

Health Research Ethics Authority

Annual Performance Report

April 1, 2025 – March 31, 2026

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1.0 Chairperson's Message

In accordance with the **Transparency and Accountability Act**, I am pleased to present the 2025-26 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.

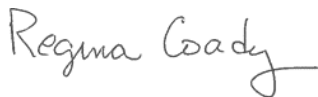
For the purposes of this document, health research refers only to health research involving human participants as defined in subsection 2(h) of the **Health Research Ethics Act**.

In the development of this Annual Report, consideration was given to the activities of the Authority and the extent to which planned and actual activities were met during fiscal year 2025-26.

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) committees 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,

A handwritten signature in cursive script that reads "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officially established with the proclamation of the **Health Research Ethics Authority Act** in July 2011, which was repealed and replaced on July 1, 2025 by the **Health Research Ethics Act (the Act)**. The Act requires that all health research involving human participants conducted in the province be approved or acknowledged by a Newfoundland and Labrador research ethics review board established in accordance with the Act. Minimal risk health research which is subject to a current research ethics approval issued within 6 months, where the research ethics approval was granted by a competent Canadian research ethics body within the meaning of the Act, s.2(f), may be conducted pursuant to an acknowledgement by the Authority. The Authority may permit the HREB to conduct a summary review of proposed health research in this Province which is subject to a current research ethics approval issued within 6 months, where the research ethics approval was granted by a not-for-profit research ethics body that was constituted in another Canadian jurisdiction and adheres to the principals of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) or its equivalent. The Authority has the power and mandate to ensure that participants in health research in Newfoundland and Labrador are protected and to facilitate the ethics review process in the province. The Authority aims to protect the people of Newfoundland and Labrador who participate in research by ensuring excellence in research ethics review within the province. The Authority is also responsible for enhancing awareness of the ethical dimension of health research.

Under the Act, the Authority is responsible for appointing the HREB. The HREB has three committees – one that reviews clinical trials (HREB-CT committee), one that reviews non-clinical trials research (HREB-NCT committee) and one that reviews genetic and genomic research (HREB-GG committee). The HREB has the legislated authority and responsibility for the ethics review and approval or acknowledgement of applications for health research projects involving human participants. By regulation, all genetics or genomics 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 9 of the Act. Currently the only research ethics body approved under section 9 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 advancement of safe, ethical, and impactful health research can provide residents with access to innovative and evidence-informed discoveries and treatments that contribute to advancements in healthcare, and improved health outcomes. 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 6 of the Act, the Authority will:

- provide oversight of the ethics review process to ensure that health research is conducted in an ethical manner; and
- be responsible for enhanced awareness of the ethical dimension of health research.

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 or acknowledgement of applications for health research projects involving human participants. By regulation, all genetics and genomics 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 9 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.

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 seven directors: a person employed by the Provincial Health Authority, a person employed by Memorial University of Newfoundland and Labrador (MUN), a person employed by the Department of Health and Community Services (HCS), three persons to represent the public of the province, and the Chairperson of the HREB, as voted by the members of the HREB, who shall be a non-voting director. The Chairperson of the Authority is appointed by the Minister of Health and Community Services after consultation with the Provincial Health Authority and MUN. The Ethics Director serves on the Board in an administrative support role. (see Appendix A). The Authority is currently comprised of four female directors. The Authority awaits the appointment of two persons to represent the public and the representative of the Provincial Health Authority.

The Ethics Director is the senior employee of the Authority and reports to the Chairperson of the Authority. Additionally, the Authority employs two Ethics Officers, one clerk stenographer and one intermediate secretary 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 2025-26 fiscal year, the Authority had operating expenditures of approximately \$533,275. Revenue of approximately \$492,967 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 2025-26 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 partners.

On July 1, 2025, the Act came into force. This replaced the Health Research Ethics Authority Act. The Authority continues to engage with partners to make them aware of the changes. The Authority has developed policies and is developing standard operating procedures to ensure alignment with the new Act.

In fiscal year 2025-26, 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 partners to communicate the work of the Authority and raise awareness of the new requirements under the Act.

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, the Access, Privacy, Security, and Information Management (APSIM), Conference and as well as NLHS Innovation Summit. The Authority continues to collaborate on several local and national working groups including the Canadian Collaboration for Child Health: Efficiency and Excellence in the Ethics Review of Research (CHEER), Accelerating Clinical Trials (ACT), CanReview, N2 Canada and Forum on Responsible Conduct of Research.

During fiscal year 2025-26, the Authority continued to engage with CHEER and finalized the Newfoundland and Labrador component of the streamlining of child health research ethics review in Canada. The Authority continues to engage with CanReview to build a Canada-wide research ethics review system that will enable single ethics review for multi-site clinical trials while ensuring the highest ethical standards and compliance with provincial legislation.

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 197 research proposals to ensure conformity with accepted scientific and ethical standards and applicable

legislation and regulations. In addition, 1502 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. Two minimal risk health research proposals, which received approval to engage in minimal risk health research under the criteria in section 11 of the Act, were submitted to the Authority for acknowledgement in line with the Authority's Notification and Acknowledgement Policy.

As well, additional HREB members were recruited across the three committees. Revision of policy framework continued throughout the year to ensure compliance with national standards for health research ethics review. Revisions to all policies and standard operating procedures were finalized to comply with the new Act.

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, by a research ethics body approved by the Authority, or by a research ethics body per section 2(f) of the Act, for all health research involving human participants conducted in the province. This is also facilitated by the requirement that the HREB, a research ethics body approved by the Authority, or a research ethics body per section 2(f) of the Act, will apply the principles of the TCPS 2 and the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use Guidance E6(R3): 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 2025-26.

Objective: By March 31, 2026 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 2025-26	Progress 2025-26
Implemented outreach and communication initiatives to support the research ethics review process.	▶ During fiscal year 2025-26, the Authority continued a robust communication strategy to communicate with partners on the work of the Authority and implementation of the Act. Communication initiatives were implemented to promote the ethical conduct of health research throughout 2025- 26. ▶ Examples of communication activities implemented include: • Held training sessions for new HREB members. • Held workshops for the NLHS Department of Research and Innovation regarding the ethics review process. • Presented at the Postgraduate Medical Education(PGME) Resident Research Day. • Presented on Ethics in Medical Research for Obstetrics and Gynecology Grand Rounds. • Delivered information sessions for researchers during MUN Research Week and engaged with research community. • Provided research ethics application training to the MUN Faculty Development Initiative 6for6, Family Care Team, School of Pharmacy, NLHS Clinical Trial Division, NLHS Research and Innovation, and MUN Undergraduate Medical Education program as well as to individual researchers who requested training. • Assisted in mock research ethics board training for students of the Masters of Health Ethics program atMUN. • Actively engaged with the clinical, research, and academic community to highlight changes to health research ethics review that were incorporated into the Act. • Collaborated with research groups, MUN students and faculty members, NLHS and the Faculty of Medicine to identify opportunities for the Authority to promote and provide information related to the ethical conduct of health research and to facilitate the HREB submission process. • Provided NLHS a monthly report listing the research projects that were reviewed and approved by the HREB for each region. • Met with partners (e.g., MUN, HCS, NLHS, and Faculty of Medicine) to communicate the work of theAuthority.

Strengthened the governance of health research ethics process in Newfoundland and Labrador.	•Collaborated with research ethics boards and research organizations across the country to stay abreast of processes and efficiencies in other jurisdictions. •Engaged with ICEHR to discuss the process of health research ethics review per the Act. ▶ The Authority revised all current policies and developed new policies as needed to align with the Act. ▶ The Authority completed substantive revisions to Standard Operating Procedures and developed new SOPs as needed to align with the Act. ▶ The Authority revised By-laws to align with the Act. ▶ The Authority continues to be part of the leadership team of CanReview, a pan-Canadian collaboration supported by the Accelerating Clinical Trials (ACT) Consortium to enable a single research ethics review for multi-site clinical trials conducted across Canada. The goal of CanReview is to improve efficiencies and study start-up times, increase Canada’s competitiveness in attracting global clinical trials, expand clinical trials to underserved, rural and remote locations, and improve equitable access to trial participation. ▶ The Authority finalized cross-institutional agreements required for research ethics review of multi-jurisdictional above minimal risk health research. ▶ HREB was expanded to include a person knowledgeable in privacy to align with section 8(2)(d) of the Act. ▶ The Authority developed processes to approve research ethics bodies for the purpose of reviewing applications for approval of health under section 9 of the Act. ▶ The Authority continued the monitoring process and initiated one for cause audit and 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.
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Implemented a plan for sustainability of the Health Research Ethics Authority.	▶ The Authority continues to engage with MUN to replace the existing ROMEO platform with a new system, called CAYUSE. ▶ The Authority had oversight over the HREB which reviewed 1502 events including amendments or changes to study proposals, annual renewals of ongoing research studies, changes in research study personnel, updates regarding 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 explore the strengthening of data protections in light of advances in artificial intelligence in the context of health research. ▶ Continued recruitment activities to strengthen the HREB membership. ▶ Through ongoing engagement with NLHS, HCS, and MUN the Authority was successful in securing additional funding to enhance long term fiscal stability commencing 2026-27 fiscal year.
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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 197 applications were reviewed by the three HREB subcommittees. HREB-NCT reviewed 146 applications, HREB-CT reviewed 47 applications and HREB-GG reviewed 4 applications. In addition, 1,502 events were reviewed for active studies. There was a total of 581 active studies as of fiscal year end March 31, 2026. Table 1 outlines the metrics for 2025-26.

The Authority reviewed two notifications of health research projects, pursuant to section 11(1) of the Act, submitted by researchers intending to carry out minimal risk health research. Both remain active.

The Interdisciplinary Committee on Ethics in Human Research (ICEHR) is an approved research ethics body under section 9 of the Act and may review applications of health research in accordance with the Act. ICEHR reviewed 4 health research projects during the 2025-26 year.

Table 1

Total Applications Reviewed				TOTAL
	HREB-NCT 146	HREB-CT 47	HREB-GG 4	197
Total Events Reviewed				
	HREB-NCT 511	HREB-CT 865	HREB-GG 126	1502
Total Active Studies*				
	HREB-NCT 357	HREB-CT 175	HREB-GG 49	581

*Point in time measure (March 31, 2026)

The Authority has been 100 per cent compliant with the 30-day time to first decision requirement. Table 2 outlines the length of time for HREB application review in 2025-26.

Table 2

	Length of time to first decision	Length of time to final decision*
Average	12.6 days	60.8 days
Median	13.4 days	48.2 days
Range	1-29 days	1-280 days

The HREB membership was expanded to include persons knowledgeable in privacy in order to align with changes to the Act. While the membership on the HREB remains compliant with the requirements mandated by TCPS 2, the Authority continues to recruit and accept new members. The stability in the HREB membership is contributing towards improving the research ethics review process.

There were no HREB decisions appealed in this fiscal year 2025-26.

Several partner meetings, education sessions, and collaboration initiatives have enhanced communication between the research community and the Authority and ensure wide dissemination of information related the Act. The Authority website also provides comprehensive, user-friendly resources for the research community. These communication initiatives continue to serve to promote the ethical conduct of health research.

5.0 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 2027-29 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 partners.

The new Act came into force July 1, 2025 enabling several advancements including but not limited to expansion to the Authority's Board of Directors composition, lengthened terms of appointment, and acceptance of specific health research approved by other jurisdictions qualified research ethics bodies. The Authority is projecting it will remain within budget for fiscal year 2026-27.

While successful in securing additional funding, the Authority continues to work with key partners, including MUN, HCS, and NLHS to plan for the long-term financial stability of the Authority 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. It will continue to identify areas of improvement to create a seamless and transparent process that accommodates all three organizations, and will continue to build positive working relationships with these bodies.

Appendix A: Health Research Ethics Authority Membership

Position Title	Appointee/ Represents
Ms. Regina Coady, Chairperson	Public
Vacant	Public
Vacant	Public
Vacant	NLHS
Dr. Tana Allan, Director	MUN
Gillian Sweeney	HCS
Dr. Fern Brunger, HREB Chairperson (non-voting)	HREB

Barbara Mason, the Authority's Ethics Director, serves on the Board of Directors in an administrative support role.

The above listing represents the composition of the Authority's Board of Directors as of March 31, 2026

Appendix B: Audited Financial Statements

Health Research Ethics Authority

Financial statements
March 31, 2026



Shape the future
with confidence

Independent auditor's report

To the Board of Directors of
Health Research Ethics Authority

Opinion

We have audited the financial statements of the **Health Research Ethics Authority** [the "Authority"] which comprise the statement of financial position as at March 31, 2026, and the statement of operations, statement of changes in net assets and statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

In our opinion, the accompanying financial statements present fairly, in all material respects, the financial position of the Authority as at March 31, 2026, and its results of operations and its cash flows for the year then ended in accordance with Canadian public sector accounting standards.

Basis of opinion

We conducted our audit in accordance with Canadian generally accepted auditing standards. Our responsibilities under those standards are further described in the *Auditor's responsibilities for the audit of the financial statements* section of our report. We are independent of the Authority in accordance with the ethical requirements that are relevant to our audit of the financial statements in Canada, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Responsibilities of management for the financial statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with Canadian public sector accounting standards, and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Authority's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the Authority or to cease operations, or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the Authority's financial reporting process.

Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Canadian generally accepted auditing standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.



As part of an audit in accordance with Canadian generally accepted auditing standards, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Authority's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Authority's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Authority to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

St. John's, Canada
May 14, 2026

Ernst & Young LLP

Chartered Professional Accountants



A member firm of Ernst & Young Global Limited

Health Research Ethics Authority

Statement of financial position

As at March 31

	2026	2025
	\$	\$
Assets		
Current		
Accounts receivable <i>[note 3]</i>	19,500	28,000
Prepaid expenses	14,960	14,604
Total current assets	34,460	42,604
Liabilities and net assets		
Current		
Accounts payable and accrued liabilities	11,559	10,844
Due to related party <i>[note 5]</i>	45,694	14,245
Total liabilities	57,253	25,089
Net assets	(22,793)	17,515
	34,460	42,604

See accompanying notes

On behalf of the Board:



Chair of the Board of Directors

Health Research Ethics Authority

Statement of operations

Year ended March 31

	2026	2025
	\$	\$
Revenue		
Support-in-kind <i>[note 5]</i>	226,467	214,845
Operating grants <i>[note 5]</i>	130,000	130,000
Other grant	10,000	
Research project approval fees	<u>126,500</u>	<u>129,000</u>
	<u>492,967</u>	<u>473,845</u>
Expenditures		
Salaries and employee benefits <i>[note 5]</i>	401,024	383,739
Professional fees <i>[note 5]</i>	62,758	25,385
Honorariums	42,761	47,589
Insurance	18,799	19,068
Telephone <i>[note 5]</i>	6,163	6,163
Equipment rentals <i>[note 5]</i>	1,180	1,177
Memberships	195	
Waste disposal/document storage <i>[note 5]</i>	160	215
Conferences and seminars	140	
Software	61	
Bank service charges	<u>34</u>	<u>166</u>
	<u>533,275</u>	<u>483,502</u>
Deficiency of revenue over expenditures for the year	<u>(40,308)</u>	<u>(9,657)</u>

See accompanying notes

Health Research Ethics Authority

Statement of changes in net assets

Year ended March 31

	2026	2025
	<u>\$</u>	<u>\$</u>
Balance, beginning of year	17,515	27,172
Deficiency of revenue over expenditures for the year	<u>(40,308)</u>	<u>(9,657)</u>
Balance, end of year	<u>(22,793)</u>	<u>17,515</u>

See accompanying notes

Health Research Ethics Authority

Statement of cash flows

Year ended March 31

	2026	2025
	\$	\$
Operating activities		
Deficiency of revenue over expenditures for the year	(40,308)	(9,657)
Changes in non-cash working capital balances related to operations		
Decrease in accounts receivable	8,500	25,000
Increase in prepaid expenses	(356)	(404)
Increase (decrease) in accounts payable and accrued liabilities	715	(2,026)
Increase (decrease) in due to related party	31,449	(12,913)
Cash provided by operating activities		
Net change in cash during the year		
Cash, beginning of year		
Cash, end of year		

See accompanying notes

Health Research Ethics Authority

Notes to financial statements

March 31, 2026

1. Organization

The Health Research Ethics Authority [the "Authority"] is a government not-for-profit organization incorporated on July 1, 2011, without share capital under the *Health Research Ethics Authority Act* [the "Act"], governed by a Board of Directors appointed by the Ministry of Health and Community Services. Under the Act, the Authority is exempt from income taxes. As of July 1, 2025 the previous Act was repealed and replaced by the *Health Research Ethics Act*.

The Authority's mandate is to ensure that participants in human health research in the Province of Newfoundland and Labrador [the "Province"] 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. Board of Directors appointed by the Ministry of Health and Community Services.

Under a memorandum of understanding, Memorial University of Newfoundland ["Memorial"] and Newfoundland and Labrador Health Services ["NLHS"] have agreed to provide both financial support in the form of operating grants and in-kind contributions to assist in the operation of the Authority.

2. Summary of significant accounting policies

Basis of presentation

The financial statements have been prepared by management in accordance with *Canadian public sector accounting standards for government not for profit organizations*, including the 4200 series of standards, as issued by the Public Sector Accounting Board, and reflect the following significant accounting policies:

Revenue recognition

The Authority follows the deferral method of accounting for contributions, which includes grants. Unrestricted contributions are recognized as revenue in the year received or receivable if the amount to be received can be reasonably estimated and collection is reasonably assured. Restricted contributions are recorded as deferred contributions until the funds are expended or amortized in accordance with the terms of the contribution.

Research project approval fees and all other revenue is recognized as earned and when collection is reasonably assured.

Health Research Ethics Authority

Notes to financial statements

March 31, 2026

Contributed materials and services

If contributed materials meet the definition of a tangible capital asset and fair value is determinable, the Authority capitalizes and amortizes the tangible capital asset. All other contributed materials are not recognized in these financial statements.

Various services have been provided to the Authority by Memorial and NLHS without charge. The costs that would otherwise associate with the support-in-kind provided by Memorial are recognized in these financial statements at fair value. The costs associated with the support-in-kind provided by NLHS have not been recorded, as the fair value is not determinable.

Financial instruments

The Authority initially records a financial instrument at its fair value, except for a related party transaction, which is recorded at the carrying or exchange amount depending on the circumstances.

The Authority classifies its financial instruments at amortized cost. This category includes accounts receivable, due from related party, and accounts payable and accrued liabilities. These items are initially recognized at fair value and subsequently carried at amortized cost, less any impairment losses.

Write-downs of financial assets are recognized when the amount of the loss is known with sufficient precision and there is no realistic prospect of recovery. Financial assets are then written down to net recoverable value, with the write-down being recognized in the statement of operations.

Use of estimates

The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as at the date of the financial statements, and the reported amounts of revenue and expenditures during the reporting period. Actual results could differ from those estimates. These estimates are reviewed periodically and, as adjustments become necessary, they are reported in the statement of operations in the period during which they become known. Areas of key estimation include determination of fair values associated with support-in-kind.

Health Research Ethics Authority

Notes to financial statements

March 31, 2026

3. Accounts receivable

Accounts receivable consist of the following:

	2026	2025
	\$	\$
Trade accounts receivable	<u>19,500</u>	<u>28,000</u>

4. Tangible capital assets

Tangible capital assets consist of the following:

	2026		2025	
	Cost	Accumulated amortization	Net book value	Net book value
	\$	\$	\$	\$
Computers	6,914	6,914		
Furniture and fixtures	10,425	10,425		
Leasehold improvements	6,246	6,246		
	23,585	23,585		

5. Related party transactions

The Authority had the following transactions with other government entities that are considered related parties:

	2026	2025
	\$	\$
Operating grant from Memorial	65,000	65,000
Operating grant from NLHS	65,000	65,000
	<u>130,000</u>	<u>130,000</u>

The support-in-kind from Memorial primarily relates to finance and administrative support, rent, and other administrative costs that are provided to the Authority by Memorial. These costs are included in their respective categories within the statement of operations and include the following:

	2026	2025
	\$	\$
Salaries and employee benefits	198,420	187,528
Rent		
Professional fees	20,544	19,762
Other expenses	7,503	7,555
	<u>226,467</u>	<u>214,845</u>

Health Research Ethics Authority

Notes to financial statements

March 31, 2026

The due to related party balances consist of the following:

	2026 \$	2025 \$
Due to Memorial University of Newfoundland	45,694	14,245

The amounts due to Memorial University of Newfoundland are non-interest bearing and due on demand.

6. Financial instruments and risk management

The Authority has exposure to credit risk and liquidity risk. The Authority's Board of Directors has overall responsibility for the oversight of these risks and reviews the Authority's policies on an ongoing basis to ensure that these risks are appropriately managed. The source of risk exposure and how each is managed is outlined below.

Credit risk

Credit risk is the risk of loss associated with a counterparty's inability to fulfill its payment obligation. The Authority's credit risk is primarily attributed to accounts receivable.

Liquidity risk

Liquidity risk is the risk that the Authority will not be able to meet its financial obligations as they become due. As at March 31, 2026, the Authority continues to be in a position to meet its obligations.

To the extent that the Authority does not believe that it has sufficient liquidity to meet current obligations, consideration will be given to obtaining additional funds through related party financing, assuming this can be obtained.

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, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2022) [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 \(2022\) \(ethics.gc.ca\)](#)

[International Council For Harmonisation Of Technical Requirements for Pharmaceuticals for Human Use](#)
[ICH Harmonised Guideline: Guideline for Good Clinical Practice E6\(R3\)](#)

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