Purpose:	To provide Island Health Research Ethics Boards (REBs) a standardized approach to ensure that REB meetings are conducted and documented in a consistent manner in order to meet regulatory and institutional requirements.
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 REB Office Personnel
	  o REB Chairs, and members
	• Environment
	  o Research Environment

Outcomes:	• To have a framework of procedures that will facilitate quality, completeness, adequate documentation, and regulatory compliance in the conduct of research in the context of Research Ethics Board meetings.

1 Responsibility

All REB members and REB Office Personnel that review human participant research in compliance with applicable regulations and guidelines.

2 Procedure

Except when a delegated review procedure is used, the REB must review proposed research at convened Full Board meetings at which a quorum is present. The Island Health REBs will generally meet at least 12 times a year or at some other frequency as determined by the REB Chairs.

The REB meeting agenda provides the meeting content and establishes a sequence of review. It also provides an overview of all items that have been previously (e.g., during the preceding time between REB meetings) reviewed and approved by delegated review procedures, a list of items that are pending review by the Full Board, and assigned reviewer(s) for each of those items. Information documented in the REB meeting agenda provides the foundation for the REB meeting minutes.

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

3 Quorum

Quorum rules must meet the minimum requirements of membership representation outlined in Island Health SOPs 533 Compostion of the Research Ethics Boards and 534 Duties of Research Ethics Board members When there is less than full attendance, decisions requiring full review should be adopted only when the members in attendance at that meeting have the specific expertise, relevant competence, and knowledge necessary to provide an adequate research ethics review of the proposals under consideration.

Quorum rules help to ensure the soundness and integrity of the research ethics review process. To maintain quorum when REB members are geographically dispersed or in unexpected circumstances (e.g., emergencies), input from member(s) is allowed by other means, such as the use of technology (see Tri Council Policy Statement (TCPS2), Article 6.10 referenced below).

Ad hoc advisors, observers, REB Office Personnel and others attending REB meetings should not be counted in the quorum for an REB. Nor should they be allowed to vote on REB decisions (see TCPS2, Article 6.5 referenced below). Decisions without a quorum are not valid or binding.

- A quorum is defined as a majority (50% + 1) of the regular and/or alternate members, including a minimum of five members, representing the scientific, ethical, community, legal or non-scientific constituencies as set out in 3.2 below:
- A quorum consists of regular and/or their alternate members and requires at least two members whose primary concerns are in scientific areas, one member whose primary concern is in a non-scientific area, one member who is knowledgeable in ethics, one member who is knowledgeable in biomedical law, and one member who has no affiliation with the institution. For drug trials, one of the scientific members must be from a medical discipline, or if regarding a dental drug, from a medical or dental discipline. A representative who is knowledgeable in complementary or alternative health care must be in attendance to review clinical trials involving natural health products for therapeutic purposes;
- A quorum must be present to proceed with a Full Board meeting;
- In all cases the REB Chair will ensure that there is adequate expertise to provide appropriate ethical and scientific review of the study(ies) in question;
- 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;
- An alternate member may attend in the place of an absent regular member in order to meet the quorum requirements outlined above. When a REB member and their alternate both attend the REB

meeting, only one is allowed to participate in the deliberations and final decisions regarding approval of any study subject to U.S. regulations;

- In unusual circumstances, should an REB member(s) not be able to be physically present during a convened meeting, but be available by telephone or videoconference, the meeting can be convened via teleconference or videoconference. The REB member(s) who is not physically present will be connected to the rest of the REB members via teleconference or videoconference. In this manner, all REB members will be able to discuss the protocol even though a member(s) is not physically present. REB members participating by teleconference or videoconference may vote provided they have had an opportunity to review all the material the other members have reviewed. REB members participating by teleconference or videoconference count towards quorum;
- Ad hoc reviewers will not be used to establish a quorum;
- REB members recusing themselves due to a conflict of interest are not counted toward quorum;
- Under very unusual circumstances (e.g. public health alerts and quarantines) the REB Chair may, at their discretion, convene an REB meeting via teleconference or videoconference. A quorum (as defined in 3.1 above) must participate for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously for a conference call to take place – "telephone polling" (where members are contacted individually) will not be accepted as a conference call;
- Only those REB members present (e.g. in person, or via teleconference or videoconference) at the Full Board meeting may participate in the deliberation and final decision regarding approval;
- Observers may be invited or permitted to attend REB meetings subject to the agreement of the REB and execution of a *Confidentiality Agreement*. Observers must disclose any vested interest in, or scientific or management responsibility for, any applications being considered at the REB meeting;
- If requested, Researchers may (in person or via teleconference or videoconference) attend the REB meetings to present their research, and respond directly to any comments or questions raised by the REB, subject to the agreement of the REB;
- Any individual not listed on the office REB membership roster may not participate in the decision of the REB.

4 Agenda Preparation

4.1 Following an administrative review of the submission (e.g., new studies, amendments, continuing review applications, reportable events) by the REB Office Personnel and the determination of the review type by the REB Chair or designee, the responsible REB Office Personnel adds any submissions requiring Full Board review to the next appropriate Full Board meeting agenda;

4.2 For submissions that were reviewed and approved via delegated review procedures, the REB will be made aware of these approvals in a timely manner. A list of new studies approved via delegated review is attached to each Full Board meeting agenda;

4.3 The REB Office Personnel distributes with the agenda any previous REB meeting minutes for Full Board review and approval, and adds any other items for information or discussion at the REB meeting (e.g., SOPs, educational articles, presentations, reports, etc.);

4.4 The REB Office Personnel, in consultation with the REB Chair or designee as necessary, reviews the agenda, confirms REB meeting attendance and assigns the reviewers;

4.5 The REB Chair or designee invites the appropriate alternate REB member to the meeting when a regular REB member is not able to attend;

4.6 All members will receive/have access via the online databases (either RISe or the Research Services Portal) to all relevant study documentation including:

a) REB Applications;
b) Proposed informed consent documents;
c) Complete protocol (for New and renewal applications);
d) Questionnaires & assessment instruments (if applicable);
e) The Investigator's Brochure (if required);
f) Study contracts and budgets (where applicable);
g) Any other supporting material, such as examples of recruitment advertising, etc..

4.7 All REB members in attendance at REB meetings are expected to bring a laptop computer and wireless internet access to the online databases to enable them to review all study documentation as listed in 4.6, together with pre-reviewer commentary and reviewer commentary;

4.8 Where an REB member does not have a laptop or device to bring to the meetings, REB Office Personnel will provide access through departmental supply;

4.9 Ad hoc advisors will receive copies of relevant submissions;

4.10 Any changes to the agenda are communicated to all REB members and REB Office Personnel. The REB Office Personnel also may issue an updated agenda notice depending on the nature of the changes.

5 Primary and Secondary Reviewers

5.1 Prior to the meeting, the REB Office Personnel, in consultation with the REB Chair or designee as necessary, will identify and assign a primary and secondary reviewer for each new research project as per SOP 534 Duties of Research Ethics Board Members, TCPS2 Article 2.4.a. Amendments and annual renewals that are required to be reviewed at the Full Board in accordance with regulatory or Sponsor requirements will be assigned to one primary reviewer;

5.2 No REB member will be assigned as a reviewer on a submission in which they are a Principal/Qualified Investigator (PI/QI) or Co-Investigator or in which there is a declared conflict of interest. In the event there is a conflict of interest for an individual not listed as PI/QI or Co-Investigator, REB Office Personnel can manually update the study in the online database system to include the REB member's conflict of interest and prevent the REB member from viewing the study;

5.3 The REB Office Personnel will issue the reviewer assignment. The assigned reviewers will receive notification via email when the meeting agenda has been created;

5.4 If study applications are inadvertently assigned to REB members with a conflict of interest, the REB member is required to notify REB Office Personnel immediately. If any of the assigned reviewers declare a conflict, the submission is reassigned to another reviewer.

6 Prior to the REB Meeting

6.1 All REB members will be sent study documentation required for review in sufficient time prior to the meeting to allow for adequate review. The documentation will be sent electronically via the online database system; REB members will receive an e-mail notifying them that the material has been sent and may be viewed at their home page;

6.2 The primary and secondary reviewers (if applicable) will conduct in-depth reviews of their assigned submissions and may submit reviewer comments prior to the REB meeting by posting in the online database system. The primary reviewer should be prepared to lead the discussion at the Full Board meeting;

6.3 All REB members are expected to conduct a review of each agenda item prior to the Full Board meeting, including previous REB meeting minutes on the agenda and any attachments to the agenda for review or discussion;

6.4 REB members who are not assigned as primary or secondary reviewers may submit their individual comments for each submission prior to the meeting via the online database system;

6.5 All REB members should be prepared to present their comments and participate in the discussion at the Full Board meeting.

7 Meeting Minute Preparation

7.1 The REB Office Personnel, using the applicable Board template will draft the REB meeting minutes including key discussions, decisions, and votes;

7.2 The key REB discussions and decisions for submissions are recorded;

7.3 The REB's concerns, clarifications, and recommendations to the PI/QI as discussed at the REB meeting are included in the REB review letter with provisos that is sent to the Investigator via the online database system. The meeting minutes outlining the REB discussion formulating the provisos are also attached to each study in the online database system. The minutes can only be viewed by the REB Office Personnel and the REB members;

7.4 The meeting may be recorded (on an encrypted device) for reference purposes and to provide additional reference information for the generation of the final draft of the minutes;

7.5 The minutes are intended to reflect what the REB decided, how it resolved controverted issues, and any determinations required by the regulations;

7.6 The draft minutes should be completed prior to the next REB meeting.

8 Meeting Minute Approval

8.1 The minutes are made available at the next appropriate REB meeting and are presented at the REB meeting for review and approval;

8.2 The REB motion and votes on the previous REB meeting minutes are recorded in the current REB meeting minutes;

8.3 If the previous REB meeting minutes are approved pending revisions, the REB Office Personnel makes the required changes, and unless the REB requests further review of the minutes prior to approval, the REB Office Personnel records the minutes as "approved by the REB."

9 Documentation

9.1 The REB meeting minutes include the following items:

a) Date, place, and time the REB meeting commenced and adjourned;
b) Names of REB members in attendance (present, teleconference, videoconference);
c) Names of REB Office Personnel present at the meeting;
d) Presence of observers;
e) Use of ad hoc advisors and their specialty;
f) List of declared conflicts of interest, a summary of any discussions, and the decision taken by the REB to address them (as applicable) or a note that none were declared;
g) A summary of key discussions and controverted issues and their resolution for each submission, as applicable;
h) The decisions taken by the REB regarding approval for each submission, as applicable;
i) The basis for requiring changes or for disapproving submissions;
j) Number of REB members in attendance for the review of each submission requiring a decision;
k) REB member(s) recused related to conflicts of interest for each submission requiring a decision;
l) Number(s) voting for, against or abstaining in the event of a vote for each submission requiring a decision;
m) Reference to any attachments to the agenda;
n) The minutes do not include reviewer comments submitted in the online database system that were not discussed at the meeting. The complete set of comments/issues for all studies are produced in a separate document and/or retained in the online database system.

9.2 In the case of US federally funded or regulated studies, the minutes will reflect that the following criteria required to approve the research are satisfied:

a) Risks to participants are minimized:
- By using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk; and
- when appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes;

b) Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result;
c) Selection of participants is equitable;
d) Informed consent will be sought from each prospective participant or their legally authorized representative;
e) Informed consent will be appropriately documented;
f) When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the participants;
g) When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;
h) When some or all of the participants are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these participants.

9.3 All REB meeting agendas and minutes are retained in the REB records;

9.4 The agendas, REB meeting minutes, and review documents are confidential and will not be released or made available unless required for inspection or auditing purposes.

10 Approval by Consensus

10.1 Members of the REB generally approve studies by consensus, which is noted as a unanimous vote in the REB minutes. Where consensus is not achieved the decision will be made by majority vote, with the minutes reflecting who was opposed to the majority decision. The REB may take the range of activities described in SOP 508 Ongoing Research Ethics Board Review Activities. Members also will determine the level of risk, the frequency of review for each protocol, appropriate monitoring, and whether third party assessment and follow up will be needed.

10.2 If an Island Health REB is reviewing a study that is funded by the US Federal Government or that is subject to the US Food and Drug Administration Regulations, study approvals shall be made by a formal counted vote specifying the number of REB members present at the time of approval, the number of members voting for, against and abstaining. The votes will be recorded in the minutes in the following format as an example: Total = 15; Vote: For – 14, Opposed – 0, Abstained 1.

11 Training

11.1 Review of the SOP.

12 Compliance Monitoring

12.1 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.

12.2 The Island Health Manager, Research Ethics& Compliance or their delegate is responsible for communicating any changes to this SOP to all relevant personnel.

12.3 Deviations from this SOP will be addressed through corrective and preventative action implementation (CAPA).

13 Definitions

- See Glossary of Terms – Research Ethics

14 Related Island Health Policy Documents

- SOP 508 Ongoing Research Ethics Board Review Activities
- SOP 533 Compostion of the Research Ethics Boards
- SOP 534 Duties of Research Ethics Board Members

15 References

- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.10
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.5
- Health Canada Natural and Non-prescription Health Products Directorate, Part 4
- Clinical Trials Ontario REB Qualification Program
- 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)
- U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111)
- U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.111(a)(2))

16 Summary of Changes

Version	Effective Date	Change Description
1.0	15 Jun 2013	New procedure
2.0	05 DEC 2022	Clarification of quorum, membership, and role of Chair and Office Personnel. Update to Minute taking procedures. Clarity around international regulations.