Purpose:	To provide Island Health a standardized approach to describe the procedures associated with the suspension or termination of the Research Ethics Board's (REB's) approval of research, including the suspension or termination of approval, and administrative holds requested by the Sponsor or the Researcher.
Context:	Island Health offers programs and services on the unceded and traditional territories of the Coast Salish, Nuu-chah-nulth, and Kwakwaka'wakw Peoples. As a signatory to the 2015 Declaration of Commitment to Cultural Safety and Cultural Humility, Island Health is committed to addressing the ongoing impacts of colonialism and Indigenous-specific racism in order to provide a culturally safe, inclusive, healthy and respectful environment. The organization is committed to strengthening diversity, equity and inclusion to enable excellence in health and care for everyone, everywhere, every time. Through these commitments, Island Health strives to deliver the highest possible standard of care and to promote safe workplaces.

Scope:	• Affected Roles
	  ○ All REB Chairs
	  ○ All REB Members
	  ○ All REB Office Personnel
	• Environment
	  ○ Research Environment
	• This SOP (Standard Operating Procedure) applies to all research submitted to Island Health's REBs.

Outcomes:	• Procedures associated with the suspension or termination of the Research Ethics Board's (REB) approval of research (including the suspension or termination of approval) .

1 Responsibility

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 by the Sponsor 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 shall notify the Researcher, and the Organizational 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. The REB may delegate regulatory authority reporting to the organization.

2 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 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.

For studies funded by the United States (U.S.) Federal Government, applicable regulations require that the REB 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 REB approval.

2.1 Suspension or Terminations of Research by the Sponsor

2.1.1 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, etc.);

2.1.2 The Researcher must immediately notify the REB of any suspensions or terminations of the research and the reasons for the action;

2.1.3 Reports of suspensions or terminations of the research by the Sponsor will be forwarded to the REB Chair or designee for review;

2.1.4 If the REB Chair or designee decides to suspend REB approval of the research, they must notify the REB at its next Full Board meeting;

2.1.5 Following the Sponsor's lifting of a suspension, if REB approval is suspended, a subsequent review must be conducted and the REB suspension must be lifted prior to resumption of the research.

2.2 **Suspension or Termination of REB Approval**

2.2.1 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 (e.g. as may be determined following REB review of reportable events or DSMB reports);
- Falsification of research records or data;
- Failure to comply with prior conditions imposed by the REB (e.g. 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 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;
- Repeated or deliberate failure to maintain accurate research records or submit required reportable event reports to the REB; or
- Any other non-conformity which the REB or Island Health considers to have serious implications to the safety of the participants or the integrity of the study.

2.2.2 The following individuals are authorized to suspend REB approval pending review by the REB responsible for continuing review of the protocol:

- Organizational Official;
- REB Chair or their designee; or
- Vice-President Knowledge, Practice and Chief Nurse Executive.

2.2.3 If an Island Health official suspends approval of the research, they must notify the REB as per applicable requirements.

2.2.4 If an Island Health official suspends approval of the research, the Principal/Qualified Investigator (PI/QI) shall be notified of:

- The requirement to suspend the study;
- The reasons for the suspension; and
- The requirement that the REB be notified immediately.

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

2.2.6 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; and
- Identification of a time frame in which the corrective measures are to be implemented.

2.2.7 The REB Chair or designee will notify the Researcher of any suspensions or terminations of REB approval, and the reasons for the decision.

2.2.8 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.

2.2.9 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 will enter into a dialogue with the Researcher concerning potential corrective measures proposed by the REB.

2.2.10 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.

2.3 Reporting Suspensions or Terminations

2.3.1 The REB Chair or designee will report any suspension or termination of REB approval to the Vice-President, Knowledge, Practice and Chief Nurse Executive or their designee, and has the authority to notify the regulatory authorities (as applicable), and the Sponsor. The REB may delegate regulatory authority reporting to the organization.

2.3.2 In accordance with U.S. Federal regulations, the REB shall report any suspensions or terminations for cause, and any serious or continuing non-compliance to the requirements of the REB by a Researcher in relation to a study funded or supported by the U.S. Federal Government to the appropriate federal regulatory authorities.

3 Training

3.1 Review of the SOP.

4 Compliance Monitoring

4.1 The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for ongoing monitoring of Island Health operations to verify compliance with this SOP.

4.2 The Island Health Manager, Research Ethics &Compliance or their delegate is responsible for communicating any changes to this SOP to all relevant personnel.

4.3 Deviations from this SOP will be addressed through corrective and preventative action implementation.

5 Definitions

- Refer to the Glossary of Terms – Research Ethics

6 References

- University of British Columbia, SOP 407 Administrative Holds, Terminations and Suspensions of Approval
- Network of Networks, SOP 407.003 Suspension or Termination of REB Approval
- U.S. Department of Health & Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.113
- U.S. Department of Health & Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.108(b)(3))

7 Summary of Changes

Version	Effective Date	Change Description
1.0	09 JAN 2023	New procedure