Health Research Ethics Authority

Annual Performance Report

April 1, 2023 – March 31, 2024

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1.0 Chairperson's Message

In accordance with the **Transparency and Accountability Act,** I am pleased to present the 2023-24 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 details the Authority's progress toward enhancement and recognition of ethical issues related to health research and achievements in its accountability requirements to the public.

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)).

In the development of this Activity Report, consideration was given to the activities of the Authority and the extent to which planned and actual activities were met during fiscal year 2023-24.

On behalf of the Authority's Board of Directors, I would like to extend our appreciation to the Chairs and the members of the Health Research Ethics Board (HREB) subcommittees for their generous commitment of time and expertise to the ethics review process and their resiliency and adaptability. This exceptional commitment enables the Authority to carry out its mandate and achieve its vision for excellence in research ethics review.

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

Sincerely,

Ms. Regina Coady, Chairperson
Health Research Ethics Authority

2.0 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 HREB. The HREB has three subcommittees – one that reviews clinical trials (HREB-CT subcommittee), one that reviews non-clinical trials research (HREB-NCT subcommittee) and one that reviews genetic and genomic research (HREB-GG 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 NL 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. Further information is available on the Authority's website, www.hrea.ca.

Vision

The vision is *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.

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's website, www.hrea.ca.

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.

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 Newfoundland and Labrador Health Services (NLHS), a representative of Memorial University of Newfoundland (MUN), a person employed by the Department of Health and Community Services (HCS) 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 NLHS and MUN. One Chairperson of the HREB and the Ethics Director sit as non-voting members of the Board (see Appendix A). The Authority is comprised of six females.

The Ethics Director is the senior employee of the Authority and reports to the Chairperson of the Authority. Additionally, the HREA employs two Ethics Officers, one administrator and one receptionist who report to the Ethics Director. The ethics office is comprised of five females.

Physical Location

The office is located at Mount Pearl Square, 760 Topsail Road, Mount Pearl, Newfoundland and Labrador (Business Entrance).

Revenues and Expenditures

During the 2023-24 fiscal year, the Authority had operating expenditures of approximately $ 494,819. Revenue of approximately $ 112,500 was derived from review fees levied on industry-sponsored research and other for-profit entities. Additional support was provided in kind by MUN and NLHS as per the Memorandum of Understanding (MOU) between the Authority, MUN, NLHS and the HCS.

The external audit conducted on the Authority’s financial statements for the 2023-24 fiscal year was completed by Ernst & Young. The audited financial statements are attached as Appendix B.

3.0 Highlights and Partnerships

In keeping with its mandate, the Authority continues to focus on enhancing public awareness of the ethical dimension of health research involving human subjects and ensuring that health research involving human subjects is conducted in an ethical manner. This is accomplished in conjunction with internal and external collaborators and stakeholders.

In fiscal year 2023-24, the Authority implemented several communication initiatives to promote the ethical conduct of health research and improve the research ethics review process. The Authority Board of Directors met with stakeholders to communicate the work of the Authority.

The Authority held several orientation and education sessions for targeted groups (HREB members, researchers, coordinators, administrators, students, faculty and senior officials from NLHS and MUN), providing education related to ethical research conduct and the process of research ethics review in the province. The sessions also provided continued support to administrators, coordinators and researchers in the HREB application process. The Authority also participated virtually in the Canadian Association of Research Ethics Boards (CAREB-ACCER) conference, and as well as NLHS Innovation Summit. The Authority continues to collaborate on several local and national working groups including the Atlantic Clinical Trial Network (ACTN), the Canadian Collaboration for Child Health: Efficiency and Excellence in the Ethics Review of Research (CHEER), Data Governance, the National Policy Modernization group, Forum on Responsible Conduct of Research, MUN Research Strategy Framework and the Pan Canadian Research Privacy Network.

Throughout fiscal year 2023-24, the Authority engaged with CHEER to facilitate the streamlining of the research ethics review in Canada through receiving a designation as a qualified REB, effective February 14th, 2024. The CHEER REB Qualification process provided assurances that the HREB is meeting the minimum standard for REB governance, membership, operations, and procedures. The qualification is maintained for a three-year period with the option of re-qualification. The Authority recognizes the importance of streamlining the ethical review process throughout Canada while ensuring the provincial legislative requirements are met. A grant was secured through CHEER to contractually hire a skilled employee to assist in this process.

The Authority continued to provide oversight of the review and decision-making on applications to conduct health research. During this time, the HREB reviewed and evaluated 217 research proposals to ensure conformity with accepted scientific and ethical standards and applicable regulations. In addition, 1,806 events were reviewed to ensure that all stages of ongoing research projects are ethically acceptable in accordance with applicable policies and regulations. Events related to research projects include, but not limited to are, annual renewals, protocol amendments, safety reports, protocol deviations, adverse events and research staff changes. As well, additional HREB members were recruited across the three subcommittees. Revision of policy framework continued throughout the year to ensure compliance with national standards for heath research ethics review.

Finally, the Authority and the parties to the Memorandum of Understanding (MOU), which outlines the contributions to be made by the parties and various processes and policies which apply to the operation and funding of the HREA, continued the review of the MOU. The parties to the MOU include the Authority, MUN, NLHS and HCS.

4.0 Report on Performance

As per the Act, the Authority has the mandate to ensure that health research conducted in NL 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 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 C). Other guidelines or standards may 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.

The Authority's annual objective and indicators are the same for the three years covered by its Activity Plan (2023-24, 2024-25 and 2025-26); however, the report provided for each year shows progress made in that fiscal year. The reporting below details progress in fiscal year 2023-24.

Objective: By March 31, 2024, the Authority will have enhanced awareness of the ethical conduct of health research in Newfoundland and Labrador, strengthened governance of the research review process and implemented a sustainability plan for the Health Research Ethics Authority.

Indicators 2023-24	Progress 2023-24
Implemented outreach and communication initiatives to support the research ethics review process.	► During fiscal year 2023-24, the Authority continued a robust communication strategy to communicate with stakeholders on the work of the Authority. Communication initiatives were implemented to promote the ethical conduct of health research throughout 2023-24. ► Examples of communication activities implemented include: • Worked in collaboration with MUN to improve the quality of reporting to the Authority and stakeholders on key metrics and research being reviewed by the HREB. • Held training sessions for new HREB members. • Held a workshop for the Department of Research and Innovation regarding the ethics review process. • Presented at the Postgraduate Medical Education (PGME) Resident Research Day. • Collaborated with research groups, MUN students and faculty members, NLHS and the Faculty of Medicine to identify

Indicators 2023-24	Progress 2023-24
	opportunities for the Authority to promote and provide information related to the ethical conduct of health research and to facilitate the HREB submission process. • Presented several sessions to these groups relating to the Authority, the HREB and the ethics review process. • Communicated with NLHS via a monthly report which provided a list of the research projects that were reviewed and approved by the HREB for each region. • Met with stakeholders (e.g., MUN, HCS, NLHS, NLCHI and Faculty of Medicine) to communicate the work of the Authority. • Collaborated with research ethics boards and research organizations across the country to stay abreast of processes and efficiencies in other jurisdictions.
Strengthened the governance of health research ethics process in Newfoundland and Labrador.	► On February 14, 2024, the HREA received CHEER qualification and now is eligible to review multi-centre, multi-jurisdictional health research on behalf of institutions agreeing to delegate research ethics review to the CHEER board of record. ► The Authority is working on developing a qualification process to approve other research ethics boards to review non-clinical trial/ non-genetic research under Section 8 of the HREA Act. ► The standard operating procedures (SOPs) have been updated to reflect the qualification process. The SOPs provide guidance and consistency in the research ethics review process. ► The Authority continued the monitoring process and completed two not-for-cause audits to ensure compliance with applicable legislation, policies, regulations and guidance in the conduct of research. ► The Authority continues to utilize the online research application system, ROMEO, situated at MUN, which allows the Authority to have access to all health research files that were reviewed, including files that were reviewed by approved bodies under the Act. Electronic access has improved accountability and reporting processes for these approved bodies. ► The Authority continues to engage MUN to replace existing ROMEO platform with a new system called CAYUSE. ► The Authority reviewed 1,806 events including amendments or changes to study proposals, annual renewals of ongoing research studies, changes in research study personnel, updates regarding

Indicators 2023-24	Progress 2023-24
	medications, devices or any other products that relate to its safety including, but not limited to, side effects, adverse reactions and hospitalizations. ► Collaborated with provincial data custodians to evolve a standard process for the secondary use of data in health research that meets both the ethical requirements as well as the data custodian requirements and streamlines the process for researchers. ► Conducted Chairperson performance evaluations which is essential to build on strengths and identify areas of improvement amongst the leaders of our HREB. ► Continued recruitment activities to strengthen the HREB membership.
Implemented a plan for sustainability of the Health Research Ethics Authority	► The Authority is engaging with NLHS and MUN to implement long term fiscal stability. ► The Authority secured in-kind office space from NLHS and moved to a new location in May 2023. ► Continued negotiations with MUN, NLHS and HCS on the review and revision of the current MOU. ► Continued engagement with HCS on the legislative amendment.

Discussion of Results:

The Authority has continued to make progress by focusing on promoting and providing oversight of the ethical conduct of health research within NL. The three subcommittees of the HREB (HREB-CT, HREB-NCT and HREB-GG) function to review and approve health research involving human subjects. Each HREB subcommittee had scheduled biweekly meetings. During this reporting period, a total of 217 applications were reviewed by the three HREB subcommittees. HREB-NCT reviewed 162 applications, HREB-CT reviewed 45 applications and HREB-GG reviewed 10 applications. In addition, 1,806 events were reviewed for active studies. Table 1 outlines the metrics for 2023-24.

Table 1

Total Applications Reviewed	217		
	HREB-NCT 162	HREB-CT 45	HREB-GG 10
Total Events Reviewed	1,806		
	HREB-NCT	HREB-CT	HREB-GG

	754	890	162
Total Active Studies*			
	HREB-NCT 311	HREB-CT 191	HREB-GG 45

*Point in time measure (March 31, 2024)

The Authority has been 100 per cent compliant with the 30-day decision requirement. Table 2 outlines the length of time for HREB application review in 2023-24.

Table 2

	Length of time to first decision*	Length of time to final decision**
Average	12.50 days	53.5 days
Median	13 days	37
Range	0-30	0-515*

*With researcher for 421 days and with HREB for 94 day

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While the membership on the HREB remains compliant with the requirements mandated by TCPS, the Authority continues to recruit and accept new members. The stability in the HREB membership is contributing towards improving the research ethics review process.

In compliance with Section 15 of the Act, an Appeal Panel was reappointed by the Authority in 2021-22. There were no HREB decisions appealed in this fiscal year 2023-24.

Several stakeholder meetings, education sessions, and collaboration initiatives have enhanced communication between the research community and the Authority. The Authority website also provides an up-to-date, comprehensive, user-friendly resource for the research community. These communication initiatives continue to serve to promote the ethical conduct of health research.

The Authority was also represented at the Canadian Association of Research Ethics Boards (CAREB) 2023 conference and the CHEER initiative.

In 2023-24, the Authority began implementation of a Chairperson Evaluation process that acknowledges and promotes high quality performance to help enhance the ethical review of health research.

8.0 Opportunities and Challenges

The Authority continues to focus on its core business and to strengthen some of its developmental activities. As an evolving entity, and as guided by the 2023-26 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 continues to experience financial challenges in 2023-24, given its limited revenue base and is projecting deficit for fiscal year 2024-25. The Authority is exploring further

opportunities to increase revenue generation in tandem with the MOU review. In keeping with its fiscal management, HREA has revised the fee structure to include all research that constitutes for profit.

Additionally, HREA is working with key stakeholders, including MUN and NLHS to plan for the long-term financial position of the HREA and to mitigate any future deficits.

The Authority is continuing to support the broader institutional and provincial efforts towards maintaining and ultimately expanding, clinical trial activity in the province.

Finally, the Authority continues to strengthen its partnerships with HCS, NLHS and MUN. 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. Kelli O'Brien, Representative	NLHS
Dr. Tana Allan, Director	MUN
Gillian Sweeney	HCS
Dr. Fern Brunger, HREB Chairperson (non-voting)	HREB
Ms. Sharon Newman, Interim Ethics Director (non-voting)	Authority Office

The above listing represents the composition of the Authority's Board of Directors as of March 31, 2024.

Appendix B: Audited Financial Statements

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)

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