HREA Approval of Newfoundland and Labrador Research Ethics Bodies Policy	**HREA-GEN04**
Issuing Authority	Health Research Ethics Authority
Signature of Administrative Authority Chairperson, HREA	Regina Coady
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Review Date	July2028

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)[1]. All such research activities are subject to ethics review processes overseen by the HREA. The HRE Act establishes the HREB.

The HRE Act allows for limited circumstances in which a research ethics body, other than the HREB, may conduct a research ethics review in compliance with the HRE Act. This Policy defines the HREA criteria respecting non-HREB ethics reviews in Newfoundland and Labrador.

Purpose:

The purpose of this policy is to ensure that an entity which conducts ethical reviews of health research which falls within the scope of the HRE Act meets or exceeds applicable standards for ethical review. This Policy is intended to give effect to the HRE Act, section 9.

This policy ensures compliance with the HRE Act and Regulations, aligning with the Tri-Council Policy Statement (TCPS2 2022)[2] and applicable laws and regulations.

Policy Statement

<u>Approval of a Newfoundland and Labrador Research Ethics Body</u>

A research ethics body operating within Newfoundland and Labrador may seek approval as a Newfoundland and Labrador REB, or NL-REB, to review applications for ethics approval of health research within the meaning of the HRE Act.

An entity which seeks to act as an NL-REB must demonstrate to the HREA that it will carry out all the obligations of a research ethics body under the Act. The entity must also demonstrate that it will adhere to the principles of TCPS2 or its equivalent.

The HREA may issue its approval to an NL-REB subject to expressly stated limitations or conditions. The NL-REB will provide information to the HREA about its research ethics processes upon request.

Following approval of an NL-REB, the HREA may refer applications which are received by the HREA for research ethics review to an NL-REB pursuant to the HRE Act, s10(2). Alternatively, it may authorize the NL-REB to directly accept applications for health research ethics review.

An NL-REB will be approved by the HREA to conduct ethical reviews only in respect of health research which is both (i) minimal risk and (ii) non-clinical. By operation of provincial law, the HREB must be the board of record for health research in Newfoundland and Labrador involving Genetics and Genomics.

RELATED DOCUMENTS

Standard Operating Procedure*: HREB Review Procedures for Delegated Research Ethics Board of Record Model- In progress*

Standard Operating Procedure*: Accepting a Qualified External Research Ethics Body Review Decision- In progress*

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
July 2025	Original version