



DUTIES OF RESEARCH ETHICS BOARD MEMBERS

SOP 534

PROCEDURE

Procedures are a series of required steps to complete a task, activity or action



Purpose:	To provide Island Health a standardized approach to describe the management and oversight of the Research Ethics Board (REB) to ensure continuity of membership and expertise to meet guidelines, regulations, and institutional mandates.
Context:	<p>Island Health offers programs and services on the unceded and traditional territories of the Coast Salish, Nuu-chah-nulth, and Kwakwaka'wakw Peoples.</p> <p>As a signatory to the 2015 Declaration of Commitment to Cultural Safety and Cultural Humility, Island Health is committed to addressing the ongoing impacts of colonialism and Indigenous-specific racism in order to provide a culturally safe, inclusive, healthy and respectful environment.</p> <p>The organization is committed to strengthening diversity, equity and inclusion to enable excellence in health and care for everyone, everywhere, every time. Through these commitments, Island Health strives to deliver the highest possible standard of care and to promote safe workplaces.</p>
Scope:	<ul style="list-style-type: none"> • Affected Roles <ul style="list-style-type: none"> ○ Vice-President, Quality, Research and Chief Nursing & Allied Health Office ○ Executive Medical Director, Medical and Academic Affairs ○ REB Office Personnel ○ REB Chairs, and members • Environment <ul style="list-style-type: none"> ○ Research Environment • This Standard Operating Procedure (SOP) applies to the activities of the Research Ethics Boards operating under the direct authority of Island Health.
Outcomes:	<ul style="list-style-type: none"> • Describes and ensures REB membership and expertise for compliance with all requirements.

1 Responsibility

- All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.
- The REB Chair or designee is responsible for clearly articulating all required duties associated with membership to the REB to potential and current REB members.
- REB members and alternates are responsible for fulfilling their duties as specified in this SOP.

2 Procedure

Each REB member's primary duty is the protection of the rights and welfare of the individual human beings that are serving as the participants of research. The reviewer must understand that they are not serving on the Board to expedite the approval of research, but to serve as a link between the Investigator, and the research participants. In order to fulfill their duties, REB members are expected to be knowledgeable of the guidelines and regulations governing human participants' protection and research ethics, and the policies of Island Health germane to human participant protection.

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The REB must be perceived to be fair and impartial, immune from pressure either by the institution’s administration, the Investigators whose protocols are brought before it, or other professional and nonprofessional sources.

The REBs operate under the direct authority of Vancouver Island Health Authority. As such, REB members serve the health authority as whole, rather than a particular site, department or hospital. Therefore, members must not allow their own interests or that of their departments to supersede their duty to protect their rights and welfare of research participants.

2.1 Attendance

- a) Regular REB members are expected to attend the regularly scheduled REB meetings. REB Members may be asked to step down if they consistently miss more than 75% of the scheduled REB meetings;
- b) REB members must notify the REB office if they will be absent for an REB meeting to ensure that quorum can still be met and/or so that an appropriate alternate may attend in their place;
- c) Alternate REB members are expected to attend the identified REB meetings for which they have confirmed their availability to replace a regular REB member;
- d) REB members are expected to be available for the entire REB meeting, not just the sections for which they have been assigned as reviewers.

2.2 Terms of Duty

- a) REB members are expected to commit to a minimum one year term and during that time, fulfill certain duties. These duties will be described prior to appointment and each REB member will be aware of their responsibilities as an REB member prior to accepting appointment to the REB.
- b) Any employee of Island Health is automatically covered by Island Health’s liability insurance. For non-employees, Island Health's liability coverage is also extended to include:
 - "members of medical and other advisory boards and committees, and medical staff and professional staff committees while acting in their capacity as committee members."
 - "physicians, interns, residents, dentists, or midwives, but only in the performance of their administrative duties on behalf of (Island Health)."
- c) All members will have a responsibility to participate in an appeal process, depending on the level of review required (i.e. office, executive, delegated, or full board). Any appeal of a decision made by another health authority, such as Fraser Health Authority, would be assessed proportionately for risk as with reviews originated by Island Health, thereby determining the level of review required.

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2.3 Duties

- a) All REB members attending an REB meeting are expected to review the relevant materials submitted for each item under review or consideration by the REB, to submit comments in advance of the REB meeting, and to be prepared to discuss each agenda item and provide input at the Full Board meeting;
- b) Each REB member is expected to fulfill specific duties based on the role as outlined below. More than one REB member may fulfill each role;
- c) **Scientific members:** Scientific members are expected to contribute to the evaluation of the research on its ethical, scientific and statistical merits. These members should also advise the Board if additional expertise in a scientific or non-scientific area is required to assess if the protocol adequately protects the rights and welfare of human participants;
- d) **Non-scientific members:** Non-scientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or provincial requirements regarding consent. Non-scientific members should advise the Board if additional experience in a non-scientific area is required to assess whether the protocol adequately protects the rights and welfare of participants and to comment on the comprehension of the consent document;
- e) **Community member(s):** Community members, including Patient Partner members, are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective. The role of the Community members on the REBs is unique and arm’s length from the institution to ensure review is fair and impartial. Their primary role is to reflect the perspective of the participant. This is particularly important when participants may be vulnerable and risks to participants are high.
- f) **Member(s) knowledgeable in relevant law:** Members knowledgeable in relevant law are expected to alert the REB to legal issues and their implications, but not to provide formal legal opinions nor to serve as legal counsel to the REB;
- g) **Member(s) knowledgeable in ethics:** Members knowledgeable in ethics are expected to guide the REB in identifying and addressing ethics issues related to the research under review;
- h) **Ad hoc advisors:** Individuals with competence in special areas may be required to provide input on issues that require expertise beyond or in addition to that available on the REB. The ad hoc advisor may be

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required to submit a written report and to participate via teleconference or to attend the REB meeting to lend their expertise to the discussions;

i) **REB Chair:** The role of the REB Chair is to provide overall leadership for the REB:

- The REB Chair and the Manager, Research Ethics & Compliance in consultation with the REB Coordinators, may recommend to the Vice-President, Quality, Research and Chief Nursing & Allied Health Office or their delegate, the Executive Medical Director, Medical and Academic Affairs the appointment of one or more Chairs to assist or act on behalf of the chairperson in particular REB matters and at REB meetings, either as a general procedure, or case-by-case basis. The REB Chair also may delegate any of their responsibilities, as appropriate to other qualified individual(s);
- Any responsibilities that are designated by the REB Chair must be documented;
- The REB Chair facilitates the review process based on Island Health policies and procedures, and the TCPS 2. The REB Chair monitors the REB’s decisions for consistency and ensures these decisions are recorded accurately and communicated to Researchers in writing in a timely fashion;
- The REB Chair ensures that all REB members are free to participate in discussions during the REB meetings. The REB Chair can ask an additional expert REB member to attend a REB meeting in order to draw their expertise in an area that may be relevant to the REB’s review and deliberations of the research;
- The REB Chair in consultation with REB Office Personnel, or other voting members of the REB, determines level of risk and the appropriateness of an application for REB Review for delegated or full REB review. The REB Chair may delegate this function to another REB member, or to REB Office Personnel as appropriate;
- The REB Chair or designee performs or delegates authority to (an) REB member(s) to perform a delegated review;
- The REB Chair or designee signs off on all REB decisions with an electronic signature via the online database;
- For REB approval of clinical trials approved by Health Canada, the REB approval letter is electronically signed by the REB Chair or designee via the online database. The REB Certificate of Approval by an online database contains required elements of the REB attestation;
- The REB Chair is empowered to suspend the conduct of a research project or clinical trial deemed to place participants at unacceptable risk pending discussion by the Full Board. The REB Chair is empowered to suspend the conduct of a study if they determine that a Researcher is not following the REB’s policies or procedures;
- The Manager, Research Ethics & Compliance will provide a report on the activities of the Island Health affiliated REBs to the Director, Research, and the Executive Medical Director, Medical and Academic Affairs on an annual basis;
- The REB Chair, in conjunction with the Manager, Research Ethics & Compliance, and such other institutional representatives as are appropriate, is responsible for ensuring that REB members are informed of all new legislation, regulations and guidelines which bear on REB review;
- The REB Chair, in conjunction with the REB Office Personnel, shall assess the educational and training needs of the REB members and REB Office Personnel, and will address any gaps identified;

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- The REB Chair or designee reviews and approves REB policies and procedures at set intervals, to ensure the REB SOPs meet all current standards;
 - In addition to the above responsibilities (germane to the members’ capacity), this person chairs meetings of the REB. Ensures that the total number of votes cast regarding any matter being considered by the REB will not exceed the number of members present. The Chair will vote if the vote is tied.
- j) **REB Co-Chair:** The REB Co-Chair or equivalent is responsible for performing the responsibilities of the REB Chair when the REB Chair is unable to do so:
- The REB Co-Chair performs all responsibilities assigned by the REB Chair;
 - The REB Co-Chair assists with the overall operation of the REB.

2.4 Primary and Secondary Reviewers:

- a) In addition to the duties described in section 2.2.a., each regular (or alternate) member is expected to act as a primary and/or secondary reviewer for assigned studies at convened meetings. The primary and secondary reviewers present their findings resulting from detailed review of all of the application materials and provide an assessment of the soundness and safety of the protocol and recommend specific actions to the Board. They may lead the discussion of the study by the convened REB. The primary and secondary reviewers are required to review the entire submission, be familiar with it, and be prepared to conduct an in depth review of all materials;
- b) Primary and secondary reviewers are provided with a protocol review checklist for their reference when reviewing all new studies assigned to Full Board. Reviewers are to post their comments, discussion points and provisos via the online database. The elements within the checklist will be discussed during the Full board meeting and posted to the study with the relevant minutes in the online database. The primary and secondary reviewers are expected to contact the REB Chair or Coordinator in advance of the convened meeting if further clarification of the Investigator is required prior to review of the submission.

2.5 Training and Education

- a) All members must adhere to Island Health policies in the discharge of their duties including the following policies:
- 25.2 Free & Informed Consent in Research
 - [25.3 Research Integrity](#)
 - [5.5.2P Respectful Workplace Policy](#)
 - [1.5.1 Confidential Information – Privacy Rights of Personal Information Policy](#)
 - [1.5.2 Confidential Information – Third Party, Island Health Business and other Non-personal Information Policy](#)
 - [5.5.1P Conflict of Interest Policy](#)

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b) Education

- [Tri Council Policy Statement 2 \(TCPS2\)](#)
- [San'yas Anti-Racism Indigenous Cultural Safety Training Program – Core Health](#)
- [Collaborative Institutional Training Initiative \(CITI\)](#) Good Clinical Practice (GCP)
- SOP 501 Research Ethics Board Terms Of Reference
- SOP 502 Activities Requiring Research Ethics Board Review
- SOP 534 Duties of REB Members

2.6 Conflict of Interest

- a) REB members are expected to follow specific REB related conflict of interest procedures.

3 Training

- 3.1 Review of the SOP.

4 Compliance Monitoring

- 4.1 The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for ongoing monitoring of Island Health operations to verify compliance with this SOP.
- 4.2 The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for communicating any changes to this SOP to all relevant personnel.
- 4.3 Deviations from this SOP will be addressed through corrective and preventative action implementation.

5 Definitions

- Refer to the Glossary – Research Ethics

6 References

- Network of Networks and Canadian Association of Research Ethics Board - Research Ethics Board Standard Operating Procedures, V 3.0
- [The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.4:](#)
- [The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.8:](#)

7 Summary of Changes

Version	Effective Date	Change Description
1.0	05 DEC 2022	New procedure

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