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| <b>Notification and Acknowledgment Policy<br/>(Minimal Risk Health Research Only)</b> | <b>HREA GEN-05</b>                                                                 |
| Issuing Authority                                                                     | Health Research Ethics Authority                                                   |
| Signature of Administrative Authority<br>Chairperson, HREA                            |  |
| Author                                                                                | Barbara Mason, Ethics Director                                                     |
| Approval Date                                                                         | July 2025                                                                          |
| Review Date                                                                           | July 2028                                                                          |

**Background:**

The Health Research Ethics Authority (HREA) has a mandate to provide oversight of the ethics review process to ensure that health research 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>.

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

A person who wishes to conduct health research in Newfoundland and Labrador must seek prior authorization through the HREA via one of two available processes, which are:

- (1) submitting an application to the HREA seeking approval; or
- (2) submitting a notification to the HREA seeking acknowledgement.

**Purpose:**

This Policy is intended to give effect to section 11 of the HRE Act. It explains what health research is eligible for the HREA's notification process, and how the HREA evaluates a notification and determines whether to issue an acknowledgment.

**Scope:**

This Policy applies to a person who intends to carry out minimal risk health research which has already been reviewed by a competent Canadian research ethics body, and which holds current research ethics approval from that body.

**Policy Statement**

1. The HREA will establish a notification process through which a person may seek an acknowledgement of their intention to conduct minimal risk health research.
2. The notification process is available for minimal risk health research which is subject to a current research ethics approval issued within 6 months of the notification, where the research ethics approval was granted by a competent Canadian research ethics body within the meaning of the HRE Act, s2(f).
3. The HREA may identify entities meeting the criteria for a competent Canadian research ethics body.
4. The HREA may develop and implement screening criteria to determine whether proposed health research is minimal risk health research.
5. The HREA may set the time at which a notification must be submitted by the Principal Investigator.
6. The HREA may set a fee to be paid for the notification process.
7. Upon receipt of a complete notification for eligible minimal risk health research, the HREA shall issue a written acknowledgement to the Principal Investigator.
8. A written acknowledgement is an authorization granted to the Principal Investigator to conduct health research as described in the notification.
9. An acknowledgment may state the duration for which it is effective. The acknowledgment shall have no effect after its stated expiry date.
10. A notification must include all of the documentation specified by the HREA. Upon receipt, the HREA will assess whether the notification is complete.
11. An incomplete notification will not receive an acknowledgment. The Principal Investigator will be advised that the notification was unsuccessful.
12. Health research which is being conducted pursuant to an acknowledgement is subject to monitoring and review by the HREB. See Policy REB-04 and related SOPs.
13. A Principal Investigator may make an application to seek research ethics approval at any time, including where proposed health research is ineligible for the notification process, or where a notification is unsuccessful and does not result in a written acknowledgement.

## RELATED DOCUMENTS

### Standard Operating Procedure: *In process*

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   |