Research Policy Manual



Code: RR Review of Research

RR1300 – APPEAL OF RESEARCH ETHICS BOARD DECISIONS

Interior Health would like to recognize and acknowledge the traditional, ancestral, and unceded territories of the Dãkelh Dené, Ktunaxa, Nlaka'pamux, Secwépemc, St'át'imc, Syilx, and Tŝilhqot'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 provide guidance regarding the Appeal process available to researchers in the event their research application, request for amendment to an approved research project, or request for renewal is not approved by the Interior Health (IH) Research Ethics Board (REB).

2.0 **DEFINITIONS**

TERM	DEFINITION
Appeal:	A process that allows a researcher to request a review of a research ethics board (REB) decision when, after reconsideration, the REB has refused ethics approval of the research.

3.0 POLICY

- 3.1 The REB may reject any research project which does not meet the standards for ethical or scientific review and where revision is unlikely to enable the REB to reach a positive determination. No other IH official may approve a study which has been previously rejected by the REB.
- 3.2 A researcher may Appeal the decision of the REB if the disagreement between the researcher and the REB cannot be resolved through a reconsideration process at a full board meeting at which the researcher will have the right to

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Policy Steward: Chief Nursing and Allied Health Officer & Professional Practice Leader					
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be heard. The researcher and REB should make every effort to resolve disagreements they may have through deliberation, consultation or advice.

- 3.3 If, after the formal reconsideration process has been exhausted and the researcher has received the REB's final written decision, a researcher is not satisfied with the decision made by the REB, the researcher has the right to make a written request to the President & CEO to initiate an Appeal for procedural or substantive reasons.
- 3.4 The researcher must justify the grounds on which a reconsideration of the decision is requested.

4.0 **PROCEDURES**

- 4.1 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):
 - 4.1.1 The original ethics application;
 - 4.1.2 The original REB decision;
 - 4.1.3 All subsequent written communications between the REB and the researcher;
 - 4.1.4 Documents and records, including a copy of the funding proposal (if appropriate);
 - 4.1.5 Relevant references or copies of pertinent policies, guidelines or legislation.
- 4.2 The REB Coordinator will acknowledge receipt of the Notice of Appeal in writing and forward a copy of the written Notice of Appeal to the Chief Nursing and Allied Health Officer and Professional Practice Leader (CNO), and to the REB Chair.
- 4.3 The CNO will inform the Vice President Human Resources (VP HR) who in turn will inform the President & CEO.
- 4.4 The President & CEO shall establish or appoint an Appeal committee that reflects a range of expertise and knowledge similar to that of the REB. The composition of the Appeal committee, as well as its terms of membership and quorum requirements, must satisfy the REB requirements in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.*
- 4.5 Members of the REB whose decision is under Appeal shall not serve on the Appeal committee.

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- 4.6 The Appeal committee shall function impartially, provide a fair hearing to those involved, and provide reasoned and appropriately documented decisions and reasons for such decisions.
- 4.7 Both the Appealing researcher and the Chair or a representative of the REB whose decision is being appealed shall be granted the opportunity to address the Appeal committee, but neither shall be present when the Appeal committee deliberates and makes a decision.
- 4.8 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. The Appeal committee's decision on behalf of IH shall be final.
- 4.9 The decision made by the Appeal committee on behalf of IH shall be communicated in writing to the researcher and to the REB whose decision was appealed. The REB will document the decision in the study file.

5.0 REFERENCES

- 1. Canadian Association of Research Ethics Boards and N2 Network of Networks (2023). Standard Operating Procedure 402.003: REB Review Decisions.
- 2. 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.
- 3. Fraser Health (2021). Policy, The Ethical Conduct of Research and Other Studies Involving Human Subjects.
- 4. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH Harmonized Guideline, Integrated Addendum to ICH E6(R1); *Guideline for Good Clinical Practice*, E6(R2), November 9, 2016.
- 5. UBC Office of Research Ethics. (2022). Policy LR9: *Research Involving Human Participants.*
- 6. UBC Office of Research Ethics (2022). Standard Operating Procedure 409: Reconsideration of REB Decisions and Appeal Process

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