COMPOSITION OF THE RESEARCH ETHICS BOARDS SOP 533

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

island health

Purpose:	To provide Island Health a standardized approach for describing membership requirements for the composition of the Research Ethics Boards (REBs) responsible for reviewing research conducted under the auspices of Island Health.
Context:	Island Health offers programs and services on the unceded and traditional territories of the Coast Salish, Nuu-chah-nulth, and Kwakwaka'wakw Peoples. 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. 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.

Scope:	• Affected Roles
	  o Vice-President, Quality, Research and Chief Nursing & Allied Health Officer
	  o Executive Medical Director, Medical and Academic Affairs
	  o REB Office Personnel
	  o REB Chairs, and members
	• Environment
	  o Research Environment
	• This Standard Operating Procedure (SOP) applies to REBs that review human participant research in compliance with applicable regulations and guidelines.

Outcomes:	• Procedures that describe membership requirements and responsibilities for the composition of the REBs.

1 Responsibility

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

2 Procedure

The membership of the REB will be sufficient to ensure the appropriate expertise, multidisciplinary backgrounds, and independence required for competent research ethics review. The membership of the Island Health Research Ethics Boards will include individuals with varying backgrounds and appropriate professional competence to review the diverse types of protocols that are received. The Board members will be qualified to ascertain the acceptability of the research in terms of institutional commitments and regulations, all applicable laws, and standards of professional conduct and practice pertaining to human participant protection.

To promote complete and adequate review of the type of research commonly reviewed by the REB, the REB must include appropriate diversity; therefore, selection of members must include a consideration of professional expertise (including both scientific and non-scientific) to assess the research submitted for review. The membership will be diverse so selection will include consideration of race, sex, cultural backgrounds, research, healthcare or professional

experience, organizational affiliation, and sensitivity to such issues as community attitudes to assess the research submitted for review.

2.1 Selection of REB Members

a) Each Research Ethics Board (REB) shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The REB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants;

b) The REB membership will not consist entirely of members of one profession;

c) REB members will be selected based on the needs of the REB as outlined below and per applicable regulations, guidelines and standards.

2.2 Composition of the REB

Research Ethics Board members are nominated by the Chair of each respective Board, in consultation with the Vice-President, Quality, Research and Chief Nursing & Allied Health Officer or delegate, and Manager, Research Ethics & Compliance, and Research Ethics Coordinators. Members are approved and appointed by the REB Chairs.

a) The membership of the REB will be in compliance with the *Food and Drugs Act* and applicable *Regulations*, the Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans, 2, the International Conference on Harmonisation Good Clinical Practice Guidelines, Research ethics oversight of biomedical clinical trials (CAN/CGSB-191.1-2013), and the U.S. Code of Federal Regulations;

b) The REB Chair or designee monitors the REB membership composition for appropriate membership in relation to the nature and volume of research submissions;

c) As the size of the REB increases, every effort will be made to ensure that the number of community representatives will also increase.

d) The REB will include at least five members represented by the following categories:
- At least two members who have expertise in relevant research disciplines, field and methodologies covered by the REB (for biomedical clinical trials, this will include at least one member who practices medicine or dentistry and who is in good standing with their regulatory body);
- At least one member who is primarily experienced in non-scientific disciplines;
- At least one member who is knowledgeable in ethics;
- At least one member who is knowledgeable in the relevant law. That member should not be the institution's legal counsel or risk manager. This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research, and

- At least one community member who has no affiliation with the organization or the Sponsor, and who is not part of the immediate family of a person who is affiliated with the organization.

e) A member may not fulfill more than one representative capacities or disciplines;

f) Where applicable, the membership shall also include at least one member who has expertise in natural health products.

g) Members will include men, women and gender diverse people a majority of whom are Canadian citizens or permanent residents, and who collectively have the qualifications and experience to review and evaluate the science, medical aspects and ethics of the proposed research.

h) Membership, when required, should include at least one member who has expertise in complementary or alternative care or pediatric health research.

i) At least one member, when possible, who is from an identifiable Indigenous communities, collectives and organizations (ICCOs) and Nations, when the REB reviews research that recruits participants from that community.

j) At least one member from a patient partner organization or group.

k) Additional membership as required by the applicable legislation or guidelines.

l) REB Office Personnel updates the REB membership roster and Office for Human Research Protections (OHRP) registration if applicable, to reflect changes to the REB membership.

2.3 Regular REB Members

a) The backgrounds of the regular members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the REB. The majority of regular members must be Canadian citizens or permanent residents under the Immigration and Refugee Protection Act;

b) Regular members shall serve an initial one year term, at which point the REB member may renew their appointment for a term of two years on the mutual agreement of the REB member, REB Chair, REB Coordinators and Manager, Research Ethics & Compliance, if required. At the end of the two year term, an additional two year renewal period may be granted upon mutual agreement of the REB member, REB Chair, REB Coordinators and Manager, Research Ethics & Compliance, if required;

c) Regular members are requested to attend 75% of REB meetings scheduled.

d) **Community Members**

- The community member(s), who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community and be willing to discuss issues and research from that

perspective. Consideration should be given to recruiting individuals who speak for the communities from which the Institution will draw its research participants. The community member(s) should not be vulnerable to intimidation by the professionals on the REB;

e) **Patient Partner Members**
- Patient Partner(s) bring their knowledge and experience from the perspective as patients to the review of research of all types. They may be specific experts in an area of health or have health community knowledge they can contribute. The patient partner members should not be vulnerable to intimidation by the professionals on the REB;

f) **Scientific Members**
- The REB will include physicians and experts in physical, behavioural, social or biological science. When an REB encounters studies involving science beyond the expertise of the members, the REB may use ad hoc reviewers to assist in the review.

2.4 Alternate Members

Alternate members are qualified voting members who serve as designated alternates for regular members, but they are not expected to attend each meeting.

a) The REB Chair or their designee, or a designated member of the REB staff, may ask an alternate member to attend a meeting in order to draw on their expertise in an area that may be relevant to that meeting's deliberations and/or to establish a quorum for that meeting in the absence of the designated regular member;

b) Only alternate REB members of comparable qualifications may substitute for an REB member (a non-scientific member may not substitute for a scientific member);

c) For studies which are required to adhere to U.S. regulations, the minutes shall document when an alternate REB member replaces a primary REB member.

2.5 REB Chair

a) Whenever possible and practicable, the REB Chair will be selected from experienced REB members who have expressed interest in becoming the REB Chair and who are familiar with the applicable regulations and guidance documents;

b) The Chair of the REB will be appointed by the Executive Medical Director, Medical and Academic Affairs for a term agreed to by both parties, but usually a minimum of two years with the possibility of reappointment for one or more additional years. At the expiry of the initial term, the appointment may

be renewable for additional term(s) with the agreement of the Chair and at the discretion of the Executive Medical Director, Medical and Academic Affairs.

c) The REB Office Personnel updates the REB membership roster and OHRP registration, if applicable, to reflect this change.

2.6 Ad Hoc Advisors

a) At their discretion, the REB Chair or designee may invite individuals with expertise and competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REB;

b) Consultation with an ad hoc advisor shall not alter the composition and representation of the REB as outlined in section 2.2 above;

c) The ad hoc advisor may be asked to participate in the REB meeting to lend their expertise to the discussions;

d) All ad hoc advisors shall sign a *Confidentiality of Information and Conflict of Interest Agreement*;

e) The ad hoc advisor may not contribute directly to the REB's decision and their presence or absence shall not be used in establishing a quorum;

f) Documentation of key information provided by the ad hoc advisor shall be summarized in the REB minutes and if available, the written report shall be placed in the relevant REB files on the applicable online database.

2.7 Observers at REB Meetings

a) The REB may allow observers to attend its meetings;

b) Observers will sign a *Confidentiality of Information and Conflict of Interest Agreement* agreeing to abide by the REB conflict of interest and confidentiality policies;

c) 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;

d) Observers shall not participate when the REB discusses its decision, reaches consensus or votes on the application;

e) The minutes will reflect the presence of any observers as well as their expertise and contributions, including when they leave the meeting, when applicable.

3 Training

3.1 Review of the SOP.

4 Compliance Monitoring

4.1 The Island Health Manager, Research Ethics & Complianceor 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

- See 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
- *U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.107):*
- *U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.107):*
- *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.4*:
- *Health Canada Natural and Non-prescription Health Products Directorate, Part 4*:
- *Health Canada Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects*:
- *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.6:*
- *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.6*:
- *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.5*:
- *ICH GCP International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use – ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Section 3.2.6*:

7 Summary of Changes

Version	Effective Date	Change Description
1.0	05 DEC 2022	New procedure