Health Research Ethics Authority

Activity Report

April 1, 2011 - March 31, 2012

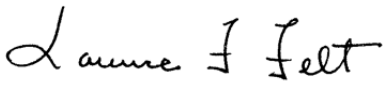
Chairperson's Message

In accordance with the *Transparency and Accountability Act*, I am pleased to present the 2011-12 Activity Report 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 has planned and reported in keeping with these requirements. This report better enabled 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 Report consideration was given to Government's strategic directions, as well as the mandate and activities of the Authority. This Annual Report provides an overview of the activities of the Authority in its first year of development and the extent to which planned and actual activities were met during fiscal year 2011-12.

As Chairperson of the Authority my signature below is indicative of the Authority's accountability for the preparation of this Activity Report and achievement of the objectives and any variances contained in this Activity Report.

Sincerely,



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Dr. Larry Felt, Chairperson
Health Research Ethics Authority

Table of Contents

1.0 OVERVIEW

The Health Research Ethics 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 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 prepared budget projections and developed a budget for review and approval by the Minister of Health and Community Services pursuant to section 20 of the Act. The Authority projected an operating budget of approximately $516,000. Of that total budget, it was projected that approximately $345,000 would 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 would be provided by MUN and Eastern Health.

The finalized audited financial statements specific to the 2011-12 fiscal year for the Authority was not available as of September 28, 2012. Upon receipt of these statements, the annual report will be promptly re-tabled in the House of Assembly.

2.0 Primary Clients

The primary clients of the Authority are the people of Newfoundland and Labrador. 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 was 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 the following core values, which transcended disciplinary boundaries and supported the full range of activities under the Authority's mandate. Each member of the Authority performed 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 was 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 contributed to this vision by engaging in activities to generate knowledge in relation to the ethical conduct of research involving human participants and promoting the integrity of the health research environment.

6.0 Mission

The HREA chose not to include a mission 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 played an important role in advancing the pursuit of knowledge while protecting and respecting research participants in order to try to prevent such occurrences. In 2011-12, the Authority focused on developmental activities, such as establishing two subcommittees of the HREB (one to review clinical trials and the other to review all other health research) and provided quality ethical review for health research conducted in Newfoundland and Labrador. The Authority required that Canadian and internationally accepted legal, ethical and regulatory principles affording protection of research participants governed the processes for HREB review and continued oversight of human health research.

As of July 1, 2011 (the date of proclamation of the Act) the HREBs reviewed and evaluated research proposals to ensure conformity with accepted scientific and ethical standards and applicable regulations and promoted the responsible conduct of research.

The Authority also held several orientation sessions for targeted groups (HREB members, researchers and administrators) to ensure awareness of the changes to the process of ethics review in the province and provide continuing support to stakeholders.

The Authority's annual objective remains the same for the three years covered by its Activity Plan; however, the report provided for each year shows progress made in that fiscal year. Thus, the comments below are pertinent to progress in the fiscal year, April 1, 2011 to March 31, 2012. This activity supported the strategic direction of accountability and stability of health and community services and the focus area of health research (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 2011-2012	Progress 2011-2012
Provided oversight in the review and decision- making on applications for	• The Authority established two subcommittees of the HREB

[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.

health research projects involving human subjects	(HREB – Clinical Trials and HREB – Non Clinical Trials) to review and approve health research involving human subjects. The HREBs alternated meetings on a weekly basis. Since July 1, 2011 a total of 210 applications were reviewed and of these 208 were approved. The remaining two applications were rejected. • The Authority established a Policy Advisory Group (PAG) to respond to requests from the staff of the Ethics Office and the Chairs of the HREBs. PAG also acts in response to new legislation, regulations and guidelines arising within federal and provincial jurisdictions, and international regulatory bodies. PAG also reviews previously approved HREB policies and developed a new policy on clinical trial substudies and banking samples for future use. • The Authority began the appointment of a Standing Appeal Panel to provide a second opinion on a decision of the HREB or a research ethics body approved by the Authority. • The Authority met monthly to discuss the operations of the organization.
Produced information for public use on the ethical review of research	• The Authority developed a publicly accessible website with information on the ethics review process for researchers, HREB members and key stakeholders: www.hrea.ca • Several orientation sessions were held to raise public awareness of the new process of ethics review in the province.

	• The Authority was represented at two conferences: The Canadian Clinical Trials Summit and The Canadian Association of Research Ethics Boards Atlantic Chapter to discuss the new model of ethical review in the province and report on the activities of the HREB's.
Established an inventory of all human health research conducted in Newfoundland and Labrador	• The Authority established a standardized form (Notification Form) that all researchers must complete when submitting an ethics application. The Notification Form captures key information that will eventually be analyzed statistically to inform the Authority's work. • The Authority inputs information into two main databases which function as an inventory of all human health research conducted in Newfoundland and Labrador. The primary database was developed and launched in May, 2011 and is housed through MUN's Research Office. The secondary database is maintained by the Authority and is internal to the Ethics Office.
Rendered decisions on the establishment of other ethical review bodies in Newfoundland and Labrador	• The Authority approved one other research ethics body under section 8 of the Act – the Interdisciplinary Committee on Ethics in Human Research (ICEHR). ICEHR is an ethics review committee of Memorial University whose focus is on ethics review of the social sciences and humanities and studies employing qualitative methods. • The Authority began planning of a site visit from an appropriate external body to conduct a

	thorough evaluation to accredit both the HREBs and ICEHR.

Discussion of Results:

The Authority has made considerable progress in its developmental activities in its first year of operation. The ethics review of human health research by the HREBs and other approved research ethics bodies has been working well. The HREA Act provides timelines for the HREB in stipulating that notice of receipt of an application must occur within 2 business days and review and response to an application must occur within 30 days. We are confident that we currently meet these timelines and are planning a review system that will enable us to continue to meet these requirements.

Annual Objective 2012 -2013:

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

Objective: By March 31, 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:

- 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

8.0 Opportunities and Challenges:

The first year of operation has allowed the Authority to lay the foundation for many opportunities in the coming years to continue progressing with developmental activities and core business.

As a new entity, and through the compilation of the 2011-2014 Activity Plan, the Authority identified the development of a communications strategy as a high priority. Particularly, given that the Authority is forming new partnerships with three very different organisations, the Authority sees this as an opportunity to continue building positive working relationships with these bodies. Subsequently, one challenge the Authority will face is creating a seamless and transparent process that accommodates all three organisations.

The Authority is continuously working towards maintaining, and ultimately expanding, clinical trial activity in the province. The Authority sees the development of its new model of ethics review as an opportunity to encourage researchers to expand their clinical trial activity to the province. This may present a challenge in the future with the trend of declining base clinical trial activity across the country.

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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