HREB Authority and Purpose Policy	**HREA-REB01**
Issuing Authority	Health Research Ethics Authority
Signature of Administrative Authority Chairperson, HREA	Regina Coady
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Background: The Health Research Ethics Authority (HREA), in fulfilling its mandate to ensure that all health research involving human participants within Newfoundland and Labrador is conducted in an ethical manner, appoints the members of the Health Research Ethics Board (HREB), as per section 8 of the Health Research Ethics Act (HRE Act).[1] The HREB has the legislated authority to review health research involving human participants.

Scope: This Policy applies to the HREB.

Purpose: The purpose of this policy is to:

1. State the purpose and authority of the HREB.
2. State the principles governing the HREB to assure that the rights and welfare of participants are protected.

Policy Statements:

1. The HREB will establish ethics review processes and provide research ethics oversight to ensure that research conducted under its mandate is designed and conducted in such a manner that it protects the rights, welfare and privacy of research participants and is consistent with policies and procedures.

2. By operation of provincial law, genetics and genomics research involving human participants within Newfoundland and Labrador must obtain approval from the HREB before research activities with human participants may begin. [*See* HRE Regulations]

3. The HREB will review applications for health research, and conduct monitoring of health research, to ensure that it meets ethical principles and complies with all applicable legislation, regulations and guidelines pertaining to human participant protection including, but not limited to, the Health Research Ethics Act[1], the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)[2], Health Canada's Food and Drug Act[3], the International Council on Harmonization Good Clinical Practice: Consolidated Guidelines[4], the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects[5], and where applicable, U.S. Federal Regulations[6].

4. The HREA may establish a process for the HREB by which members of the public, including research participants, may voice their concerns, ask questions, and request information about health research and their participation in it, to a member of the HREA staff

5. The HREB shall apply the requirements of the applicable U.S. regulations to the extent that they vary from the protections set out in the applicable Canadian regulations and guidelines.

RELATED DOCUMENTS

Standard Operating Procedure 101: *HREB Authority and Purpose*

Standard Operating Procedure 602: *Communication – Research Participants*

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:* https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf

3. *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

4. *Health Canada Notice- Release of* ICH E6(R2): Good Clinical Practice: Notice - Interim Implementation of International Council for Harmonisation (ICH) Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) - Canada.ca
ICH Official web site : ICH GCP - ICH harmonised guideline integrated addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) ICH Consensus Guideline - ICH GCP

5. *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects:* WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects – WMA – The World Medical Association

6. *U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46):* CFR-2016-title45-vol1-part46.pdf (govinfo.gov); Electronic Code of Federal Regulations (eCFR)
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 50 (21 CFR 50): Electronic Code of Federal Regulations (eCFR)

VERSION HISTORY

Revision Date	Summary of Changes

April 2021	Original version
April 2024	TCPS 2 (2022)
July 2025	HRE Act (2025)