HREB Authority and Purpose Policy	**HREA-REB01**
Issuing Authority	Health Research Ethics Authority
Signature of Administrative Authority Chairperson, HREA	Regina Coady
Author	Sharon Newman, Ethics Director
Approval Date	April 30, 2024
Scheduled Review Date	April 30, 2027

Background: The Health Research Ethics Authority (HREA) was established by the HREA Act and came into effect on July 1, 2011. In fulfilling its mandate to ensure that all health research involving human participants within Newfoundland and Labrador is conducted in an ethical manner, the HREA appoints the members of the Health Research Ethics Board (HREB), as per section 7 of the HREA Act. The HREB has the legislated authority to review health research involving human participants. Research Ethics Office (REO) Personnel provide administrative and other health research ethical review expertise and support to the HREA and HREB, as per Section 6 of the HREA Act. REO Personnel may also engage with researchers and students to provide education and consultation.

Scope: All HREB members and REO Personnel are responsible for ensuring that the requirements of this policy are met.

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. Health research involving human participants will be reviewed and approved by the HREB or a research ethics body approved by the HREA before any research activities with human participants may begin. The HREB will review all health research involving human participants under its jurisdiction.

2. The HREB will review and oversee 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 Authority 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].

3. 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.

4. Research participants will have a process to voice their concerns, questions and request information regarding their participation or potential participation in research, in confidence, to an informed individual on the HREB or in the REO office.

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.

6. HREA gives authority to the Ethics Director to approve HREB Standard Operating Procedures (SOP) through consultation with the Chairs of the HREB.

RELATED DOCUMENTS

Standard Operating Procedure 101: *HREB Authority and Purpose*

Standard Operating Procedure 602: *Communication – Research Participants*

1. *Health Research Ethics Authority Act:* An act to establish a health research ethics authority for the province. (2011). Retrieved from: SNL2006 CHAPTER H-1.2 - HEALTH RESEARCH ETHICS AUTHORITY ACT (assembly.nl.ca)

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)