RA0400 – RESEARCH ETHICS BOARD MEETING ADMINISTRATION

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 provide direction for the preparation, management and documentation of Interior Health (IH) Research Ethics Board (REB) meetings to ensure compliance with regulatory and institutional requirements.

2.0 DEFINITIONS

3.0 POLICY

The Chair has overall responsibility for ensuring that the REB meets regulatory and institutional requirements and the principles for REB meetings as outlined in the *Tri-Council Policy Statement,* Health Canada regulations, and the *US Code of Federal Regulations*.

The REB reviews proposed research at regularly scheduled meetings at which requirements for quorum and representation are met according to the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans* (TCPS2) and the *REB Terms of Reference*.

3.1 Quorum

3.1.1 A quorum is a majority (50% plus 1) of the standing and substitute members of the REB, and includes members representing the capacities outlined in the *REB Terms of Reference*. The Chair will ensure that quorum requirements are met for the duration of each meeting. Should

quorum fail during a full board meeting (e.g. through recusal of REB members with conflicts of interest or early departures), the REB may not make further decisions unless quorum can be restored.

3.1.2 At the start of the meeting, REB members are reminded of their obligation to orally declare any real, potential or perceived Conflicts of Interest (COI). COI are documented in the meeting minutes. If recused, the REB member must abstain from voting on matters related to the conflict.

3.2 Ad Hoc Advisors and Observers

3.2.1 Observers may attend a REB meeting by invitation of the Chair.

3.2.2 An ad hoc advisor with expertise and competence in special areas may be invited to assist in the review of issues that require that expertise beyond or in addition to that available to the REB. The ad hoc advisor may be asked to participate in the REB meeting discussion but may not contribute directly to the REB's decision or vote, and their presence or absence will not be used in establishing a quorum.

3.2.3 Documentation of key information provided by the ad hoc advisor will be summarized in the meeting minutes and his/her written report (if applicable) will be added to the study file.

3.2.4 Where the REB finds that an observer qualifies as an expert in relation to the research under consideration, the observer may be allowed to contribute input if it is relevant and significant to the discussion. Observers shall not be counted in the quorum, or participate when the REB discusses its decision, reaches consensus or votes on the application.

3.2.5 All external ad hoc advisors and observers will sign a confidentiality form and agree to abide by the REB conflict of interest and confidentiality policies.

3.3 Meeting Attendance:

REB members are situated in various locations and may attend a REB meeting in person, via teleconference, or via videoconference. All members will be able to participate in the review of the research application discussion and voting. To allow for appropriate discussion to take place, all members must be

connected simultaneously. Telephone polling, where members are contacted individually, will not be accepted as a conference call.

3.4 Primary Reviewers

3.4.1 Prior to the meeting, the Research Ethics Board Coordinator and/or the Chair will identify primary reviewers for each research project. Post-approval activities that require full Board review in accordance with regulatory or sponsor requirements will be assigned to at least one primary reviewer, which may be the REB Coordinator or one of the primary reviewers of the original study.

3.4.2 Primary reviewers will receive copies of all research project documents submitted with the application for the project they are assigned.

3.4.3 No REB member will be assigned as reviewer for a project in which they are named as a member of the research team. If a project is inadvertently assigned to a REB member with a conflict of interest, the member will notify the REB Coordinator immediately. If an assigned reviewer declares a conflict, the submission will be reassigned to another reviewer.

3.5 Researcher Attendance

The Chair, in consultation with the primary reviewers, may invite the PI or the PI's delegate to attend a REB meeting to address questions about the research application. The Chair will ensure that the invitees attend only that portion of the meeting necessary to address concerns. The PI or delegate cannot attend the reviewer's presentation, the vote or the discussion of any project including his/her own.

3.6 Meeting Materials

3.6.1 REB meeting materials will be uploaded to the secure REB ExtraNet site and members notified of the agenda package availability in sufficient time prior to the meeting to allow for adequate review.

3.6.2 Meeting materials will include:

3.6.2.1 Meeting agenda

3.6.2.2 Previous meeting minutes in draft

3.6.2.3 Reports on research activities

3.6.2.4 The complete application package as submitted for new studies under review and for post-approval activities requiring full board review.

3.6.2.5 Information related to business items.

3.6.3 All REB members in attendance are expected to access the meeting materials they have received.

3.6.4 Primary reviewers will submit their completed *Application Review Form* to the Research Ethics Board Coordinator or post their review in RISe in advance of the meeting.

3.7 Meeting Documentation

3.7.1 The REB Coordinator will record minutes of each REB meeting. Documentation will include:

3.7.1.1 Start and end times;

3.7.1.2 Attendance including REB members, guests, and staff;

3.7.1.3 Acknowledgement of the Traditional Territories on which the meeting is taking place;

3.7.1.4 Excusal and re-entry to the REB meeting of any person during the meeting;

3.7.1.5 Any declarations of conflict of interest;

3.7.1.6 Action on agenda items;

3.7.1.7 Summary of discussion and decisions; and

3.7.1.8 Voting for each decision, including: number of votes for, number of votes against and number of members who abstained.

3.7.2 For U.S. federally funded or regulated studies, the minutes will reflect: discussion of risks and benefits to participants, equitable selection of

participants, informed consent process, monitoring of data, protection of privacy, and protection of the rights and welfare of vulnerable participants.

3.7.3 The REB meeting minutes document the actions that occur during a REB meeting and should enable a reader who was not present at the meeting to determine how and with what justification the REB arrived at its decisions. They should also provide the REB with sufficient detail to help it reconstruct the discussion at a later date if required.

3.7.4 Meeting minutes are sent to REB members with each meeting agenda package in draft form and reviewed and approved by consensus at the following meeting. Any corrections requested by REB members will be noted in the approved version of the minutes.

3.7.5 REB meeting minutes are available to the institution, researchers, funding agencies and other relevant authorities involved in research as required. All requests for access to minutes must be reviewed by the Chair and the IH Freedom of Information Office.

3.7.6 All REB meeting documents are filed by the Research Ethics Board Coordinator and retained for twenty-five years per IH policyAL0700 Records - Retention, Storage and Destruction of.

4.0 PROCEDURES

4.1 Research Ethics Board Coordinator

Schedules meeting dates; books meeting room and videoconference; prepares agenda package and uploads it to the REB ExtraNet site; circulates meeting invitations to members and guests; takes the minutes; and prepares the provisos and/or Approval Certificates related to studies and post-approval activities reviewed at the meeting.

4.2 REB members

4.2.1 Standing members are expected to regularly attend all REB meetings.

4.2.2 Substitute members are invited to attend all REB meetings to promote their continuous learning, but are not required to do so unless they are filling in for a standing member at the request of the Chair, in order to provide expertise as a Primary Reviewer or to

achieve quorum.

4.2.3 Substitute members attending a meeting assume the privilege of a single vote for REB decisions at that meeting.

4.2.4 All members will provide one week's notice to the REB Coordinator if they cannot attend a meeting to ensure that quorum can still be met and/or so that an appropriate alternate may attend in his/her place.

4.2.5 All members are expected to review the meeting materials distributed in the meeting package in advance, and to be prepared to discuss each agenda item and provide input at the full Board meeting.

4.2.6 REB members assigned as primary reviewers will conduct and present their review at the meeting and submit their *Application Review Form* to the REB Coordinator or post it in the RISe study file.

4.3 REB Chair

4.3.1 Responsible for presiding over REB meetings.

4.3.2 Ensures that quorum requirements of membership representation are met at each meeting.

4.3.3 May assume the role of 'one member knowledgeable in ethics' if required to meet membership requirements.

4.3.4 Ensures that the total number of votes cast plus absentions regarding any matter being considered by the REB matches the number of voting members present.

4.3.5 Prepares or reviews the written communication to researchers conveying REB decisions.

4.3.6 Reports on matters of interest to the REB.

5.0 REFERENCES

1. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedure 203.003: *Duties of REB Members*.

2. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedure 302.003: *REB Meeting Administration*.

3. 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.

4. Interior Health (2018). Administrative Policy Manual: AD0100 Welcome and Acknowledgement of First Nation Traditional Territory.

5. Interior Health. (2022). Administrative Policy Manual: AL0700 Records - Retention, Storage and Destruction of.

6. Interior Health (2023). Administrative Policy Manual: AR0400 - Privacy and Management of Confidential Information

7. Interior Health (2017). Administrative Policy Manual: AF0100 - Transparency and Freedom of Information.

8. Interior Health. (2021) Research Policy Manual: RA0700 - Confidentiality of Information.

9. Interior Health. (2019). IH Board Policy Manual: 3.18 *Research Ethics*

10. Interior Health (2023). *Research Ethics Board, Terms of Reference*.

11. 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.

12. UBC Office of Research Ethics. (2022). Standard Operating Procedure 302: *REB Meeting Administration*.