


<b>Review of Health Research by the HREB Policy</b>	<b>HREA-REB03</b>
Issuing Authority	Health Research Ethics Authority
Signature of Administrative Authority Chairperson, HREA	
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Approval Date	July 2025
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**Background:**

The Health Research Ethics Authority (HREA) has a mandate to provide oversight of the ethics review process to ensure that health research involving human participants within Newfoundland and Labrador is conducted in an ethical manner.

Research activities in relation to human health, health care and health care systems conducted within Newfoundland and Labrador must comply with the *Health Research Ethics Act* (HRE Act)<sup>1</sup>. All such research activities are subject to ethics review processes overseen by the HREA.

The HREB is the statutory research ethics review body affiliated with the Authority.

**Scope:** This Policy applies to the HREB. It does not apply to another research ethics body.

**Purpose:** The purpose of this policy is to:

1. Articulate the principles of the Tri-Council Policy Statement<sup>2</sup>, as well as the HRE Act, as they relate to the research ethics review and approval of health research; and
2. Establish a research ethics review process. It also establishes the criteria by which the HREB may conduct a summary review, or grant approval, where approval has been issued by a Qualifying REB.

**Policy Statements:**

1. The Authority receives applications from Principal Investigators who wish to carry out health research. The Authority may refer an application for research ethics review to the HREB.
2. Upon being referred an application for research ethics review, the HREB will review the research to ensure it will be conducted in accordance with the Tri- Council Policy Statement and, as applicable, by the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use Guidance E6: Good Clinical Practice: Consolidated Guideline.
3. The HREB will carry out its research ethics review in accordance with applicable guidance, including but not limited to legislation, regulation, policy, SOPs, and relevant organizational/institutional

criteria.

4. The HREB may, in accordance with criteria established by the HREA, approve or conduct a summary review of an application where the proposed health research project has been approved by a not-for-profit research ethics body in another jurisdiction.
5. The HREB will provide the Principal Investigator with one of the following review decisions within 30 days of submission of a complete application: approve, approve pending changes, or refuse to approve.
6. A Principal Investigator may request a reconsideration of a decision of the HREB. A reconsideration may be appealed by the Principal Investigator. *See Policy AP-01 and related SOPs.*
7. A Principal Investigator must request written approval for a substantive change to a health research project by seeking an amendment through the application or notification process (HRE Act, s12).
8. The HREA may establish criteria permitting the HREB to conduct a summary review of proposed health research in this Province where the Principal Investigator demonstrates that a not-for-profit research ethics body in another jurisdiction ("Qualifying REB") has approved the health research (HRE Act, section 10(8)).
9. A Qualifying REB must satisfy the following criteria:
  - a) Is constituted in a Canadian jurisdiction;
  - b) Adheres to the principles of TCPS2 or its equivalent.
  - c) Is a not-for-profit entity.
10. A person who holds research ethics approval from a Qualifying REB who wishes to conduct health research in Newfoundland and Labrador is required to submit an application to the HREA and indicate, with satisfactory proof, that a prior approval is in effect. The HREB has discretion to determine whether the application is eligible for summary review. If not eligible, the application will be subject to the HREB's standard ethics review processes.
11. The HREB will adopt a proportional approach to ethics assessment based on the level of risk of the research.
12. For all health research (i) which has received approval from the HREB, or (ii) in respect of which the Authority has received a notification and issued an acknowledgement, the HREB is responsible for the following:
  - Monitoring and review of research activities (HRE Act, s13) (*See Policy REB-04*)

- Receiving close-out reports (HRE Act, s14).

13. The HREB may state the duration for which an approval is provided for health research activities, and the approval shall have no effect after the stated expiry date.
14. The HREB may make by-laws respecting its duties and powers under the HRE Act (HRE Act, s8(8)).
15. The HREB shall establish procedures for conducting research ethics oversight during publicly declared emergencies. Any modifications to the usual procedural requirements for review will be proportionate to the complexity and urgency of the emergency, and to the risks posed by the research under review. Any modifications that are made in the application of research ethics policies and procedures during a publicly declared emergency will be made publicly available via the HREA website.

## RELATED DOCUMENTS

**Standard Operating Procedure 102: *Activities Requiring HREB Review***

**Standard Operating Procedure 401: *HREB Review Decisions***

**Standard Operating Procedure 402: *Delegated Review***

**Standard Operating Procedure 403: *Initial Review – Criteria For HREB Approval***

**Standard Operating Procedure 404: *Ongoing HREB Review Activities***

**Standard Operating Procedure 405: *Continuing Review***

**Standard Operating Procedure 406: *Research Completion***

**Standard Operating Procedure 408: *Reconsideration of HREB Decisions and Appeal Process***

**Standard Operating Procedure 501: *HREB Review During Publicly Declared Emergencies***

**Standard Operating Procedure 601: *Communication - Researcher***

1. *Health Research Ethics Act: An act respecting health research ethics.* (2025). Retrieved from: [SNL2024 CHAPTER H-1.03 - HEALTH RESEARCH ETHICS ACT \[In force July 1/25\]](#)
2. The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. Retrieved from: <https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf>

## VERSION HISTORY

Revision Date	Summary of Changes
January 2021	Original version
April 2024	TCPS 2 (2022)
July 2025	Health Research Ethics Act (2025)