



Purpose:	To describe the process for ethical review of research involving human participants that qualifies for harmonized review by Island Health Research Ethics Boards (REBs) and one or more other REBs through an agreement or otherwise.
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"> ○ REB Office Personnel ○ REB Chairs ○ REB Members • Environment <ul style="list-style-type: none"> ○ Research Ethics Environment
Outcomes:	<ul style="list-style-type: none"> • Streamline the ethical review process for multi-jurisdictional studies.

1 Responsibility

1.1 All Island Health REB Office Personnel, Chairs, and members are responsible for these procedures.

2 Background

Island Health REBs partner with other institutions including academic and health authority REBs through agreements where applicable for the purpose of harmonized ethics review of multi-jurisdictional research, noting that:

- Official agreements are not required for the ethics review of minimal risk research.
- Above minimal risk research an agreement is required which includes the components outlined in the [Tri-Council Policy Statement 2 \(TCPS2\), Article 8.1](#).
- In line with TCPS 2 concept of proportionality, Island Health REBs review multi-jurisdictional applications using one of the three approaches:

Maintained by:	Research Ethics & Compliance						
Issuing Authority:	Vice President, Quality, Research and Chief Nursing & Allied Health Officer						
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- 2.2.1 Direct Reciprocity:** The Island Health REB will accept the review of another REBC network institution without review when the project is minimal risk and meets one of the following criteria:
- a) The participants and their data are under the jurisdiction of a partner institution(s) and Island Health involvement includes only an affiliated researcher on the project.
 - b) The application is for the secondary use of research data and a partner REB is determined to be the Board of Record.
 - c) Another partner REB is determined to be the Board of Record and the application is considered to be minimal risk.
- 2.2.2 Partial Review:** The Island Health REBs will look at the application for site specific requirements for research that is minimal risk or above minimal risk, and meets one of the following criteria:
- a) Another partner institution REB is designated as the Board of Record, the application has some risk involved but is still considered minimal risk, local participants will be recruited, and an Island Health researcher is involved.
 - b) Another partner institution REB is designated as the Board of Record, the application is considered above minimal risk for participants but there are no local Island Health participants being recruited, and an Island Health researcher may be involved at sites outside Island Health.
- 2.2.3 Full Review:** The Island Health REB will conduct a full ethics review when the project is either minimal risk or above minimal risk and meets the following criteria:
- a) The Island Health REB is designated as the Board of Record.
 - b) The project is considered to be above minimal risk for local participants, but another partner institution is designated as the Board of Record.

3 Procedures

Island Health REBs follow the models and documents for harmonized ethical review set out by Research Ethics British Columbia (REBC) where applicable.

Island Health REBs apply these models and follow TCPS2, Chapter 8 regarding multi-jurisdictional research studies in order to maximize reciprocity nationally, where applicable.

Island Health REB Office Personnel, in consultation with REB Chairs, may establish reciprocal review agreements where appropriate following institutional and national policies.

Where an Island Health REB is the Board of Record; REB Office Personnel and/or REB Chair or designee will determine the level of risk and appropriate level of review for the research project per guidance provided by REBC.

Below refers only to research ethics review. Operational approval from the Island Health is not considered part of this process.

3.1 Researcher

3.1.1 Submits a complete application for ethical review via the Provincial Research Ethics Platform (PREP) housed by University of British Columbia (also called RISE, an online database system).

3.1.2 Identifies and meets local ethical requirements at all sites involved.

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- 3.1.3 Obtains operational approval from all sites involved.
- 3.1.4 Submits all Continuing Review Activities (Amendments, Renewals, Safety Reports, Protocol Deviations, and Closure Forms) to the Board of Record via the RISE electronic platform.

3.2 Research Ethics Boards

- 3.2.1 Following the REBC models:
- 3.2.2 **Direct Reciprocity:** REB Office Personnel will review the application received from a partner institution. If it fits the criteria outlined in section 1.2.1 for Direct Reciprocity, they will inform the partner REB administration according to the REBC models and guidance that they will not participate in the review. Documentation is available via the online database system.
- 3.2.3 **Partial Review:** REB Office Personnel will review the application received from a partner institution. If it fits into the criteria outlined in section 1.2.2 for Partial Review they will inform the partner REB administration that they would like to participate as indicated by the REBC minimal risk model and review Board of Record provisos and application for site specific concerns. If the study fits the criteria outlined in 1.2.2 the REB Office Personnel will inform the Board of Record that they would like to participate in their full board review by submitting site specific ethical review comments before the meeting.
- 3.2.4 **Full Review:** REB Office Personnel will review the application. If the study fits the criteria outlined in 1.2.3 the Island Health REB will take full responsibility for the review and include other sites as per the REBC review models. If the application fits the criteria in 1.2.3 the Island Health REB will fully participate in the full board meeting of the partner institution.

- 3.3 **Procedure Evaluation:** To ensure appropriate oversight of this SOP it will be reviewed by the Manager, Research Ethics & Compliance, the Research Ethics Coordinators, and the REB Chairs annually.

4 Training

- 4.1 Review of the SOP.

5 Compliance Monitoring

- 5.1 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.
- 5.2 The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for communicating any changes to this SOP to all relevant personnel.
- 5.3 Deviations from this SOP will be addressed through corrective and preventative action implementation.

6 Definitions

See the Glossary of Terms – Research Ethics

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7 Related Island Health Policy Documents

- SOP 505 Research Ethics Application Review Process

8 References

- [Tri-Council Policy Statement \(TCPS2\): Ethical Conduct for Research Involving Humans, Article 8.1](#)
- [Research Ethics British Columbia](#)
- Interior Health, RR0200 – Harmonized Ethics Review
- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.
- Research Ethics British Columbia, (2019).
- British Columbia Ethics Harmonization Initiative (2013).
- *BC Research Ethics Review Reciprocity Agreement*, April 2013.
- British Columbia Ethics Harmonization Initiative. (2016). [Harmonized Above Minimal Risk Ethics Review Model – Initial Review.](#)
- British Columbia Ethics Harmonization Initiative. (2016). [Harmonized Minimal Risk Ethics Review Model.](#)
- UBC Behavioural Research Ethics Board. (2016). *Conditions for Maximal Reciprocity for Studies Submitted to BCEHI Partner Institutions.*

9 Summary of Changes

Version	Effective Date	Change Description
1.0	01 JUN 2017	New Document
2.0	XXX	Updated procedures to reflect changes in organization. Changed title from Maximal Reciprocity BCEHI to Harmonized Research Ethics Review. Updated based on TCPS 2 2022. Changed Issuing Authority from Director, Research to Vice President, Quality, Research and Chief Nursing & Allied Health Officer

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