancel HREB approval following its review at a Full Board meeting.

The HREB Chairperson or designee shall notify the Researcher, and the appropriate officials at the Researcher's organization, as applicable, of any suspension or cancellation of HREB approval of the research and has the authority to notify the regulatory authorities (as applicable) and the Sponsor. The HREB may delegate regulatory authority reporting to the Researcher's organization, as applicable.

As per section 26 of the HREA Act, where the HREA and/or HREB believes, on reasonable grounds, that a person has failed to comply with a determination or direction of the HREB, the matter shall be referred to the appropriate official of the licensing body of the profession of which the person is a member who shall deal with it as an allegation. Where a person is not licensed under an Act to regulate a health care or other profession, the failure to comply with a determination or direction of the HREB shall be communicated to the person's employer.

4.0 PROCEDURE

As a result of ongoing review activities, the HREB may require that research be modified, or may suspend or cancel HREB 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 legislation, regulations and guidelines. The HREB also has the authority to suspend new enrollment while additional information is requested.

A decision to suspend or to cancel the HREB'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 cancellation of the research will take place.

The HREB has the authority to suspend or to cancel the HREB's approval of the research. The HREB Chairperson 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.

For studies funded by the U.S. Federal Government, applicable regulations require that the HREB have the authority to suspend or terminate research.

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

4.1 Suspension or Terminations of Research by the Sponsor

4.1.1 The sponsor of the research may suspend or terminate the research (e.g., following results of interim analyses, due to inadequate drug availability, in response to a Data and Safety Monitoring Board (DSMB) recommendation, due to pre-planned stopping criteria).

4.1.2 The Researcher must immediately notify the HREB of any suspensions or terminations of the research and the reasons for the action.

4.1.3 Reports of suspensions or terminations of the research by the sponsor will be forwarded to the HREB Chairperson or designee for review.

4.1.4 If the HREB Chairperson or designee suspends HREB approval of the research, he/she must notify the HREB at its next Full Board meeting.

4.1.5 If HREB approval is suspended, a subsequent review must be conducted and the HREB suspension must be lifted prior to resumption of the research following the sponsor's lifting of a suspension.

4.2 Suspension or Cancellation of HREB Approval

4.2.1 If any concerns are raised during the HREB's oversight of the research that are related to new information or to the conduct of the research, the HREB may suspend or cancel its approval of the research as appropriate. These concerns may include the following:

- the research not being conducted in accordance with the HREB-approved protocol or HREB requirements;
- the research is associated with unexpected serious harm to participants (i.e., as may be determined following HREB review of reportable events or DSMB reports);
- falsification of research records or data;
- failure to comply with prior conditions imposed by the HREB (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 limit administration of the investigational drug or device to those research participants under the Researcher's supervision;
- repeated or deliberate failure to comply with conditions placed on the research by the HREB, by the sponsor, or by regulatory agencies;
- repeated or deliberate failure to obtain prior HREB review and approval of amendments or modifications to the research;
- repeated or deliberate failure to maintain accurate research records or submit required reportable event reports to the HREB; or
- any other non-conformity which the HREB considers to have serious implications to the safety of the participants or the integrity of the study.

4.2.2 The HREB Chairperson or designee is authorized to suspend HREB approval of research. If the HREB Chairperson or designee suspends approval of the research, he/she must notify the HREB at its next Full Board meeting.

4.2.3 The HREB is authorized to cancel its approval of the research following a review at a Full Board meeting.

4.2.4 Prior to suspending or cancelling HREB approval, the HREB 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;

- the appropriateness/feasibility of withdrawal of enrolled participants and the specific procedures for their safe withdrawal;
- the appropriateness/feasibility of informing participants of the suspension or cancellation;
- the appropriateness/feasibility of requiring the applicant to report adverse events or outcomes to the HREB; and
- identification of a time frame in which the corrective measures are to be implemented.

4.2.5 The HREB Chairperson or designee will notify the Researcher of any suspensions or cancellations of HREB approval, and the reasons for the decision.

4.2.6 Unless otherwise stated by the HREB, when the HREB Chairperson or designee suspends or cancels ethics approval of the research, no further activities can take place other than the submission of an amendment or reportable events.

4.2.7 If the research is suspended or cancelled, the HREB Chairperson or designee will issue a formal letter to the Researcher with the reason(s) for the HREB action and the corrective measures proposed by the HREB.

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

4.2.9 In the event of such a suspension or cancellation, the HREB will take appropriate actions to protect the rights and welfare of the currently enrolled participants in suspended or cancelled research.

4.3 Reporting Suspensions, Terminations or Cancellations

4.3.1 The HREB Chairperson or designee will report any suspension or cancellation of HREB approval to the appropriate officials at the Researcher's organization, as applicable. The HREB has the authority to notify the regulatory authorities and the sponsor as applicable and may delegate regulatory authority reporting to the Researcher's organization, as applicable.

4.3.2 As per section 26 of the HREA Act, where the HREA and/or HREB believes, on reasonable grounds, that a person has failed to comply with a determination or direction of the HREB, the matter shall be referred to the appropriate official of the licensing body of the profession of which the person is a member who shall deal with it as an allegation.

4.3.3 Where a person is not licensed under an Act to regulate a health care or other profession, the failure to comply with a determination or direction of the HREB shall be communicated to the person's employer.

4.3.4 In accordance with U.S. Federal regulations, the HREB shall report any suspensions or cancellations for cause, and any serious or continuing non-compliance to the requirements

of the HREB by a Researcher in relation to a study funded or supported by the U.S. Federal Government to the appropriate federal regulatory authorities.

5.0 REFERENCES

Health Research Ethics Authority Act: An act to establish a health research ethics authority for the province. (2011). Retrieved from: SNL2006 CHAPTER H-1.2 - HEALTH RESEARCH ETHICS AUTHORITY ACT (assembly.nl.ca)

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 6: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022) (ethics.gc.ca)

U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.113): Electronic Code of Federal Regulations (eCFR)

U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.108): Electronic Code of Federal Regulations (eCFR)