HREB Organization and Operations Policy	**HREA-REB02**
Issuing Authority	Health Research Ethics Authority
Signature of Administrative Authority Chairperson, HREA	Regina Coady
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Approval Date	April 30, 2024
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. The HREA Act mandates that Health Research Ethics Board (HREB) members will be appointed in keeping with the principles contained in the Tri-Council Policy Statement. 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.

Purpose: The purpose of this policy is to outline the principles of the Tri-Council Policy Statement and the HREA Act, as they relate to:

1. Organization and operations of the HREB; and
2. Administrative review and documentation procedures.

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

Policy Statements:

1. The HREB will be appointed by the HREA as mandated by sections 7 and 8 of the HREA Act. Members of the HREB will be appointed based on appropriate expertise, training and experience to ascertain the acceptability of proposed research in terms of ethical principles, and applicable regulations, guidelines and standards pertaining to human participant protection.

2. HREB members and REO Personnel will be provided detailed training in responsibilities, regulations, guidelines, ethical principles and policies applicable to human participant research.

3. HREB membership (e.g., appointments, terms) will meet applicable regulatory composition requirements and maintain the appropriate diversity, experience and expertise for the type and volume of research reviewed. Conflicts of interest will be managed as per HREA policy and Standard Operating Procedure 105A.

4. The HREB is accountable for its activities and decisions. Controls will be applied to ensure that documentation related to HREB review and approval of research are signed by a person or persons having the appropriate authority to do so.

5. HREB members rely on the documentation provided by the Researcher to make the required determinations for review of research projects. The requirements for HREB submissions will be made available to all Researchers. An HREB application will be scheduled for HREB review when the information and materials submitted are complete. Applications will be submitted using the Researcher Portal online system.

6. The HREB will meet as required to ensure review decisions are available within 30 calendar days of receipt of a complete research application. HREB meetings will be administered to ensure that quorum is present throughout meetings. In addition, procedures will be in place to ensure a complete agenda is available to guide the meeting, and minutes are taken to accurately reflect the meeting proceedings.

7. The REO will retain all relevant records to provide a complete history of all actions related to the HREB review and decision of submitted research. Such records must be retained for the length of time required by applicable regulations and guidelines. Relevant records will be available to authorized regulatory authorities, representatives of the organizations, Researchers and funding agencies, as required.

RELATED DOCUMENTS

Standard Operating Procedure 103: ***Training and Education of HREB Members and REO Personnel***

Standard Operating Procedure 105A: ***Conflicts of Interest – Board Members and REO Personnel***

Standard Operating Procedure 106: ***HREB Signatory Authority***

Standard Operating Procedure 201: ***Composition of the HREB***

Standard Operating Procedure 202: ***Management and Duties of HREB Members***

Standard Operating Procedure 301: ***Research Submission Requirements***

Standard Operating Procedure 302: ***HREB Meeting Administration***

Standard Operating Procedure 303: ***Document Management***

Standard Operating Procedure 403: ***Initial Review – Criteria for HREB Approval***

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: 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

VERSION HISTORY

Revision Date	Summary of Changes
January 2021	Original version
April 2024	TCPS 2 (2022)