Health Research Ethics Authority

Activity Plan

April 1, 2011 - March 31, 2014

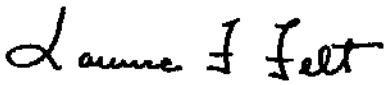
Chairperson's Message

In accordance with the *Transparency and Accountability Act*, I am pleased to present the 2011-14 Activity Plan for the Health Research Ethics Authority (HREA) hereafter referred to as the Authority. The Authority has been included under the *Transparency and Accountability Act* as a Category 3 entity and 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, as well as the mandate and activities of the Authority.

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.

Sincerely,



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Dr. Larry Felt, 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 Act* (the Act) in July, 2011. The Act requires that all health research 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 human 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 human health research.

The Authority is responsible for appointing the Health Research Ethics Board (HREB). The HREB has the legislated authority and responsibility for the ethical review and approval of applications for health research projects involving human subjects. By regulation, all clinical trials and genetics research conducted in Newfoundland and Labrador must be reviewed by the HREB. Other forms of human health research may be reviewed by the HREB or by other approved research ethics bodies established pursuant to section 8 of the Act.

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 of Newfoundland and Labrador (MUN), a representative employed by the Department of Health and Community Services and a public representative of the province. The Chairperson of the Authority is appointed by the Minister of Health and Community Services after consultation with the Eastern Regional Health Authority and Memorial University of Newfoundland. 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. The Ethics Officer is responsible for the operations and management of the Ethics Office and the HREB.

Funding

The Authority has prepared budget projections and is in process of developing a budget for review and approval by the Minister of Health and Community Services pursuant to section 20 of the Act. The Authority will have an operating budget of approximately $516,000. Of that total budget, approximately $345,000 will be derived from revenue collected from review fees levied by industry-funded contract research sponsored by pharmaceutical and other for-profit entities. The remaining funding will be provided by MUN and Eastern Health.

2.0 Primary Clients

The primary client of the Authority is the people of Newfoundland and Labrador who participate in research. The Authority seeks to protect the people of Newfoundland and Labrador by ensuring that the specific stakeholders conducting health research, such as students, researchers, health professionals, health organizations, community groups, and sponsors, receive excellence in research review by members of research ethics boards (REBs). All of this activity is conducted under the Authority outlined in the HREA Act.

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;
- enhance public awareness of the ethical dimension of health research involving human subjects;

4.0 Values

The Authority has developed their own set of values. The following core principles/values transcend disciplinary boundaries and support the full range of activities under the Authority's mandate. Each member of the Authority will perform their responsibilities in accordance with the following:

Quality – Valuing and promoting the pursuit of excellence in research and ethical 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.

Concern for Welfare – Respecting and protecting research participants and assessing risks and potential benefits associated with participation in health research.

Performance Section

5.0 Vision

Excellence in Ethical Research Review

The Authority is committed to this vision by ensuring that all 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 research involving human participants and promote the integrity of the health research environment.

6.0 Mission

The HREA has chosen not to include a mission at this time as it would be redundant of the mandate, which is provided in Section 3.0: Mandate and the objective, which is in Section 7.0: Annual Objective.

7.0 Annual Objectives

As stated in the *Tri-Council Policy Statement*[1], health research may entail risks to participants and others. These risks can be trivial or profound, physical or psychological, individual or social. Ethical principles and guidelines play an important role in advancing the pursuit of knowledge while protecting and respecting research participants in order to try to prevent such occurrences. Over the course of 2011-2014, the Authority will provide quality ethical review for health research conducted in Newfoundland and Labrador to achieve this end.

In meeting this objective, the HREB (and any other approved research ethics body) shall require 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 human health research. The HREB shall evaluate a research proposal to ensure conformity with accepted scientific and ethical standards, and applicable regulations to promote the responsible conduct of research.

The Authority has taken the strategic directions of Government into consideration during the planning process. The strategic direction of accountability and stability of health and community services and the focus area of health research relates to the work of the Authority (see Appendix B).

Objective: By March 31, 2012, 2013, 2014, the Authority will have provided quality ethical review of health research in Newfoundland and Labrador.

Measure: Provided quality ethical review of health research.

Indicators 2011-2014:

- Provided oversight in the review and decision- making on applications for health research projects involving human subjects
- Produced information for public use on the ethical review of research
- Established an inventory of all human health research conducted in Newfoundland and Labrador
- Rendered decisions on the establishment of other ethical review bodies in Newfoundland and Labrador

[1] The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* is a joint policy of Canada's three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC), or "the Agencies." This Policy expresses the Agencies' continuing commitment to the people of Canada to promote the ethical conduct of research involving humans. As a condition of funding, the Agencies require that researchers and their institutions apply the ethical principles and the articles of this Policy and be guided by the application sections of the articles.

The above objectives and indicators apply to the 2011-12, 2012-13 and 2013-14 fiscal years and will be reported on in the respective annual reports by the Authority.

Appendix A: Health Research Ethics Authority Membership

Position Title	Appointee/ Represents
Dr. Larry Felt, Chairperson	MUN
Pending appointment	Eastern Health
Ms. Jeannie House, Director	Public
Ms. Tracy King, Director	Department of Health and Community Services
Dr. Fern Brunger, HREB Chairperson	Division of Community Health and Humanities, Faculty of Medicine, MUN
Ms. Patricia Grainger, Alternate HREB Chairperson	Research Office, Centre for Nursing Studies
Ms. Sandra Reid, HREA, Ethics Officer	HREA Ethics Office

Appendix B– Strategic Directions

Strategic directions are the articulation of desired physical, social, or economic outcomes and normally require action by or involvement of, more than one government entity. They summarize the outcomes desired for the health sector and are communicated to entities that plan and report in collaboration with the Department.

Strategic Direction
Title: Accountability and stability of health and community services
Outcome: Improved system performance and sustainability

Health is a priority of Government, such that record investments have been made for several consecutive years. In 2010, health and community services consumed approximately 42 % of all government expenditures with the largest percentage allocated to regional health services (74.8 %). The ability to sustain the provision of quality services requires the coordination and integration of services, increased standardization and monitoring of clinical practice and service, and innovation. A focus on increased monitoring and evaluation, the achievement of balanced budgets, the stabilization of health human resources and increased utilization of information for evidence based practice will lead to a more sustainable health system and contribute to improved health outcomes for the people of the Province.

Focus Areas of the Strategic Direction 2011-2017	The Strategic Direction of Improved Accountability and Stability in the Delivery of Health and Community Services within Available Resources, is		
	Addressed by		
	Activity Plan	Operational Plan	Work Plan
Health Research	x		

Appendix C – 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

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