



Purpose:

To provide Island Health a standardized approach for the process by which a Researcher might seek reconsideration of an Research Ethics Board (REB) decision, and ultimately, appeal the REB decision to the Research Ethics Appeal Committee.

Context:

Island Health offers programs and services on the unceded and traditional territories of the Coast Salish, Nuuchah-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
 - All REB Chairs and members
 - All REB Office Personnel
 - Vice President, Quality, Research and Chief Nursing & Allied Health Officer
 - Executive Medical Director, Research
- Environment
 - Research Environment
- This Standard Operating Procedure (SOP) applies to all research submitted to the Island Health's REBs.

Outcomes:

- Procedures that indicate the process for Researchers to submit an appeal of an REB decision, and the establishing of a Research Ethics Appeal Committee when required.

1 Responsibility

All REB Office Personnel and REB Chairs and members are responsible for the procedures described in this SOP.

2 Procedure

- 2.1** Island Health REBs are guided by the principles of natural justice in their decision-making. In fulfilling their mandate, Island Health REBs shall function impartially, provide a fair hearing to the Researchers involved, and provide reasoned and appropriately documented opinions and decisions.

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2.2 Reconsideration

- 2.2.1 A Researcher may request, and the REB has an obligation to provide, prompt reconsideration of the REB’s decision. Initial reconsideration may be by way of informal discussion between the Researcher and the Chair of the REB;
- 2.2.2 If the matter is resolved through this information process, the resolution will be documented in the online database system and will also be reflected in the ethics application and study materials as appropriate;
- 2.2.3 If informal discussions do not result in a resolution of the issues, the Researcher may request formal reconsideration. In order to receive formal reconsideration, the Researcher shall submit a written request to the relevant REB;
- 2.2.4 Reconsideration will take place at the next regularly scheduled Full Board Meeting;
- 2.2.5 The onus is on Researchers to justify the grounds on which they request reconsideration by the REB and to indicate any alleged breaches to the established research ethics review process, or any elements of the REB decision that are not supported by Tri Council Policy Statement (TCPS2) or applicable institutional policies;
- 2.2.6 The Researcher may provide additional information for the Board’s consideration, and may also attend the Full Board Meeting in person; however, the Researcher shall not be present during the REB’s deliberations;
- 2.2.7 The Researcher shall submit any additional information for consideration on or before the application deadline for the next available Full Board meeting;
- 2.2.8 The Researcher and the REB must have fully exhausted the formal reconsideration process and the REB must have issued its final decision before the Researcher may initiate an appeal;

2.3 Notice of Appeal

- 2.3.1 If, after the completion of the relevant REB’s reconsideration, a Researcher is still not satisfied with the decision made by an REB, the Researcher may seek an appeal of that decision by sending a written Notice of Appeal to the Manager, Research Ethics & Compliance, who has been delegated authority by the Vice President, Quality, Research and Chief Nursing & Allied Health Officer to receive and manage appeals as outlined in this SOP;
- 2.3.2 The written Notice of Appeal must be filed with the Manager, Research Ethics & Compliance within thirty (30) working days of the final decision being received by the Researcher;

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2.3.3 The appeal process is NOT a forum to merely seek a second opinion of the REBs decision. Instead, the Notice of Appeal must clearly state the grounds on which the appeal is being made and should be accompanied by supporting documentation. Such supporting documentation may include (but is not limited to):

- The original ethics application,
- The original REB decision,
- All subsequent written communications between the REB and the Researcher,
- Documents and records, including a copy of the funding proposal (if appropriate),
- Relevant references or copies of pertinent guidelines, internal and external policies, and legislation;

2.3.4 An appeal may be based on procedural grounds (e.g., alleged noncompliance with the REB’s terms of reference or procedures) or substantive grounds (e.g., alleged noncompliance with a specific article of the TCPS2 or a relevant regulation or guideline);

2.3.5 The Manager, Research Ethics & Compliance will acknowledge receipt of the Notice of Appeal in writing and forward a copy of the written Notice of Appeal to the Vice President, Quality, Research and Chief Nursing & Allied Health Officer; Executive Medical Director, Research, and the Chair of the REB;

The Chair of the REB will within fifteen (15) working days from the date the Manager, Research Ethics & Compliance received the Notice of Appeal, provide written acknowledgement of the Notice of Appeal and, if the Chair of the REB deems it necessary, a response and documentation clarifying the REB’s decision;

2.3.6 The Chair of the REB will send the response and documentation to the Research Ethics & Compliance, who in turn will forward a copy to the Vice President, Quality, Research and Chief Nursing & Allied Health Officer, Executive Medical Director, Research, and the Researcher.

2.4 Composition of the Research Ethics Appeal Committee

Upon receipt of a Notice of Appeal, the VP, Quality, Research and Chief Nursing & Allied Health Officer or their delegate shall appoint members to the Research Ethics Appeal Committee (“Appeal Committee”) for the purpose of hearing the appeal;

2.4.1 Members of both Island Health REBs (Clinical and Health REBs) shall be eligible for appointment to the Appeal Committee; however, there is no requirement for both REBs to be represented on the Appeal Committee;

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- 2.4.2** The composition of the Appeal Committee must reflect the range of expertise and knowledge similar to that of the REB whose decision is being appealed, and must also meet the procedural requirements of the TCPS2, and applicable institutional policies and procedures
- 2.4.3** Specifically, the Appeal Committee shall consist of at least five (5) members.
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. It shall consist of:
 - (a) At least 2 members shall have broad expertise in the methods or in the areas of research that are covered by the relevant REB,
 - (b) At least one member shall be knowledgeable in ethics,
 - (c) At least one member shall be knowledgeable in law, and
 - (d) At least one member shall have no affiliation with the health authority, but shall be recruited from the community served by the health authority;
- 2.4.4** The Appeal Committee may appoint adhoc experts as required;
- 2.4.5** Members of the Appeal Committee must all be free of conflicts of interest in relation to the study under appeal. In addition, no member of the Appeal Committee may be a member of the REB whose decision is under appeal, or can have been a member of the REB when the decision being appealed was made;
- 2.4.6** The Appeal Committee will be appointed on an ad hoc basis;
- 2.4.7** The Appeal Committee will appoint one of its members to serve as Committee Chair.
- 2.4.8** Administrative support for the Appeal Committee will be provided through the Research Ethics and Compliance Office.

2.5 The Appeal

- 2.5.1** The onus is on the Researcher who filed the Notice of Appeal to justify the grounds of the appeal, and to indicate any breaches to the research ethics review process or any elements of the REB decision that are not supported by the TCPS2, relevant regulations or guidelines, or applicable institutional policies and procedures;
- 2.5.2** The Appeal Committee shall have the authority to review negative decisions made by an REB. In so doing, it may approve, reject or request modifications to the research proposal. Its decision on behalf of the institution shall be final;

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- 2.5.3 The Manager, Research Ethics & Compliance will assemble and distribute the Notice of Appeal and supporting documentation (including the REB minutes pertaining to the submission) to the Appeal Committee for review, with a copy to the Chair of the REB whose decision is under review and the Researcher;
- 2.5.4 A meeting of the Appeal Committee, with provision for presentations by both the Researcher and the REB Chair (or other representative of the REB as delegated by the Chair), will be organized by the Research Ethics & Compliance Office and held within **sixty (60) calendar days** of receipt of the Notice of Appeal by the Manager, Research Ethics & Compliance. Both parties may be accompanied by a colleague of their choice who will not participate in the meeting;
- 2.5.5 Meetings of the Appeal Committee will be conducted in accordance with the principles of natural justice. Both the Researcher and the REB representative have the right to speak to issues raised in the Notice of Appeal and supporting documentation and the Appeal Committee may ask questions throughout the process. Neither party shall be present when the Appeal Committee deliberates and makes a decision;
- 2.5.6 The majority decision of the Appeal Committee will be final and binding and will normally be communicated within **thirty (30) calendar days** of the meeting;
- 2.5.7 The Chair of the Appeal Committee will communicate the decision of the Appeal Committee in writing, including a summary of the issues, factual findings, conclusions and reasons for the decision to the Researcher, the Chair of the REB, the Vice President, Quality, Research and Chief Nursing & Allied Health Officer or delegate and the Manager, Research Ethics & Compliance;

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2.5.8 The Chair of the REB will be responsible for any implementation and follow up required through the REB.

3 Training

3.1 Review of the SOP

4 Compliance Monitoring

4.1 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.

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

- Refer to the Glossary of Terms – Research Ethics

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6 References

- [University of British Columbia, SOP 409: Reconsideration of REB Decisions and Appeal Process](#)
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Articles [6.18](#) & [6.20](#):
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, [Article 6.19](#)

7 Summary of Changes

Version	Effective Date	Change Description
1.0	19 DEC 2022	New procedure

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