

RR0200 – HARMONIZED ETHICS REVIEW

Interior Health would like to recognize and acknowledge the traditional, ancestral, and unceded territories of the Dākelh Dené, Ktunaxa, Nlaka’pamux, Secwépemc, St’át’imc, Syilx, and T̓silhqot’in Nations, where we live, learn, collaborate and work together.

Interior Health recognizes that diversity in the workplace shapes values, attitudes, expectations, perception of self and others and in turn impacts behaviors in the workplace. The dimensions of a diverse workplace includes the protected characteristics under the human rights code of: race, color, ancestry, place of origin, political belief, religion, marital status, family status, physical disability, mental disability, sex, sexual orientation, gender identity or expression, age, criminal or summary conviction unrelated to employment.

1.0 PURPOSE

To describe the process for ethical review of research involving human participants that qualifies for Harmonized review by the Interior Health (IH) Research Ethics Board (REB) and one or more other Research Ethics Boards through a Reciprocity Agreement.

2.0 DEFINITIONS

TERM	DEFINITION
<i>Board of Record</i>	<i>The Research Ethics Board with primary authority for the ethics review and oversight of a research project.</i>
<i>Direct Reciprocity</i>	<i>Acceptance by a REB of the review and approval provided by one of its partner boards. When a REB offers Direct Reciprocity for a partner board’s review, it does not undertake an additional ethical review.</i>
<i>Harmonized Review</i>	<i>Ethical review of a research project jointly by two or more Research Ethics Boards who are party to a Reciprocity Agreement.</i>
<i>Multi-Jurisdictional Research</i>	<i>Research involving multiple institutions and/or multiple Research Ethics Boards.</i>
<i>Reciprocity Agreement</i>	<i>An Agreement between academic institutions and health authorities which outlines the terms for ethical review of the same research study jointly by two or more Research Ethics Boards of the institutions.</i>

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Policy Steward: Chief Nursing and Allied Health Officer & Professional Practice Leader		
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<i>RISe</i>	<i>The Research Information System electronic platform housed at the University of British Columbia and used for REB review of all research in BC involving two or more Research Ethics BC (REBC) partner institutions. Also known as the Provincial Research Ethics Platform.</i>
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3.0 POLICY

3.1 The IH REB partners with other academic and Health Authority REBs through a Reciprocity Agreement for the purpose of Harmonized ethics review of Multi-Jurisdictional research. The partnership is supported by Research Ethics BC.

3.2 The IH REB will review Multi-Jurisdictional research according to the Research Ethics BC *Guidance for Harmonized Ethics Review of Multi-Jurisdictional Studies*. This Guidance is in line with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* concept of proportionality. The IH REB will use one of three possible approaches:

3.2.1 **Direct Reciprocity:** The IH REB may accept the ethics review of another REB partner institution without additional review when one of the other REBC partner REBs is the Board of Record, Examples of situations where Direct Reciprocity for a partner board’s review is appropriate include:

3.2.1.1 IH involvement is limited to an IH-affiliated researcher on the project; none of the research activity occurs under the auspices of Interior Health.

3.2.1.2 IH is added via an amendment to an existing application approved by a partner board for administrative purposes, e.g. to facilitate access to archival tissues in the custody of an IH Laboratory.

3.2.1.3 IH is added to the application as a proactive measure in the event that IH participants are recruited from outside of the Health Authority (e.g. employees via professional associations or patients via community-based recruitment).

3.2.2 **Delegated review:** The IH REB may conduct a delegated review focusing on site specific requirements. Examples of situations in which delegated review is appropriate include:

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- 3.2.2.1 A partner institution REB is designated as the Board of Record and has already approved the study; IH is being added as an Amendment.
- 3.2.2.2 A partner institution REB is designated as the Board of Record and has provided the initial review of the application; IH reviews the application and adds any additional provisos to the Board of Record review.
- 3.2.3 **Full review:** The IH REB will conduct a full board review when the project is above minimal risk and the IH REB is designated as the Board of Record.
 - 3.2.3.1 IH REB reserves the right to promote a research study to full board review if substantive ethical concerns are identified during the review of a project submitted as minimal risk.

4.0 PROCEDURES

4.1 Researcher

- 4.1.1 Submits a complete application for ethical review via the RISE platform.
- 4.1.2 Identifies and meets local ethical requirements at all sites involved.
- 4.1.3 Obtains operational approval from all sites involved.
- 4.1.4 Submits all Continuing Review Activities, including but not limited to Amendments, Renewals, Safety Reports, Protocol Deviations, and Closure Forms to the Board of Record via the RISE electronic platform.

4.2 Research Ethics Board

- 4.2.1 The IH REB along with other participating REBs will agree upon a Board of Record prior to commencing the Harmonized ethical review. The Board of Record is determined by an algorithm built into the RISE platform. Participating REBs have the ability to override the algorithm if there is mutual agreement that a different REB should be Board of Record.
- 4.2.2 If the IH REB is the Board of Record; the REB Coordinator and/or Chair will determine the level of risk and appropriate level of review for the research project.

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- 4.2.3 If the IH REB is the Board of Record for a minimal risk project, the delegated review is assigned to an IH REB member. The initial review is shared with partner REBs via RISE. Partner boards will add any additional provisos. The REB Coordinator collates all provisos and forward them to the PI via RISE.
- 4.2.4 If the IH REB is the Board of Record for an above minimal risk project, the IH REB Coordinator assigns the study for Harmonized review to all partner boards via the RISE platform. Partner boards may choose to: have a member attend the IH REB meeting; provide their comments to the IH REB in advance of the meeting date in lieu of attending the meeting; or agree to Direct Reciprocity for the Board of Record review and decision.
- 4.2.5 Partner REB members attending the IH REB meeting will review study documents in advance of the meeting. The additional members will be counted as part of the quorum for the vote on the Harmonized study and be included in the discussion, decision process and voting for the Harmonized study. A summary of the discussions, decision and vote will be documented in the RISE file in addition to the meeting minutes.
- 4.2.6 If the IH REB is the Board of Record, it will coordinate continuing review activities for the research project and share all approved research related documents with the partnering REBs via the RISE platform.
- 4.2.7 Where the IH REB is not the Board of Record, it will participate in all initial and continuing review activities with the Board of Record per the applicable approach to review; Direct Reciprocity, delegated review or full review. This may be delegated to the IH REB Coordinator.

5.0 REFERENCES

1. British Columbia Ethics Harmonization Initiative. *BC Research Ethics Review Reciprocity Agreement*, April 2013.
2. British Columbia Ethics Harmonization Initiative. (2016). *Harmonized Minimal Risk Ethics Review Model*. Retrieved from <https://www.bcahsn.ca/sites/default/files/2021-02/6.-m-j-review-model-above-min-risk-29-aug-2016.pdf>.
3. British Columbia Ethics Harmonization Initiative. (2016). *Harmonized Above Minimal Risk Ethics Review Model – Initial Review*. Retrieved from <https://www.bcahsn.ca/sites/default/files/2021-02/5.-m-j-review-model-min-risk-29-aug-2016.pdf>

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4. 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.
5. Research Ethics BC. (January 2, 2019). *Guidance for Harmonized Ethics Review of Multi-Jurisdictional Research Studies: Includes Minimal Risk and Above Minimal Risk Studies*.
6. Research Ethics BC. (September 30, 2019). *Pilot Model for Harmonization of Clinical Trials*.

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