TITLE	**101: HREB Authority and Purpose**
SCOPE	The activities of the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	HREA Board of Directors
EFFECTIVE DATE	April 2021

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to:

1. State the organizational authority under which the HREB is established and empowered.
2. Define the purpose of the HREB.
3. State the principles governing the HREB to assure that the rights and welfare participants are protected
4. State the authority of the HREB.

2.0 DEFINITIONS

See Glossary of Terms

3.0 RESPONSIBILITIES

HREB members and Research Ethics Office (REO) Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 PROCEDURE

The HREB will maintain and follow all written policies and procedures consistent with federal and provincial legislation and regulations, good clinical practice and ethics guidelines when reviewing proposed research.

4.1 Statement of Organizational Authority

- The HREB is established and empowered under Section 7 of the HREA Act. The HREA has authorized the HREB to review health research involving human participants in Newfoundland and Labrador. This includes all activities whose primary goal is to generate knowledge in relation to human health, health care and health care systems, and involving human beings as research participants, health care information respecting human beings and human biological material. Human beings as research participants includes human remains, cadavers, tissues, biological fluids, embryos and foetuses, and records pertaining to them.
- All health research under the jurisdiction of the HREB will be reviewed and approved by the HREB before any research activities with human participants may begin.

4.2 Purpose of the HREB

- The purpose of the HREB is to protect the rights and welfare of human participants participating in health research.
- 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].

4.3 Governing Principles

The HREB is guided by the ethical principles regarding all research involving human participants as set forth in the Core Principles of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans as follows:

- Respect for Persons:
  - Recognize the intrinsic value of human beings and the respect and consideration they are due; and
  - Incorporate moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.
- Concern for Welfare:
  - Aim to protect the welfare of participants, and, in some circumstances to promote that welfare in view of any foreseeable risks;
  - Provide participants with enough information to be able to adequately assess risks and potential benefits associated with their participation; and
  - Ensure that participants are not exposed to unnecessary risks.
- Justice:
  - Obligation to treat people fairly with equal respect and concern; and
  - Vulnerable or marginalized people may need to be afforded special attention in order to be treated justly in research.

4.4 HREB Authority

4.4.1 The HREB is established to review health research involving human participants, as described in section 4.1 of this SOP.

4.4.2 The HREB has the authority to ensure that all research conducted under its oversight is designed and conducted in such a manner that it protects the rights, welfare and privacy of research participants.

Specifically, the HREB has the authority to:

- establish the ethics review processes, and provide research ethics oversight to ensure the ethical conduct of health research;

- approve, approve subject to changes or refuse to approve any health research activity that falls within its jurisdiction as per Section 9(1) of the HREA Act;
- ensure that the Researcher has policies and procedures to protect the rights, safety and welfare of research participants;
- request, receive and share any information involving the research that the HREB considers necessary to fulfill its mandate, while maintaining confidentiality and respecting privacy;
- conduct continuing ethics review to protect the rights and welfare and privacy of research participants;
  Continuing review activities include, but are not limited to:
  - review of regular progress reports;
  - review of changes in the design or conduct of the study prior to implementation;
  - review of unanticipated problems and serious adverse events;
  - monitoring to determine that a study is being conducted as approved;
  - observation of the informed consent process; and
  - any other review procedure deemed to be necessary to protect the rights and welfare of human participants.
- monitor the research activities of persons engaged in health research involving human participants, as per Section 11 of the HREA Act;
- suspend or cancel the ethics approval for the research as per Section 11 of the HREA Act;
- place restrictions on the research;
- take any actions considered reasonably necessary, and consistent with policies and procedures, to ensure the protection of the rights, safety, and well-being of participants in research conducted under the HREB's jurisdiction; and
- notify the appropriate licensing body or employer of an individual who has failed to comply with a direction of the HREB, as per Section 26 of the HREA Act.

5.0 SPECIFIC RESEARCH

5.1 Research Subject to US Regulations

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

6.0 REFERENCES

1. *The Health Research Ethics Authority Act*: 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:* tcps2-2018-en-interactive-final.pdf (ethics.gc.ca)
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)