RR1200 – SUSPENSIONS AND TERMINATIONS OF RESEARCH ETHICS BOARD APPROVAL

Interior Health would like to recognize and acknowledge the traditional, ancestral, and unceded territories of the Dãkelh Dené, Ktunaxa, Nlaka'pamux, Secwépemc, St'át'imc, Syilx, and Tŝilhqot'in Nations, where we live, learn, collaborate and work together.

Interior Health recognizes that diversity in the workplace shapes values, attitudes, expectations, perception of self and others and in turn impacts behaviors in the workplace. The dimensions of a diverse workplace includes the protected characteristics under the human rights code of: race, color, ancestry, place of origin, political belief, religion, marital status, family status, physical disability, mental disability, sex, sexual orientation, gender identity or expression, age, criminal or summary conviction unrelated to employment.

1.0 PURPOSE

To describe the actions of the Interior Health (IH) Research Ethics Board (REB) required for administrative Suspensions requested by the researcher or sponsor, or suspending or terminating a previously approved research project for cause.

2.0 DEFINITIONS

TERM	DEFINITION
Suspension:	*A temporary or permanent halt to all research activities pending future action by the REB, the sponsor and/or the researcher.*
Termination:	*A permanent halt by the REB, by the sponsor and/or by the researcher to all or some research activities.*

3.0 POLICY

3.1 The REB is responsible for determining whether any information received throughout the course of a research project requires the Suspension or Termination of REB approval for that project.

3.2 As a result of ongoing review activities, the REB may require that the research be modified, or may suspend or terminate ethical approval if the risks to the research participants are determined to be unreasonably high. Examples are projects 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 policies. The REB also has the authority to suspend new enrollment while additional information is requested.

3.3 The REB must consider the safety, rights and well-being of the participants already enrolled in the research before deciding to suspend or terminate any project. Specifically, the REB must consider 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.

3.4 The Chair or Designee is not authorized to terminate REB approval; however, the Chair or Designee is authorized to suspend REB approval, which must be reported to the REB at the next full Board meeting. The REB is authorized to terminate REB approval following its review at a full Board meeting.

3.5 Any requests to lift a Suspension or to reapprove the research must be reviewed by the REB at a full Board meeting.

3.6 The REB Chair or Designee shall notify institutional officials as well as the researcher of the REB's decision to suspend or terminate REB approval of a research project.

4.0 PROCEDURES

4.1 Researcher or Sponsor Initiated Suspension

4.1.1 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.

4.1.2 The researcher is responsible for providing written notification to the REB and the IH site investigator of any Suspensions or Terminations of the research by the sponsor, and providing a detailed explanation for the action.

4.1.3 The researcher must notify participants affected by the decision to suspend or terminate the research.

4.1.4 The researcher must notify the REB that the researcher or sponsor intends to lift the voluntary Suspension prior to resuming any research activity, via the submission of an Amendment application. The researcher shall not resume any research activity until the REB has approved the Amendment.

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4.2 Suspension or Termination of REB Approval

4.2.1 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:

4.2.1.1 The research not being conducted in accordance with the REB-approved application documents or REB requirements;

4.2.1.2 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);

4.2.1.3 Failure to comply with prior conditions imposed by the REB (e.g., under a Suspension or provisional approval);

4.2.1.4 Repeated or deliberate failure to properly obtain or document consent from research participants;

4.2.1.5 Repeated or deliberate failure to limit administration of the investigational drug or device to those research participants under the researcher's supervision;

4.2.1.6 Repeated or deliberate failure to comply with conditions placed on the research by the REB, by the sponsor, or by regulatory agencies;

4.2.1.7 Repeated or deliberate failure to obtain prior REB review and approval of amendments to the research; or

4.2.1.8 Repeated or deliberate failure to maintain accurate research records or submit required reportable event reports to the REB.

4.2.1.9 Falsification of research records or data;

4.2.2 The Chair, Designee, or institutional officials are 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.

4.2.3 If an institutional official suspends approval, s/he must notify the REB. Institutional officials may include the Chief Nursing and Allied Health Officer and Professional Practice Leader (CNO), the Vice President,

Human Resources, Population Health and Pandemic Response (VP HR), or another member of the Senior Executive Team.

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

4.2.5 Prior to suspending or terminating REB approval, the REB must consider:

4.2.5.1 Risks to current participants;

4.2.5.2 Actions to protect the safety, rights and well-being of currently enrolled participants;

4.2.5.3 The appropriate care and monitoring of research participants;

4.2.5.4 Whether withdrawal of enrolled participants is warranted and the specific procedures for their safe withdrawal;

4.2.5.5 Whether adverse events or outcomes should be reported to the REB;

4.2.5.6 Identification of a time frame in which the corrective measures are to be implemented.

4.2.6 The Chair or Designee will notify the researcher of any Suspensions or Terminations of REB approval, and the reasons for the decision.

4.2.7 Unless otherwise stated by the REB, when the 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.

4.2.8 If the research is suspended or terminated, the 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.

4.2.9 If REB approval of a research project has been suspended, the Suspension may be lifted after corrective actions are completed to the REB's satisfaction.

4.3 Reporting Suspensions or Terminations

4.3.1 The Chair or Designee will report any Suspension or Termination of REB approval to the VP HR via the CNO and has the authority to notify the regulatory authorities (as applicable), and the sponsor. The VP HR may refer the matter to the IH Board as appropriate. The REB may delegate regulatory authority reporting (as applicable) to the institution per policy *RA0900 Reportable Events*.

4.3.2 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 research project funded or supported by the U.S. federal government to the appropriate federal regulatory authorities.

5.0 REFERENCES

1. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedure 407.003: Suspension or Termination of REB Approval.

2. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Article 6.15, December 2022.

3. Fraser Health Authority. (2021). Research and Evaluation Policy: *The Ethical Conduct of Research and Other Studies Involving Human Participants*.

4. Interior Health. (2022). Research Policy Manual: RA0900 Reportable Events.

5. Interior Health. (2022). Research Ethics Manual: RR1100 REB Management of Non-Compliance.

6. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH Harmonized Guideline, Integrated Addendum to ICH E6 (R1); *Guideline for Good Clinical Practice*, E6(R2), November 9, 2016.

7. Office for Human Research Protections (2022) Guidance on Reporting Incidents. Accessed on June 7, 2023 at Guidance on Reporting Incidents to OHRP (2011) | HHS.gov

8. UBC Office of Research Ethics. (2022). Standard Operating Procedure 407: *Administrative Holds, Terminations and Suspensions of Approval*.

9. US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46, section 46.113).

10. US Food and Drug Administration Code of Federal Regulations, Title 21, Volume 1: Part 56, Institutional Review Boards, (21CFR56, section 56.113).