Purpose:	Island Health Research Ethics Boards (REBs) are mandated to assess the ethical acceptability of any research activity conducted at Island Health to assure achievement of ethical standards as set out or in compliance with national and appropriate international regulatory and guidance standards.

Scope:	• Affected Roles
	  ○ REB Chairs or joint Co-Chairs (Chair)
	  ○ REB Members
	  ○ Research Ethics Office
	  ○ Executive Medical Director, Medical Affairs & Research
	• Environment
	  ○ Island Wide
	  ○ Research Environment
	• All research involving human participants, remains, cadavers, tissues, biological fluids, embryos or fetuses, and human data at Island Health requires research ethical review and approval before the research begins.
	• Island Health maintains two REBs that provide the required ethical review prior to study implementation. The two Island Health REBs are the Clinical Research Ethics Board (CREB) and the Health Research Ethics Board (HREB).
	• The mandate of the two REBs is to assess the ethical acceptability, and determine that:
	  ○ research proposed involving human participants meets scientific and ethical standards;
	  ○ all proposed research complies with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2);
	  ○ proposed clinical trials research complies with the International Committee on Harmonization – Good Clinical Practices (ICH E6 GCP); and
	  ○ research is conducted as outlined in the approved protocol and that the rights, safety and wellbeing of human participants are protected.

Outcomes:	This procedural document facilitates shared understanding of the composition of the REBs, and responsibilities of affected roles for conduct and documentation of REB review processes.

1 Purpose

1.1 The REBs are responsible for reviewing, approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research.

1.2 The REBs will conduct reviews that are proportionate to the level of risk that is proposed by the research with respect to both the magnitude of the potential harm and the probability or likelihood of the harm occurring. Risk will be deemed either above or minimal risk and weighed against the stated benefits of the research.

1.3 Above minimal risk research will require a full board review and minimal risk research is eligible for delegated review in accordance with regulatory requirements including TCPS2.

1.4 The Research Ethics Office will determine the most appropriate REB to review the application. The CREB has the expertise to review clinical trials and invasive medical intervention studies whereas the HREB predominantly reviews behavioral and health science services studies.

1.5 A REB review will result in a response letter to the researcher outlining the various comments, issues and concerns to be addressed. The researcher is invited to enter into a collaborative relationship with the REB in responding to the letter that eventually results in the REB being satisfied that the ethical standards set out in guidance and legislation will be followed over the course of the study. At this point a Certificate of Approval will be issued to demonstrate the ethical review has been completed. NOTE: At Island Health, ethical review is only part of the approval process. Institutional Approval to conduct research will only be granted once BOTH ethical review and operational approvals from affected departments have been received.

1.6 Should the researcher and the REB not reach agreement, further reconsideration may be requested, followed by an appeal process. Island Health has a reciprocal agreement with Fraser Health Authority REB to provide research ethics applicants at each of the health authorities with an appeal mechanism for decisions of its respective REB, in compliance with TCPS2.

1.7 The REBs will demonstrate a commitment to professional growth, specifically with regard to advancing research ethics knowledge, through leading and attending quality professional development and learning opportunities.

1.8 The REBs will actively participate and support the provincial and national harmonization initiatives for the improvement and consistent approach to ethics review within British Columbia and/or Canada.

2 Composition

2.1 Members are appointed by the Chair of each respective Board, in consultation with the Executive Medical Director, Medical Affairs and Research.

2.2 All appointments will be made in accordance with TCPS2 guidelines on membership. Each of the REBs will have at least five core members, including both men and women, of whom:

a) Two members have relevant knowledge and expertise in the content area
b) One member is knowledgeable in ethics
c) One member is knowledgeable in the law relevant to health-related research
d) One member has no affiliation with the institution, but is recruited from the community served by Island Health

2.3 Each REB has a Chair appointed by the Executive Medical Director, Medical Affairs and Research 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. The Chair presides over the regular meetings, and signs the written communication to researchers conveying REB decisions. The Chair may also provide advice on administrative matters pertaining to research ethics or research ethics consultations to researchers.

2.4 Members may volunteer or be identified for recruitment by the Research Ethics Staff and/or Chair in accordance with REB membership requirements and identified specific skill sets that the candidate possesses. The potential board member's CV is reviewed by the Chair and, after an interview to determine interest and commitment, an appointment is offered.

2.5 The usual membership term is two years , but the term may be less or extended upon mutual agreement between the Research Ethics Office, Chair and board member.

2.6 Members will be categorized as follows:

- Regular member – appointed for a term agreed upon between the Chair and the member; responsible for reviews as requested and attending 75% of the meetings held
- Ad hoc Advisor – appointed for a term agreed upon between the Chair and the member; responsible for conducting reviews and attending meetings upon request based on their expertise
- Non-voting Member – appointed for a term agreed upon between the Chair and the member; responsible for conducting reviews and attending meetings upon request based on their expertise; cannot be considered part of quorum for the conduct of the meetings; generally there to provide their expertise for administration of reviews (such as the Coordinator for the REB or the Research Privacy Specialist).

3 Duties and Responsibilities

3.1 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

3.2 REB members are responsible for informing the Research Ethics Office if a protracted period of absence is anticipated, i.e. leave, vacation, etc. and a decision will be made by the Chair regarding a temporary leave or resignation from the board based on the circumstances of the absence.

3.3 Ad hoc advisors may be consulted where the REB requires expertise not available from the current membership. An ad hoc member may be appointed for a certain period of time, or may be appointed for only one review or one meeting.

3.4 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)."

3.5 REB members must disclose real, potential or perceived conflicts of interest to the REB and, where necessary, the member must withdraw from the REB deliberations and decisions.

3.6 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.

4 Meetings

4.1 The REBs meet regularly in person, either monthly or bi-monthly and at the request of the Chair. Occasional unscheduled meetings may also be required.

4.2 Quorum is achieved when all five required members set out in Section 2.2 and at least 50%+1 of the voting members of the REB (including the five required members) participate in the decision making for each review requiring a full board decision.

4.3 REB members are expected to regularly attend meetings. Frequent unexplained absences will prompt a discussion between the Chair, the member, and the Manager, Research Compliance & Ethics in order to gain an understanding of absences and clarify expectations.

4.4 If a member wishes to resign, this should be done in writing to the Chair of the REB.

4.5 In the rare circumstances that a member of the REB needs to be asked to step down, this would be at the discretion of the Executive Medical Director, Medical Affairs & Research.

5 Training

5.1 Research Ethics office staff and REB members who are overseeing research on human participants will receive initial and ongoing training regarding the responsible review and oversight of research and the policies and procedures that accompany such activities.

5.2 The REB Chairs, in consultation with the Research Ethics office, establish the educational and training requirements for REB members who review research. This may include arranging for an active member to mentor a new member.

5.3 The Manager, Research Compliance and Ethics, establishes the educational and training requirements for Research Ethics office staff.

5.4 REB members will receive initial training, that may include mentoring by a fellow member, and be expected to participate in continuing training in areas relevant to their responsibilities.

5.5 New members are required to complete the TCPS2 tutorial within 1 month of appointment, and prior to actively participating in the ethics review process, and attend meetings (either in person or by electronic participation) as set out in Section 2.6 to be in good standing.

5.6 In addition, it is mandatory that all CREB members complete Good Clinical Practice (GCP) training to ensure they comply with the regulatory requirements that govern clinical trials in accordance with requirements of Health Canada.

5.7 All members are required to read and acknowledge this Terms of Reference document, as well a the Research Ethics Review Policy as part of their training.

5.8 The REB Chair will receive additional training in areas relevant to their additional responsibilities, as applicable and relevent.

5.9 REB staff will receive initial and continuing training in the areas relevant to their responsibilities.

5.10 REB members and Research Ethics Office staff will be encouraged to attend workshops and other educational opportunities focused on REB functions. Island Health will support such activities to the extent possible and as appropriate to the responsibilities of members and staff.

5.11 Training and continuing education for the REB members will be documented and held in the Research Ethics office.

6 Accountability

6.1 The REBs are accountable to the Island Health Chief Executive Officer through the Executive Medical Director, Medical Affairs and Research.

7 Reporting

7.1 Decisions will be recorded in the meeting minutes of the respective REB. Notification to the research applicant will be in writing from the Chair of the respective Board.

7.2 Minutes of all REB meetings are prepared following the meeting and retained as follows:

- 5 years from the date of study closure of a study; or
- 25 years from the date of study closure for studies pertaining to a sponsored clinical trial regulated by Health Canada or the FDA.

8 Summary of Changes

Version	Effective Date	Change Description
1	01 JAN 2013	N/A – new document – replaces TOR dated 02 April 2007
2	01 DEC 2016	Updated format; removal of references to Joint Sub Committee with UVic; addition of ad hoc and non-voting member requirements; refining of data retention for minutes; reduced normal appointment period from 3 years to 2 years; addition of training requirements.