1. INTRODUCTION

(1) The Interior Health Authority (the “Authority”) is committed to exemplary standards of organizational behaviour and practice. Only by a consistent focus on this goal can the Authority earn and maintain the trust of those it serves, the staff and medical staff, those it does business with, and the public in general.

(2) Exemplary standards of organizational behaviour and practice includes active research and knowledge translation programs, and clear ethical frameworks that govern conduct and review of research and clinical activity that the Authority may engage in or support.

(3) Decision making independence in reviewing the ethical applicability of all research involving humans conducted by the Authority or with the support of the Authority is desired.

2. COMMITMENT TO RESEARCH AND KNOWLEDGE TRANSLATION

(1) The Authority has an objective of a well-focused, productive, and recognized research and knowledge translation program through:

(a) an active search for research opportunities that match organizational strength and capabilities;

(b) review of studies conducted within its jurisdiction or under its auspices;

(c) research knowledge sharing;

(d) participation in Provincial initiatives to expand health services research capacity in British Columbia; and

(e) a coordinated effort to develop collaborative research partnerships with university-based researchers and other health authorities.

(2) The Authority is an organization that:

(a) has the depth of resources and breadth of activity to support a broad research and knowledge translation program as part of the continuing search for knowledge, innovative health promotion techniques and new treatment options that will benefit those it serves and society as a whole;
(b) has an obligation to enhance research capacity and to use the knowledge gained to support evidence-based decisions and care delivery; and

(c) will ensure that ethical and other obligations of competent research are met through the establishment of a multi-disciplinary Research Ethics Board that is independent in its decision-making.

3. COMMITMENT TO ETHICAL RESEARCH

(1) All research that involves human subjects conducted by Authority staff and medical staff, in Authority facilities or programs, or in which the Authority is a collaborative partner, will be subject to initial and continuing ethics reviews throughout the duration of the undertaking to ensure that the:

(a) studies recognize, respect and protect the rights of individual human subjects and respect human dignity;

(b) proposed research interventions are morally and ethically acceptable; and

(c) researchers meet their obligations regarding honest and thoughtful inquiry, rigorous analysis, high scientific standards, and professional criteria.

(2) Researchers enjoy important freedoms and privileges that include freedom of inquiry and the right to disseminate the results thereof, freedom to challenge conventional thought, independence, and the privilege of conducting research involving human subjects.

(3) In addressing the obligations for ensuring ethical review, approval and conduct of research studies the Authority will be guided by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, which requires the establishment of an independent, multi-disciplinary research ethics process.
RESEARCH AND RESEARCH ETHICS

(4) The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans is a living document intended to provide ethical guidance to researchers and the Research Ethics Boards that oversee the ethical conduct of research involving humans in Canada. It provides a framework for Research Ethics Boards to identify and collaboratively resolve ethical issues in research in order to protect the interests of research participants, maximize the benefits of the research, and minimize the harms. It was produced for the three major Canadian research granting agencies by a 12-member, multi-disciplinary panel with membership drawn from across the country, with the assistance of a substantial number of expert working groups and a broad consultation process.

4. ADMINISTRATIVE PROGRAM

(1) The realization of these policy objectives will require an appropriate allocation of resources and the development of a comprehensive administrative program.

(2) This program must:
   (a) ensure the protection of research subjects;
   (b) ensure the protection of the Authority, including its medical, nursing and other staff as well as affiliated parties;
   (c) serve to encourage research that is beneficial to the Authority;
   (d) ensure the efficient use of available resources;
   (e) provide an environment that facilitates dialogue on research; and
   (f) promote the need to take ethical issues into consideration in all decision-making related to the research and knowledge translation program.

(3) The Authority’s research and knowledge translation program, and the Research Ethics Board, functions under the authority of the Board of Directors (the “Board”).

(4) The Board assigns to the President and Chief Executive Officer (the “CEO”) overall responsibility for the organization and leadership of the research and knowledge translation program.

(5) The CEO may re-assign specific accountabilities to a Director of Research, or other such individual(s), competent to guide and directly oversee the research and knowledge translation program and the Research Ethics Board.
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(6) The CEO, with the assistance of the Director of Research or other such individual(s), will develop for Board approval:

(a) a broad strategic plan for the enhancement and direction of the research and knowledge translation program in the Authority; and

(b) the Terms Of Reference For The Research Ethics Board.

(7) The CEO will assign the research and knowledge translation program and the Research Ethics Board appropriate priority in its corporate strategic and operational planning and ensure the provision of the required administrative support.

5. POLICY REVIEW

(1) This Policy, together with the research and knowledge translation strategic plan, and the Terms Of Reference For The Research Ethics Board will be reviewed from time to time in light of experience gained or at any time it becomes apparent that changes or additions are needed.
1. PURPOSE

To provide an independent multi-disciplinary body for the review of all research involving human participants conducted under the auspices of Interior Health: in Interior Health facilities/programs; by Interior Health staff or physicians; or with Interior Health staff, physicians and/or patients.¹

The Interior Health Research Ethics Board is compliant with the high ethical standards as set out in the following documents:

- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2);
- Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects;
- CAN/CGSB-191.1-2013: Research Ethics Oversight of Biomedical Clinical Trials;
- Health Canada Food and Drug Regulations Part C Division 5;

To ensure that the ethical obligations of research are met before the research commences, thereby protecting research participants, Interior Health and affiliated parties.
2. DEFINITIONS

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” and in other policies/guidance as “subject” or “research subject”.

3. ORGANIZATION

The Interior Health Research Ethics Board functions under the authority of the Interior Health Board of Directors. Responsibility for the Research Ethics Board’s organization and leadership is assigned by the Board of Directors to the President and Chief Executive Officer.

4. FUNCTIONS

The Research Ethics Board is established to review all research involving human participants guided by the ethical principles of respect for persons, concern for welfare and justice.

Specifically the Research Ethics Board has the authority to:

4.1 Establish the ethics review processes, and provide research ethics oversight to ensure the ethical conduct of the research;

4.2 Approve, require modifications to, or disapprove any research activity that falls within its jurisdiction;

4.3 Ensure that the researcher has policies and procedures to protect the rights, safety and welfare of research participants;

4.4 Request, receive and share any information involving the research that the Research Ethics Board considers necessary to fulfill its mandate, while maintaining confidentiality and respecting privacy;

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2 TCPS2, Glossary
3 TCPS2, Article 6.2
4 CAREB, SOP101.001
RESEARCH AND RESEARCH ETHICS

APPENDIX 1 – RESEARCH ETHICS BOARD TERMS OF REFERENCE

4.5 Conduct continuing ethical review to protect the rights, welfare and privacy of research participants;

4.6 Suspend or terminate the ethics approval for the research;

4.7 Place restrictions on the research;

4.8 Take any action considered reasonably necessary, and consistent with policies and procedures, to ensure the protection of the rights, safety, and well-being of participants in research conducted under the Research Ethics Board’s jurisdiction

4.9 Collaborate with other Research Ethics Boards where an agreement exists for harmonized ethical review of research involving human participants.

4.10 Cooperate with any Research Ethics Appeal Board that may be established by the President and Chief Executive Officer in response to an appeal of the Research Ethics Board’s decision regarding a proposal.

4.11 Respond to Enquiries from relevant regulatory authorities.

5. MEMBERSHIP

5.1 The standing members of the Research Ethics Board will consist of:

- A Chair appointed by the Interior Health Board of Directors in consultation with the President and Chief Executive Officer;
- An alternate Chair appointed by the Interior Health Board of Directors in consultation with the President and Chief Executive Officer to act during periods of unavailability of the Chair. The Alternate Chair will be selected from the standing members of the Research Ethics Board with recommendation from the Chair;
- A minimum of eight standing members appointed by the President and Chief Executive Officer in consultation with the Chair

Standing members shall include at least the following representation capacities:
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- Two members whose primary experience and expertise is in health sciences and who have broad experience in research methods. If the study is a clinical trial, one member will be from a medical discipline or, if the study is in respect of a drug to be used for dental purposes only, will be from a medical or dental discipline;
- One member knowledgeable in ethics;
- One member knowledgeable in relevant law;
- One member from the community who has no affiliation with Interior Health;\(^5\)
- One member whose primary experience and expertise lie outside health sciences;\(^6\)
- One member who is a current member of the University of British Columbia Okanagan Behavioral Research Ethics Board;
- One member from the faculty of the University of British Columbia Southern Medical Program.

Members shall normally serve in only one capacity. See Appendix A for role statements.

The majority of Research Ethics Board members will be Canadian citizens or permanent residents under the Immigration Act.

Research Ethics Board membership will consist of both men and women of varying backgrounds including consideration of race, gender, cultural backgrounds and community attitudes.

Each standing member has the privilege of registering a single vote for REB decisions.

Appointment of standing members is for a two year term with the option of reappointment for successive terms. Terms of appointment shall be balanced to maintain continuity while ensuring diversity of opinion, and reappointment is related to the needs of the Research Ethics Board.

Research Ethics Board membership is reviewed annually to ensure an adequate roster of standing members, substitute members, and reviewers.

\(^5\) TCPS2, Article 6.4
\(^6\) 45 CFR 46.107
5.2 Substitute Members

- Are chosen by the Chair in consultation with the President and Chief Executive Officer;
- Are invited by the Chair to participate in Research Ethics Board deliberations when a standing member is absent in order to meet quorum and/or representation capacities as stipulated above;
- Substitute members do not have regular voting privileges for REB decisions. In the event a substitute member is attending a meeting in the absence of a standing member, the substitute member assumes the privilege of a single vote for REB decisions at that meeting;
- Have no limits to their term of appointment; and
- Will receive orientation to the Research Ethics Board and will be invited to attend continuing education and other events organized for the Research Ethics Board.

5.3 Board of Directors Representative

A representative from the Board of Directors may attend Research Ethics Board meetings as an observer.

5.4 Ad-Hoc Expert Advisors

The chair will establish a roster of ad-hoc advisors with specific expertise not available in standing membership.

The chair may request written reports from the expert advisors to be forwarded to the Research Ethics Board meetings or may invite advisors to attend Research Ethics Board meetings for the duration of a specific review. The expert advisor will not be present during Research Ethics Board decisions.

5.5 Research Ethics Reviewers

The chair will establish a roster of reviewers who may be asked to review studies as necessary to address volume or other operational demands.

Normally, reviewers will participate in delegated reviews only and will not attend Research Ethics Board meetings; term of appointment is not limited.
RESEARCH AND RESEARCH ETHICS

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Reviewers will receive orientation to research ethics review.

5.6 Administrative Support

The institution shall provide appropriate administrative resources for the effective and efficient operation of the Research Ethics Board.

6. MEETINGS

6.1 Meetings will be conducted face-to-face (or by videoconference or teleconference for exceptional circumstances) on a regular monthly schedule.

6.2 A quorum will be a majority (50% plus 1) of the standing or substitute members of the Research Ethics Board, including the Chair or his/her delegate. The Chair will ensure that minimum requirements of membership representation are met at each meeting.

6.3 REB decisions are made by consensus and verified by a majority vote of the REB members present at a Full Board meeting; with the exception of those who have recused themselves in accordance with the conflict of interest policies. The REB Chair abstains from voting except to break a tie vote.

6.4 The Chair will ensure that the total number of votes cast regarding any matter being considered by the Research Ethics Board will not exceed the number of members present, plus the vote of the Chair only if the vote is tied.

6.5 The Research Ethics Board may hold additional special meetings, retreats and/or workshops as required fulfilling its functions.

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7 TCPS2, Article 6.2
8 TCPS2, Article 6.10
9 TCPS2, Article 6.9
6.6 The Research Ethics Board and/or researchers may request informal meetings in order to expedite and facilitate the review process. Such informal meetings will not, however, substitute for the formal review process.\(^{10}\)

6.7 Minutes will be kept of each meeting. Minutes will include:\(^{11}\)

- Member attendance (if substitute members are in attendance, their status as substitute members as well as whom they are replacing will be noted);
- Decisions of the Research Ethics Board and the vote on these decisions including the number of members voting for, against, and abstaining;
- Decisions for requiring changes in or disapproving research;
- A written summary of the meeting discussion.

7. QUALITY ASSURANCE

7.1 All members of the Research Ethics Board will comply with conflict of interest guidelines established for the Research Ethics Board.

7.2 All members of the Research Ethics Board will review and comply with IH policy and guidelines regarding privacy and management of confidential information.

7.3 The Research Ethics Board will periodically review Research Ethics Board related practices and make recommendations for change to the President and CEO.

7.4 The Research Ethics Office will prepare an annual written report on the activities of the Research Ethics Board, to be delivered by the President and CEO to the IH Board of Directors.

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\(^{10}\) TCPS2, Article 6.10

\(^{11}\) TCPS2, Article 6.17
7.5 The Chair of the Research Ethics Board will keep the Scientific Director of Research and the President and CEO informed about the work of the Research Ethics Board by timely reporting of concerns with regard to research studies in which any of the following have been identified: unanticipated problems involving risk to participants or others; serious or continuing non-compliance; or suspension or termination of approved research by the Research Ethics Board.

8. CONTINUING EDUCATION

8.1 The institution will provide Research Ethics Board members with the necessary training opportunities to effectively review the ethical issues raised by the types of research studies submitted for review.  

9. REFERENCES


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12 TCPS2, Article 6.7


Appendix 1.A

Research Ethics Board Members - Role Statements

Scientific Members:

Scientific Members are expected to contribute to the evaluation of the research on its ethical, scientific and statistical merits and standards of practice. These members should also advise the Research Ethics Board if additional expertise in a scientific or non-scientific area is required to assess whether the research adequately protects the rights and welfare of human participants.

Non-Scientific Members:

Non-Scientific Members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. Non-scientific members should advise the Research Ethics Board if additional experience in a non-scientific area is required to assess whether the research adequately protects the rights and welfare of participants and to comment on the comprehension of the consent document.

Community Members:

Community Members are expected to provide input regarding their knowledge about the local community and be able to discuss issues and research from that perspective.

Members knowledgeable in relevant law:

Members knowledgeable in relevant law are expected to alert the Research Ethics Board to legal issues and their implications, but not to provide formal legal opinions nor to serve as legal counsel to the Research Ethics Board.

Members knowledgeable in ethics:

Members knowledgeable in ethics are expected to guide the Research Ethics Board in identifying and addressing ethics issues related to the research under review.
Ad hoc Advisors:

Ad hoc Advisors are individuals with competence in special areas who may be required to provide input on issues that require expertise beyond or in addition to that available on the Research Ethics Board. The ad hoc advisor may be required to submit a written report and to participate via teleconference or to attend the Research Ethics Board meeting to lend his/her expertise to the discussions.

Chair:

The Research Ethics Board Chair or designee provides overall leadership to the Research Ethics Board:

- The Chair can delegate any of his/her responsibilities, as appropriate to the Alternate Chair or other qualified individual(s);
- Any responsibilities that are delegated by the Chair must be documented;
- The Chair or designee facilitates the review process based on organizational policies and procedures, and applicable regulations and guidelines. The Chair or designee determines the level of risk of each research project. The Chair or designee monitors the Research Ethics Board’s decisions for consistency and ensures that decisions are recorded accurately and communicated to Researchers in writing in a timely fashion;
- The Chair or designee ensures that all Research Ethics Board members are free to participate in discussions during the Research Ethics Board meetings. The Chair or designee can ask a substitute Research Ethics Board member to attend an Research Ethics Board meeting in order to draw his/her expertise in an area that may be relevant to the Research Ethics Board’s review and deliberations of the research;
- The Chair or designee determines the appropriateness of a Full Board or delegated review of the research;
- The Chair or designee performs or delegates authority to (an) Research Ethics Board member(s) to perform a delegated review;
- The Chair or designee signs off on all Research Ethics Board decisions in writing;
- For Research Ethics Board approval of clinical trials approved by Health Canada, the Research Ethics Board approval letter which includes the Research Ethics Board attestation, is signed by the Chair or designee;
The Chair or designee can suspend the conduct of any research project deemed to place participants at unacceptable risk pending discussion by the Full Board. The Chair or designee can suspend the conduct of the research if he/she determines that a Researcher is not adhering to the Research Ethics Board approved protocol or to the Research Ethics Board’s policies and procedures;

The Chair or designee, in conjunction with the Research Ethics Office staff and other organizational representatives as applicable, ensures the Research Ethics Board members are informed of all new legislation, regulations, policies and guidelines pertaining to human participant research and shall advise the organization on policies and procedures related to research conduct;

The Chair, in conjunction with the Research Ethics Office staff, shall assess the educational and training needs of the Research Ethics Board members and Office Personnel, and will address any gaps identified;

The Chair or designee reviews and approves Research Ethics Board policies and procedures at set intervals, to ensure they meet all current standards.

Alternate Chair:

The Research Ethics Board Alternate Chair or equivalent is responsible for performing the responsibilities of the Chair when the Chair is unable to do so:

- The Alternate Chair performs all responsibilities assigned by the Chair;
- The Alternate Chair assists with the overall operation of the Research Ethics Board.