

## RA0200 – RESEARCH ETHICS BOARD MEMBERSHIP

Interior Health would like to recognize and acknowledge the traditional, ancestral, and unceded territories of the Dākelh Dené, Ktunaxa, Nlaka’pamux, Secwépemc, St’át’imc, Syilx, and T̓silhqot’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 composition and management of the Interior Health (IH) Research Ethics Board (REB) to ensure its functions comply with regulatory and institutional requirements pertaining to research involving human participants.

### 2.0 DEFINITIONS

TERM	DEFINITION
<i>Research Ethics Board</i>	<i>A body of researchers, community members, and others with specific expertise (e.g. in ethics or in relevant research disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution’s jurisdiction or under its auspices.</i>

### 3.0 POLICY

#### 3.1 Responsibility for Operations

3.1.1 The REB functions under the authority of the IH Board of Directors. The Board of Directors assigns responsibility for the REB’s organization and leadership to the President & CEO.

3.1.2 The REB is supported by the REB Coordinator who reports to the Chief Nursing and Allied Health Officer & Professional Practice Leader.

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3.2 Appointments

- 3.2.1 The President & CEO, acting on behalf of the Board of Directors will appoint, or remove, a Chair selected on the basis of experience and knowledge of research ethics.
- 3.2.2 The President & CEO, acting on behalf of the Board of Directors, will appoint or remove REB members.
- 3.2.3 The composition of membership for the REB is specified in the REB *Terms of Reference* and aligns with the requirements of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)* the International Conference on Harmonization Good Clinical Practice Guidelines, and the US Code of Federal Regulations.
- 3.2.4 Conditions of the terms of appointment for members are specified in the REB *Terms of Reference*. All members are expected to abide by IH policies for confidentiality of information and conflict of interest. IH employees sign an annual Information Privacy and Security Agreement as part of their employment. Community members will be asked to sign an annual Confidentiality Agreement.
- 3.2.5 The REB Chair or Designee monitors the REB membership composition for appropriate membership in relation to the nature and volume of research submissions and in accordance with TCPS2.

3.3 Resignations and Removals

- 3.3.1 A REB member may resign before the conclusion of his/her term upon provision of notice to the REB Chair or Designee.
- 3.3.2 In the event that a member misses a significant amount of meetings so that the Chair identifies a concern, the member will be asked to step down. The member’s resignation will be documented in their REB member file.
- 3.3.3 The REB Chair or Designee may otherwise remove a REB member at any time, if they are not fulfilling their designated REB duties in a timely, competent and ethical manner.
- 3.3.4 A REB member should resign immediately upon determination of research misconduct, mismanaged conflict of interest or any other

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relevant behavior that could be perceived as compromising his/her ethical judgment.

3.3.5 A REB member who accepts an employment, consultancy, or other position that would put them in a conflict of interest with their REB duties shall resign from the REB.

3.3.6 Upon the departure of a member, the composition of the REB shall be reviewed. Every effort will be made to recruit a similarly qualified replacement if required to preserve the level of experience and expertise and to ensure the continuity of the functions of the REB.

3.4 Compensation

3.4.1 The Chair is compensated, in alignment with other BC REB practices, in recognition of the leadership and responsibilities of the Chair role in overseeing the functions of the REB.

3.4.2 Participation by an IH employee as a REB member is considered a part of their employment and will not warrant additional compensation beyond reasonable expenses incurred through participation.

3.4.3 Participation by non-salaried physicians is compensated per Physician Compensation guidelines.

3.4.4 Community members will receive reimbursement for travel expenses according to IH policy *AP 0300 Travel Expense*.

3.5 Liability Insurance

REB members are indemnified by Interior Health insurance coverage supplied by the Health Care Protection Program (HCPP) while they are acting in their capacity as REB members.

**4.0 PROCEDURES**

4.1 IH President & CEO

4.1.1 Appoints members upon recommendation from the REB Chair.

4.1.2 Removes members as required to meet guidelines, legislative requirements, and/or operational requirements, upon recommendation from the REB Chair.

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4.2 REB Chair

- 4.2.1 Makes recommendations to the President & CEO to ensure continuity of experience and knowledge in REB membership.
- 4.2.2 The REB Chair or Designee is responsible for clearly articulating all required duties associated with membership to the potential and current REB members.
- 4.2.3 Together with the REB Coordinator, provides for the training and education requirements of REB members.
- 4.2.4 Together with the REB Coordinator is responsible for ensuring that REB members are informed of all new legislation, policies or guidelines which bear on REB review.
- 4.2.5 Recommends appointments and accepts resignations of REB members.

4.3 REB Members

- 4.3.1 Fulfill their responsibilities per the conditions of their terms of appointment as specified in the *REB Terms of Reference*.
- 4.3.2 Standing members are expected to attend the regularly scheduled REB meetings. REB members may be asked to step down if they regularly miss scheduled REB meetings.
- 4.3.3 Substitute members are invited to all meetings and are expected to come prepared to discuss agenda items and to vote.
- 4.3.4 Participate in education and training requirements relevant to their responsibilities.
- 4.3.5 Notify the Chair and REB Coordinator in writing of any intention to resign prior to the end of a term.

4.4 REB Coordinator

- 4.4.1 Provide consistency, expertise and administrative support to the REB. Duties may include:

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- 4.4.1.1 Pre-review of submissions to the REB;
- 4.4.1.2 Management of administrative issues involving REB research ethics oversight as described in REB policies;
- 4.4.1.3 Implementation of REB directives;
- 4.4.1.4 Provision of advice and information to the REB, researchers; and IH staff; and
- 4.4.1.5 Responding to requests for consultation on matters pertaining to research and research ethics.
- 4.4.2 Is designated as a REB member and expected to attend REB meetings; may participate in discussions but will not be counted in determining a quorum and will not have voting privileges.
- 4.4.3 May perform delegated reviews in accordance with the delegated review procedure.
- 4.4.4 Reviews the *REB Terms of Reference* and REB policies every three years or as required, makes recommendations for changes, and submits to the REB for review, and then to the Board of Directors for approval.
- 4.4.5 Maintains a roster of the REB membership including: names of members, their earned degrees and representative capacity; current and archived lists are retained according to Research Ethics policy [RA0500 REB Records Management](#).
- 4.4.6 Maintains the REB registration with the U.S. Office for Human Research Protection (OHRP) Federal Wide Assurance program.
- 4.4.7 Together with the Chair, provide for and document the education and training requirements for REB members.
- 4.4.8 Maintain REB member files including: CV, other supporting documents related to education, training and expertise, letter of appointment, and confidentiality agreements.
- 4.4.9 Participate in education and training requirements relevant to professional responsibilities.

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### 5.0 REFERENCES

1. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedure 104.003: *Management of REB Office Personnel*.
2. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedure 201.003: *Composition of the REB*.
3. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2019). Standard Operating Procedure 202.003: *Management of REB Membership*.
4. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedure 203.003: *Duties of REB Members*.
5. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedure 204.003: *REB Office Personnel Serving as REB Members*.
6. 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*, 2022.
7. Health Canada, Food and Drug Regulations, Part C, Division 5, *Drugs for Clinical Trials Involving Human Subjects* (GUI-0100), March 14, 2023 version 2.
8. 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.
9. Interior Health. (2022). Administrative Policy Manual: [AP0300 Travel and Meeting Expense](#).
10. Interior Health. (2023). *Research Ethics Board, Terms of Reference*.
11. Interior Health. (2023). Research Policy Manual: [RA0500 REB Records Management](#).
12. UBC Office of Research Ethics. (2022). Standard Operating Procedure 201: *Composition of the Board*.
13. UBC Office of Research Ethics. (2022). Standard Operating Procedure 202: *Management of the Board*.

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14. UBC Office of Research Ethics. (2022). Standard Operating Procedure 203: *Duties of REB Members*.
15. US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46).
16. US Food and Drug Administration Code of Federal Regulations, Title 21, Volume 1:
  - i. Part 50, Protection of Human Subjects, (21CFR50).
  - ii. Part 56, Institutional Review Boards, (21CFR56).

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