HREB Monitoring Policy	**HREA-REB04**
Issuing Authority	Health Research Ethics Authority
Signature of Administrative Authority Chairperson, HREA	Regina Coady
Author	Barbara Mason, Ethics Director
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Review Date	July 2028

Background: The Health Research Ethics Authority (HREA)[1] was established to ensure that health research within Newfoundland and Labrador is reviewed in an ethical manner.

The HREA oversees the Health Research Ethics Board (HREB), which conducts monitoring and review of health research activities within Newfoundland and Labrador to ensure the research is being conducted ethically and in compliance with the authorization held by the Principal Investigator.

Purpose: The purpose of this policy is to:

1. Promote responsible research conduct and review.
2. Support Researcher compliance with applicable guidelines, regulations and legislation related to health research.
3. Specify the process for monitoring and review of health research by the HREB.

Scope:

This Policy applies to the HREB and to a person conducting health research in Newfoundland and Labrador pursuant to an authorization, meaning either (i) an approval issued by the HREB; or (ii) an acknowledgement issued by the HREA.

This Policy does not apply in respect of an approval issued by a Newfoundland and Labrador research ethics body (NL-REB). [*See* Policy HREA GEN-04, Approval of Newfoundland and Labrador Research Ethics Bodies Policy, and associated SOPs.]

Policy Statements:

1. The Principal Investigator shall ensure that their health research activities are conducted in compliance with the applicable research ethics approval or acknowledgement. This includes responsibility to identify a substantive change to a health research project, and to seek updated approval or acknowledgement accordingly.

2. The Principal Investigator shall provide the HREB with timely notification of a reportable event.

3. The HREB shall monitor health research activity which falls within the scope of this Policy.

4. The HREB may initiate or re-open a review of health research activities in accordance with criteria established by the HREB, including but not limited to on a routine or randomly selected basis; in response to a complaint; or upon being advised of a reportable event.

5. The HREB may appoint one or more of its members, or another person, to conduct all or part of a review into health research activities in the manner directed by the HREB.

6. As a result of information obtained through its review, the HREB may form the opinion that the health research project ought to be cancelled, or suspended until deficiencies identified by it have been corrected.

7. Where a research project is suspended or cancelled by the HREB, the HREB shall advise the HREA and the Principal Investigator, and it may advise such third parties as are required to carry out the objects of the HRE Act.

8. Where the HREA or the HREB forms the opinion, on reasonable grounds, that a person has failed to comply with their legal obligations in the conduct of health research, the matter will be reported to the person's licensing body or employer, as the case may be.

9. The HREB is periodically subject to external regulatory inspections and audits. The HREB will comply with applicable laws, regulations, and policy requirements.

Related Documents:

Standard Operating Procedure 901: ***Monitoring HREB Approved Research***
Standard Operating Procedure 902: ***External Inspections or Audits***
Standard Operating Procedure 903: ***Non-Compliance***

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]

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. Retrieved from: https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf

Health Canada Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects (Schedule 1024): Guidance Document: Part C, Division 5 of the Food and Drug Regulations "Drugs for Clinical Trials Involving Human Subjects" (GUI-0100) - Summary - Canada.ca

Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6(R2), Notice - Interim Implementation of International Council for Harmonisation (ICH) Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) - Canada.ca

U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46): 2018 Requirements (2018 Common Rule) | HHS.gov

U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56):https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart

VERSION HISTORY

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