Health Research Ethics Authority

Activity Plan

April 1, 2020 - March 31, 2023

Chairperson's Message

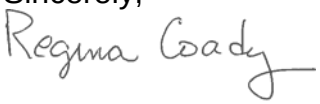
In accordance with the **Transparency and Accountability Act**, I am pleased to present the 2020-23 Activity Plan for the Health Research Ethics Authority hereafter referred to as the Authority. Under the **Transparency and Accountability Act** the Authority is defined as a Category 3 entity, and as such, will be planning and reporting in keeping with these requirements. This plan better enables the Authority to enhance recognition of ethical issues related to health research and achieve its accountability requirements to the public.

In the development of this Activity Plan, consideration was given to Government's strategic directions in the area of health and community services: strengthening the research ethics review process and enhancing awareness of the ethical conduct of health research in Newfoundland and Labrador will ensure excellence and integrity in health research, thereby benefiting the people of this province.

My signature below is indicative of the Authority's accountability for the preparation of this Activity Plan and achievement of the objectives contained in this Activity Plan.

For the purposes of this document, health research refers only to health research involving human participants as defined in the **Health Research Ethics Authority Act** (subsection 2(d)).

Sincerely,



Ms. Regina Coady, Chairperson
Health Research Ethics Authority

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1.0 OVERVIEW

The Authority was officially established with the proclamation of the **Health Research Ethics Authority Ac**t (**the Act**) in July 2011. **The Act** requires that all health research involving human participants conducted in the province be reviewed and approved by a Newfoundland and Labrador research ethics review board established in accordance with **the Act**. The Authority has the power and mandate to ensure that participants in health research in Newfoundland and Labrador are protected and to facilitate the ethics review process in the province. The Authority aims to protect the people of Newfoundland and Labrador who participate in research by ensuring excellence in research ethics review within the province. The Authority is also responsible for providing public awareness and education on ethics issues related to health research involving human participants.

Membership

The Authority is an independent, not-for-profit corporation with an administrative board appointed by the Minister of Health and Community Services. The Authority has four directors: a representative of the Eastern Regional Health Authority (Eastern Health), a representative of Memorial University (MUN), a representative employed by the Department of Health and Community Services and a person to represent the public of the province. The Chairperson of the Authority is appointed by the Minister of Health and Community Services after consultation with Eastern Health and MUN. One Chairperson of the Health Research Ethics Board (HREB) and the Ethics Director sit as non-voting members of the Board (see Appendix A).

The Ethics Director is the senior employee of the Authority and reports to the Board of Directors of the Authority.

Funding

The Authority's operating budget will be derived from revenue collected from review fees levied by industry-sponsored research and other for-profit entities as well as funding provided from MUN and Eastern Health. Additional support is provided in kind by MUN and Eastern Health as per the Memorandum of Understanding (MOU) between the Authority, MUN, Eastern Health and the Department of Health and Community Services.

2.0 Mandate

Pursuant to section 5 of **the Act**, the Authority will:

- ensure that all health research involving human subjects within the province is conducted in an ethical manner; and
- enhance public awareness of the ethical dimension of health research involving human subjects.

Further information is available on the Authority website, www.hrea.ca.

3.0 Values

Quality – Promoting the pursuit of excellence in research and ethics review of all health research in Newfoundland and Labrador.

Integrity – Promoting a consistent culture of transparency and accountability in decision-making and communication to all of our stakeholders and holding ourselves to the highest ethical standards.

Collaboration – Recognizing and valuing the diversity of our stakeholders and engaging in a positive manner that is respectful of others and their different perspectives.

Responsiveness – Recognizing and adapting to the changing research and regulatory environment.

Justice – Promoting the fair and equitable distribution of benefits and burdens of research participation in such a way that no portion of the population is unduly burdened by the harms of research or denied the benefits of knowledge generated.

4.0 Primary Clients

The general public, health researchers and health research participants are the primary clients of the Authority. In fulfilling its mandate, the Authority works closely with its key stakeholders including MUN, Eastern Health and the Department of Health and Community Services.

5.0 Vision

Excellence in Research Ethics Review

The Authority is committed to this vision by ensuring that all health research involving human participants is based on good science, meets ethical standards, and complies with international best practice. The Authority will contribute to this vision by engaging in activities to generate knowledge in relation to the ethical conduct of health research involving human participants and promoting the integrity of the health research environment.

6.0 Lines of Business

Under **the Act**, the Authority is responsible for appointing the HREB. The HREB has the legislated authority and responsibility for the ethics review and approval of applications for health research projects involving human participants. By regulation, all clinical trials and genetics research conducted in Newfoundland and Labrador must be reviewed by the HREB. Other forms of health research may be reviewed by the HREB or by other approved research ethics bodies established pursuant to section 8 of **the Act**. The HREB, and any approved research ethics body under **the Act**, are accountable to the Authority.

The Authority is responsible for appointing a standing Appeal Panel. Researchers who request an appeal from a decision of the HREB or a research ethics body approved by the Authority may apply to the standing Appeal Panel of the Authority. As well, the Authority is consulted by the Minister of Health and Community Services in the appointment of the Constituent Committee.

7.0 Annual Objective

The Authority's mandate ensures that health research involving human participants conducted in Newfoundland and Labrador is conducted in an ethical manner. This is achieved by requiring ethics approval by the HREB or a research ethics body approved by the Authority for all health research involving human participants conducted in the province. This is also facilitated by the requirement that the HREB or a research ethics body approved by the Authority will apply the principles of the Tri-Council Policy Statement (TCPS) and as applicable, the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use Guidance E6: Good Clinical Practice: Consolidated Guideline in the review and continued oversight of health research (see Appendix B). These are Canadian and international guidelines for the ethical conduct of research involving humans and/or human biological materials. Other guidelines or standards may also be applied to the review and oversight of health research as approved by the Authority.

Ethical principles and guidelines play an important role in advancing the pursuit of knowledge while protecting and respecting research participants. Over the course of 2020-23, the Authority will promote the ethical conduct of health research within Newfoundland and Labrador by implementing communication initiatives to promote the ethical conduct of health research.

In meeting its objective the Authority endeavors to implement initiatives towards improving the research ethics review process. Consideration will be given to recommendations received during an external review by Clinical Trials Ontario in 2018-19 and in consultation with stakeholders in the research community.

Lastly, the Authority hopes to enhance the governance of the ethical conduct of health research in the province. To this end, the Authority aims to implement a monitoring process for approved health research in Newfoundland and Labrador.

The Authority will be reporting on the following Objective and Indicators in each of the three years covered in this plan.

Objective: By March 31, 2021, 2022, 2023, the Authority will have implemented initiatives to strengthen the ethics review process for health research and enhanced awareness of the ethical conduct of health research in Newfoundland and Labrador.

Indicators 2020-21:

- Implemented and monitored compliance with standard operating procedures (SOPs) for the research ethics review process.
- Developed and implemented strategies to enhance the governance of the research ethics review process.
- Implemented outreach and communication initiatives to support the research ethics review process.

Appendix A: Health Research Ethics Authority Membership

As of 31 March 2020:

Position Title	**Appointee/ Represents**
Ms. Regina Coady, Chairperson	Public
Ms. Elaine Warren, Director	Eastern Health
Dr. Ray Gosine, Director	MUN
Ms. Gerrie Smith, Director	Department of Health and Community Services
Dr. Fern Brunger, HREB Chairperson (non-voting)	Health Research Ethics Board
Ms. Sandra Veenstra, Ethics Director (non-voting)	HREA Research Ethics Office

Appendix B – Reference Documents

The following reference documents support the work of the Authority and can be accessed at:

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2018 (https://ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf)

Guidelines for Good Clinical Practice of the International Committee on Harmonization (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php#a2.0)

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