Health Research Ethics Authority

Activity Plan

April 1, 2014 - March 31, 2017

Chairperson's Message

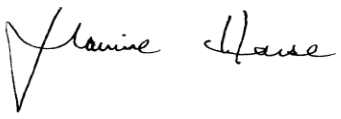
In accordance with the *Transparency and Accountability Act*, I am pleased to present the 2014-17 Activity Plan for the Health Research Ethics Authority (HREA) hereafter referred to as the Authority. Under the *Transparency and Accountability Act* the Authority is defined as a Category 3 entity, and 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; however, none apply directly to the work of the Authority for this planning cycle.

My signature below is indicative of the Authority's accountability for the preparation of this Activity Plan and achievement of the objective 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* (Section 2(d)).

Sincerely,



_____
Ms. Jeannie House, Chairperson
Health Research Ethics Authority

Table of Contents

1.0 OVERVIEW

The Authority was officially established with the proclamation of the *Health Research Ethics Authority Act* (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 health research in the province. The Authority is also responsible for providing public awareness and education on ethics issues related to health research involving human participants.

Under the Act, the Authority is responsible for appointing the Health Research Ethics Board (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 a second opinion on a decision of the HREB or a research ethics body approved by the Authority may, after consultation with the HREB or other approved research ethics body, appeal the decision to the standing Appeal Panel of the Authority.

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 4 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. The Chairperson of the HREB is a non-voting member of the Authority (see Appendix A).

An Ethics Officer 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 MOU between the Authority, MUN, Eastern Health and the Department of Health and Community Services.

2.0 Primary Clients

The primary clients of the Authority are the people of Newfoundland and Labrador who participate in research. The Authority aims to protect the people of Newfoundland and Labrador by ensuring excellence in research ethics review within the Province.

3.0 Mandate

In keeping with 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.

4.0 Values

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

Integrity – Valuing and 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 – Valuing and 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.

Performance Section

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 Annual Objective

The Authority's mandate ensures that health research conducted in Newfoundland and Labrador (NL) is conducted in an ethical manner. One way of achieving this is by requiring ethics review by the research ethics board (or a research ethics body approved by the Authority) for all health research conducted in the province. Another is through the requirement that Canadian and internationally accepted legal, ethical and regulatory principles affording protection of research participants shall govern the processes for review and continued oversight of health research.

Ethical principles and guidelines play an important role in advancing the pursuit of knowledge while protecting and respecting research participants. Over the course of 2014-2017, the Authority will promote the ethical conduct of health research within NL by focusing on the development of a communications strategy to enhance public awareness of the ethical dimension of health research involving human subjects.

In meeting this objective the Authority endeavors to develop and implement initiatives to improve the review process. Consideration will be given to feedback received during the first three years of operation and in consultation with stakeholders in the research community.

Lastly, the Authority hopes to foster a stronger accountability process for other approved research ethics bodies under the Act who review health research in the province. To this end, the Authority aims to enhance the governance of ethics review of health research in NL.

The Authority will report on the same objective for the duration of this Activity Plan (2014-2015, 2015-2016 and 2016-2017); however, the indicators which the Authority will report on will change each fiscal year and will be identified in the relevant annual report.

Objective: By March 31, 2015, the Health Research Ethics Authority will have promoted and provided oversight of the ethical conduct of health research within Newfoundland and Labrador (NL)

Measure: Promoted and provided oversight of the ethical conduct of health research within NL

Indicators:

- Initiated the development of a communications strategy
- Implemented initiatives towards improving the review process

- Clearly defined the accountability process for research ethics bodies approved under the authority of the HREA
- Provided oversight of the review and decision-making on applications to conduct health research

Appendix A: Health Research Ethics Authority Membership

As of April 1, 2014:

Position Title	**Appointee/ Represents**
Ms. Jeannie House, Chairperson	Public
Ms. Katherine Chubbs	Eastern Health
Pending appointment	MUN
Ms. Karen Stone, Director	Department of Health and Community Services
Dr. Fern Brunger, HREB Chairperson	Division of Community Health and Humanities, Faculty of Medicine, MUN
Ms. Sandra Reid, HREA, Ethics Officer	HREA 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 of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010 (http://www.pre.ethics.gc.ca/default.aspx)

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)

Contact Information

Ethics Office

Health Research Ethics Authority
Suite 200, 2nd floor, 95 Bonaventure Avenue
St. John's, NL. A1B 2X5

t: 709-777-6974
f: 709-777-8776
e: info@hrea.ca

web: www.hrea.ca