RR1400 – RESEARCH PARTICIPANT CONCERNS

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 that must be taken by the Interior Health (IH) Research Ethics Board (REB) in response to concerns from Participants in Research that has been approved by the IH REB and is being conducted under the auspices of Interior Health.

2.0 DEFINITIONS

TERM	DEFINITION
Research:	*An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.*
Participant:	*An individual whose data or responses to interventions, stimuli, or questions by a researcher are relevant to answering a Research question; also referred to as "Human Participant" in Canada. In other policies and guidance the terms "subject" or "Research Subject" are used.*

3.0 POLICY

3.1 The REB respects the three core principles of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*: respect for persons, concern for welfare and justice.

3.2 Research Participants should be able to voice their concerns, questions and request information regarding their participation or potential participation in Research, in confidence, to an informed individual on the REB.

3.3 Research Participants are encouraged to contact (by telephone or in writing) the REB with questions and concerns, using the contact information provided in the informed consent document(s). If requested, the identity of the Participant will not be recorded or shared.

3.4 The REB will respond to a concern received from a Research Participant and work with the Participant to obtain a description of the concern and resolve issues to the satisfaction of the Participant

4.0 PROCEDURES

4.1 Research Ethics Board Coordinator

4.1.1 Receives the concern by email, in writing, or by phone.

4.1.2 Notifies the Chair of the concern.

4.1.3 Reviews the concern with the Participant and informs him/her of the right to withdraw from the Research project at any time. Reaffirms that withdrawing will have no impact on their medical care, employment, or any other benefit to which they are entitled. Resolves the concern, if possible, to the satisfaction of the Research Participant.

4.1.4 Informs the Research Participant that he/she may contact the Chair directly to review the concern if it has not been resolved. If the Participant wishes, the REB Coordinator will pass his/her contact information to the Chair for follow up with them.

4.1.5 Documents all conversations and interventions related to resolution of the concern. In the event the Participant chooses to withdraw from the study, ensures all appropriate documentation is completed and filed in the study file. The records should be de-identified and maintained securely in the relevant study file.

4.1.6 Provides a written report of the investigation and resolution to the Research Participant and the researcher, for any investigations which are not referred to the Chair.

4.2 REB Chair

4.2.1 Investigates concerns referred to the Chair and documents all conversations with the Research Participant, researcher or other involved persons.

4.2.2 Reviews the concern with the Participant and informs him/her of the right to withdraw from the Research project at any time. Reaffirms that withdrawing will have no impact on their medical care, employment, or any other benefit to which they are entitled. Resolves the concern, if possible, to the satisfaction of the Research Participant.

4.2.3 Documents all conversations and interventions related to resolution of the concern. In the event the Participant chooses to withdraw from the study, ensures all appropriate documentation is completed and filed in the study file. The records should be de-identified and maintained securely in the relevant study file.

4.2.4 Provides a written report of the investigation and resolution to the Research Participant and the researcher.

4.2.5 Informs the researcher of any actions to be taken and arranges for monitoring if necessary.

4.2.6 Notifies the REB of the concern at the next scheduled REB meeting and keeps REB members informed of the status of the investigation until it is resolved.

4.2.7 Notifies the Chief Nursing and Allied Health Officer and Professional Practice Leader (CNO) as appropriate.

4.2.8 The Chair and/or CNO may report the concern to other parties such as the IH site Executive Director, the IH Vice President Human Resources (VP HR), the sponsor, a partner REB, or a regulatory authority if required per the circumstances of the event, and/or per policy *RA0900 Reportable Events*.

4.2.9 If the concern cannot be resolved, the Participant will be referred to the process in the IH Board policy *3.15 Safe Reporting*.

4.3 Researcher

4.3.1 Notifies REB Chair promptly of any Participant concerns received.

4.3.2 Works with Participant to ensure the prompt and smooth withdrawal from the Research project, should the Participant choose to withdraw.

4.3.3 Applies to the REB for an Amendment to the protocol should the outcome of the investigation into the complaint necessitate changes.

4.3.4 If the complaint is not resolved and pertains to a matter that may pose risk to other Participants, suspends the Research until such time as the matter is resolved and/or the risk to Participants is removed.

4.3.5 Receives and complies with direction from the REB and/or the CNO or VP HR regarding further actions to be taken.

5.0 REFERENCES

1. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedure 602.003: *Communication – Research Participants*.

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*, December 2022.

3. 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.

4. Interior Health. (2018). Board Policy Manual: 3.15 Safe Reporting.

5. UBC (2018) Standard Operating Procedure 602: *Communication – Research Participants*