Newfoundland
Labrador

Government of Newfoundland and Labrador
Department of Health and Community Services
Policy, Planning and Evaluation Division

COR-2018-074693

September 27, 2018

Ms. Sandra Barnes
Clerk of the House of Assembly
Government of Newfoundland & Labrador
P.O. Box 8700
St. John's, NL
A1B 4J6

Dear Ms. Barnes:

Re: Health Research Ethics Authority 2017-18 Annual Activity Report

On behalf of the Honourable John Haggie, Minister of Health and Community Services, I wish to submit the 2017-18 Annual Activity Report for the Health Research Ethics Authority for tabling in the House of Assembly as required under the *Transparency and Accountability Act*. Six copies of the report are enclosed. Please note, however, that the report does not include audited financial statements as required by the *Health Research Ethics Authority Act* and the *Transparency and Accountability Act* as they are not yet finalized. Once the financial statements are finalized, the report will be submitted to you for re-tabling.

Should you have any questions, please feel free to contact me at 729-5249.

Respectfully submitted,

Seamus Breen, Director
Policy, Planning and Evaluation Division

cc: John Abbott, Deputy Minister
Michael Harvey, Assistant Deputy Minister
Scott Winters, Program and Policy Development Specialist

Health Research Ethics Authority

Activity Report

April 1, 2017 – March 31, 2018

Chairperson's Message

In accordance with the **Transparency and Accountability Act,** I am pleased to present the 2017-2018 Activity Report 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, has planned and reported in keeping with these requirements. This report allowed 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 the activities of the Authority in its seventh year of development and the extent to which planned and actual activities were met during fiscal year 2017-2018.

As Chairperson of the Authority my signature below indicates the Authority's accountability for the results reported in this Activity Report.

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. Regina Coady, 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 (NL) 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 NL are protected and to facilitate the ethics review process 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 two subcommittees – one that reviews clinical trials and genetic research (HREB-CT subcommittee) and one that reviews non-clinical trials research (HREB-NCT subcommittee). 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 not-for-profit research ethics bodies established pursuant to Section 8 of the Act. Currently the only research ethics body approved under Section 8 is Memorial University's Interdisciplinary Committee on Ethics in Human Research (ICEHR). 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, after consultation with the HREB or other approved research ethics body, apply 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 a Board with 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 HREB sits as a non-voting member of the Authority (see Appendix A).

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

Funding

During the 2017-2018 fiscal year, the Authority had operating expenditures of approximately $473,131. Revenue of approximately $24,000 was derived from review fees levied on industry-sponsored research and other for-profit entities. Funding was also provided by MUN and Eastern Health. Additional support was 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.

The external audit conducted on the Authority's financial statements for the 2017-2018 fiscal year will be completed by Ernst & Young. The finalized audited financial statements, once received, will be attached as Appendix B.

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

The Authority has developed the following core values, which transcended disciplinary boundaries and supported the full range of activities under the Authority's mandate. The HREA performed its 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.

5.0 Vision

Excellence in Research Ethics Review

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

6.0 Annual Objective

As per the Act, the Authority has the mandate to ensure 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 HREB or a research ethics body approved by the Authority for all health research involving human participants 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 (see Appendix C). Ethical principles and guidelines play an important role in advancing the pursuit of knowledge while protecting and respecting research participants.

In fiscal year 2017-2018, the Authority focused on promoting the ethical conduct of health research within NL by implementing communication initiatives to promote the ethical conduct of health research. The Authority also implemented initiatives towards improving the research ethics review process. In addition, the Authority worked towards enhancing the governance of the ethical conduct of health research in the province. Lastly, the Authority continued to focus on amending the MOU, drafting by-laws, establishing the Constituent Committee and examining the Act. This work was not completed however, and will continue in 2018-2019.

In fiscal year 2017-2018, the Authority provided oversight of the review and decision-making on applications to conduct health research. During this time the HREB reviewed and evaluated 292 research proposals to ensure conformity with accepted scientific and ethical standards and applicable regulations.

The Ethics Director of the Authority also held sixteen orientation and education sessions for targeted groups (HREB members, researchers and administrators) to ensure awareness of the process of research ethics review in the province and provide continued support to administrators and researchers submitting applications to the HREB.

The Authority's annual objective and indicators are the same for the three years covered by its Activity Plan (2017-2018, 2018-2019 and 2019-2020); however, the report provided for each year shows progress made in that fiscal year. The reporting below details progress in fiscal year 2017-2018.

Objective: By March 31, 2018, the Authority will have promoted and provided oversight of the ethical conduct of health research within NL.

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

Indicators 2017-2018	Progress 2017-2018
Implemented communication initiatives to promote the ethical conduct of health research	► During fiscal year 2017–2018 the Authority experienced an extended vacancy in the Ethics Officer role and this impacted capacity to implement a robust communication plan. However, as of fiscal year end the recruitment process was completed with the incumbent scheduled to start in April 2018. A key priority of the Ethics Director and Ethics Officer roles is to develop a formalized communication plan.

Indicators 2017-2018	Progress 2017-2018
	Much work has been done towards developing a basis for a communication strategy and work has been completed to communicate with stakeholders on the work of the Authority. Implementing communication initiatives to promote the ethical conduct of health research will continue into the next fiscal year's work plan as it continues to be a priority. ► Examples of communication activities implemented this year include: – Maintained a publicly accessible website with information on the ethics review process for researchers, HREB members and key stakeholders: www.hrea.ca. – Continued working with a contracted external company to re-design the HREA website to provide a more up-to-date, comprehensive, user-friendly resource for the research community. The website is currently undergoing a vulnerability assessment before going live. – Ethics Director worked in collaboration with MUN to advance the quality of reporting to the Authority on key metrics and research being reviewed by both HREB subcommittees. – Participated in National Health Ethics Week by holding two drop-in consultation sessions for researchers at Memorial University during this week. – Held 16 training and education sessions regarding the Authority, the HREB and the ethics review process. – During fiscal year 2017-2018, information collected via the online application forms for ethics review continued to form the basis of a communication strategy for the different Regional Health Authorities whereby the Authority was able to provide feedback on what research was being reviewed and approved for the various regions. – Conducted stakeholder survey. – Collaborated with stakeholders at MUN in the development of "Patient Engagement and Research Ethics Guidelines".

Indicators 2017-2018	Progress 2017-2018
Implemented initiatives towards improving the research ethics review process	► Continued the development of standard operating procedures (SOPs) to ensure consistency in handling applications at the Ethics Office and HREB review. ► Collaborated with the Office of the Privacy Commissioner (OIPC) to discuss the review process regarding requirements for organizational approval in NL for the secondary use of data in health research. This resulted in a guidance piece issued by the OIPC directed at the various data custodians in the province. ► Participated in a national consent working group to develop a common consent template for oncology clinical trials. ► Conducted two stakeholder surveys to solicit feedback on the various aspects of the research ethics review process. ► Commenced a LEAN analysis of various aspects of the research ethics review process. ► Commenced an examination of the Act and the development of by-laws and governance policies. ► Carried out extensive recruitment activities to strengthen the HREB membership.
Worked to enhance the monitoring process for approved health research	► Through the online research application system, ROMEO, the staff of the Authority had access to all health research files that were reviewed, including files that were reviewed by approved bodies under the act. Electronic access improved accountability and reporting processes for these approved bodies. ► The Authority began dialogue with the University regarding the requirements under the Responsible Conduct of Research (RCR) Framework to support and promote a positive research environment.

Discussion of Results:

The Authority has continued to make progress in its seventh year by focusing on promoting and providing oversight of the ethical conduct of health research within NL. The two subcommittees of the HREB (HREB – Clinical Trials and HREB – Non Clinical Trials) continue to function to review and approve health research involving human subjects. The HREB subcommittees alternated meetings on a weekly basis. During this reporting period, a total of 292 applications were reviewed by the two HREB subcommittees. The Authority received three appeals during fiscal year 2017-2018. One was subsequently withdrawn. At the end of the reporting period the remaining two appeals were currently before an appeal board.

A common theme in the responses to the stakeholder survey was related to delays in HREB reviews. A number of factors contributed to this, including a vacant Ethics Officer position at the HREA and insufficient HREB membership at times to meet quorum at all scheduled meetings. Another contributing factor in the delays may be related to the research ethics review process. Based on this feedback from the stakeholder survey, the Authority has undertaken several initiatives to enhance the Ethics Approval Process including a LEAN analysis of the research ethics review process and collection and analysis of associated metrics. This work is ongoing. The Authority has also stabilized its Human Resource capacity by: filling the Ethics Officer position, increased membership on the HREB and re-establishing the appeal panel.

Lastly, the Authority was represented at four conferences: the Canadian Association of Research Ethics Boards (CAREB) National Annual General Meeting and Conference, the CAREB Regional Conference, the Public Responsibility in Medicine and Research (PRIM&R) Advancing Ethical Research (AER) Conference, and the Clinical Trials Ontario (CTO) Conference.

7.0 Opportunities and Challenges:

The seventh year of operation has allowed the Authority to continue to focus on its core business, and to strengthen some of its developmental activities. As an evolving entity, and as guided by the newly developed 2017-2020 Activity Plan, the Authority will continue to promote and provide oversight of the ethical conduct of health research within NL and focus on enhanced communication with stakeholders.

The Authority faced some challenges during the fiscal year 2017-2018 with staff turnover in the Ethics Officer position. With this position vacant for an extensive period, progress was limited in relation to a key priority – implementing communication initiatives to promote the ethical conduct of health research. However, the Authority continued work on many communications initiatives such as re-designing the HREA website which is an opportunity to enhance communications to various stakeholders and function as a more up-to-date, comprehensive, user-friendly resource for the research community. Another associated challenge has been the ongoing recruitment and retention of members to serve on the HREB. Finally, the operation of the Authority has been impacted by an application filed in the Newfoundland and Labrador Supreme Court in March 2018 relating to the 30 day research ethics review time specified in the Act. Much media attention occurred related to this matter and the case was unresolved at the end of this reporting period.

The Authority is continuing to work towards maintaining, and ultimately expanding, clinical trial activity in the province. The ongoing trend of declining base clinical trial activity across the country has been experienced in NL as well and may present challenges in the future; however, there are continuing opportunities to streamline and increase efficiency of the process. Based on responses to the stakeholder survey that was initiated by the Authority, ongoing quality improvement initiatives will be developed to address some areas of feedback that was provided by the researchers.

Finally, the Authority continues to strengthen its partnerships with the Department of Health and Community Services, Eastern Regional Health Authority and Memorial University of Newfoundland. The review of the MOU was ongoing at the end of this reporting period. This will continue to be an opportunity to identify areas of improvement to create a seamless and transparent process that accommodates all three organizations and continue building positive working relationships with these bodies.

Appendix A: Health Research Ethics Authority Membership

Position Title	Appointee/ Represents
Ms. Regina Coady, Chairperson	Public
Ms. Elaine Warren, Director	Eastern Health
Dr. Ray Gosine, Director	MUN
Mr. Michael Harvey, Director	Department of Health and Community Services
Ms. Patricia Grainger, HREB Chairperson (non-voting)	HREB
Ms. Sandra Veenstra, HREA, Ethics Director (non-voting)	HREA Ethics Office

During fiscal year 2017-2018 the Authority had turnover in the Chairperson and public representative position, as well as the Eastern Health representative. The above listing represents the composition of the HREA Board on March 31, 2018.

Appendix B: Audited Financial Statements

Pending.

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 2014 (http://www.pre.ethics.gc.ca/default.aspx)

Guidelines for Good Clinical Practice of the International Committee on Harmonization (https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/ich/efficac/e6r2-step4-eng.pdf)

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