Review of Health Research by the HREB Policy	**HREA-REB03**
Issuing Authority	Health Research Ethics Authority
Signature of Administrative Authority Chairperson, HREA	Regina Coady
Author	Sharon Newman, Ethics Director
Original Approval Date	January 25, 2021
Scheduled Review Date	January 25, 2024

Background: The Health Research Ethics Authority (HREA) was established by the HREA Act and came into effect on July 1, 2011. The HREA Act mandates that all health research conducted in Newfoundland and Labrador requires the approval of the Health Research Ethics Board (HREB) or a research ethics body that has been approved by the HREA. 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. Articulate the principles of the Tri-Council Policy Statement, as well as the HREA Act, as they relate to the research ethics review and approval of health research; and
2. Establish a research ethics review process.

Policy Statements:

1. The HREB will review health research to ensure it will be conducted in accordance with the Tri-Council Policy Statement and, as applicable, by the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use Guidance E6: Good Clinical Practice: Consolidated Guideline.

2. 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.

3. Exemption from HREB review will be based on legislative, regulatory, guideline and relevant organizational and/or institutional criteria. This determination will be made by the HREB.

4. The HREB will provide the Researcher/applicant with one of the following review decisions within 30 days of submission of a complete application: approve, approve pending changes, or refuse to approve.

5. A Researcher/applicant may request a reconsideration or an appeal of the decision of the HREB.

6. The HREB will adopt a proportionate approach to ethics assessment based on the level of risk of the research.

7. The HREB will receive and review any new information generated throughout the course of the research that might affect the rights, safety and well-being of research participants. Any changes to the health research project will be approved by the HREB or ethics body before the changes may be implemented.

8. The HREB will review the continuing approval of research at intervals appropriate to the degree of risk, but not less than annually. Completion of research will also be reviewed by the HREB.

9. The HREB will have established procedures to continue to provide the necessary research ethics oversight during publicly declared emergencies. Any modifications to the usual procedural requirements for review will be proportionate to the complexity and urgency of the emergency, and to the risks posed by the research under review. Any modifications that are made in the application of research ethics policies and procedures during a publicly declared emergency will be reported to researchers and stakeholders via the HREA website.

RELATED DOCUMENTS

Standard Operating Procedure 102: ***Activities Requiring HREB Review***
Standard Operating Procedure 401: ***HREB Review Decisions***
Standard Operating Procedure 402: ***Delegated Review***
Standard Operating Procedure 403: ***Initial Review – Criteria For HREB Approval***
Standard Operating Procedure 404: ***Ongoing HREB Review Activities***
Standard Operating Procedure 405: ***Continuing Review***
Standard Operating Procedure 406: Research Completion
Standard Operating Procedure 501: ***HREB Review During Publicly Declared Emergencies***
Standard Operating Procedure 601: ***Communication - Researcher***

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)

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. Retrieved from: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc