

# **Health Research Ethics Authority**

## **Annual Performance Report**

**April 1, 2024 – March 31, 2025**

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## 1.0 Chairperson's Message

In accordance with the **Transparency and Accountability Act**, I am pleased to present the 2024-25 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 2d).

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 2024-25.

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,

A handwritten signature in cursive script that reads "Regina Coady".

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](http://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](http://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 2024-25 fiscal year, the Authority had operating expenditures of approximately \$483,502. Revenue of approximately \$129,000 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 2024-25 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 December 2024 Bill 64 received Royal Assent. On July 1, 2025, the Health Research Ethics Act, an Act respecting health research ethics will come into force. This will replace the **Health Research Ethics Authority Act**. HREA is engaging with stakeholders to make them aware of impending changes and is developing policies and standard operating procedures to ensure alignment with the new Act.

In fiscal year 2024-25, 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, 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 Atlantic Clinical Trial Network (ACTN), the Canadian Collaboration for Child Health: Efficiency and Excellence in the Ethics Review of Research (CHEER), Accelerating Clinical Trials (ACT), CanReview, and Forum on Responsible Conduct of Research.

Throughout fiscal year 2024-25, the Authority continued to engage with CHEER to facilitate the streamlining of child health research ethics review in Canada. In November 2024, CanReview was selected by Accelerating Clinical Trials (ACT) to develop a pan-Canadian single research ethics review process. HREA's Ethics Director is a member of the leadership team for CanReview. The Authority recognizes the importance of streamlining the ethical review process throughout Canada while ensuring the provincial legislative requirements are met.

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 206 research proposals to ensure conformity with accepted scientific and ethical standards and applicable regulations. In addition, 1810 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 health research ethics review. Revisions to all policies and Standard Operating Procedures were initiated to comply with the new Health Research Ethics Act (HRE Act) scheduled to come into force July 1, 2025.

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 2024-25.

**Objective:** By March 31, 2025 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 2024-25  | Progress 2024-25  |
|---|---|
| Implemented outreach and communication initiatives to support the research ethics review process. | <div><div>►</div><div>During fiscal year 2024-25, 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 2024-25.</div></div> <div><div>►</div><div>Examples of communication activities implemented include:<ul style="list-style-type: none"><li>Held training sessions for new HREB members.</li><li>Held a workshop for the NLHS Department of Research and Innovation regarding the ethics review process.</li></ul></div></div> |

| Indicators 2024-25  | Progress 2024-25  |
|---|---|
|   | <ul style="list-style-type: none"> <li>• Presented at the Postgraduate Medical Education (PGME) Resident Research Day.</li> <li>• Presented on Ethics in Medical Research for Obstetrics and Gynecology Grand Rounds.</li> <li>• Delivered information sessions for researchers during MUN Research Week and engaged with research community.</li> <li>• Provided research ethics application training to the MUN Faculty Development Initiative 6for6, Family Care Team, NLHS Clinical Trial Division, NLHS Research and Innovation, Graduate Student Lab, MUN Undergraduate Medical Education program as well as to individual researchers who requested training.</li> <li>• Assisted in mock research ethics board training for students of the Masters of Health Ethics program at MUN.</li> <li>• Actively engaged with clinical and research community to discuss impending legislative amendments to the <b>Health Research Ethics Authority Act</b>.</li> <li>• 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.</li> <li>• 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.</li> <li>• Met with stakeholders (e.g., MUN, HCS, NLHS, and Faculty of Medicine) to communicate the work of the Authority.</li> <li>• Collaborated with research ethics boards and research organizations across the country to stay abreast of processes and efficiencies in other jurisdictions.</li> </ul> |
| <p><b>Strengthened the governance of health research ethics process in Newfoundland and Labrador.</b></p> | <p>► In November 2024 HREA became 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,</p>   |



| Indicators 2024-25   | Progress 2024-25  |
|--|---|
|  | <p>rural and remote locations, and improve equitable access to trial participation.</p> <ul style="list-style-type: none"> <li>▶ The Authority is developing a process to approve research ethics bodies for the purpose of reviewing applications for approval of health under section 8 of the HREA Act.</li> <li>▶ The Authority continued the monitoring process and completed one not-for-cause audit to ensure compliance with applicable legislation, policies, regulations and guidance in the conduct of research.</li> <li>▶ 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 <b>the Act</b>. Electronic access has improved accountability and reporting processes for these approved bodies.</li> <li>▶ The Authority continues to engage with MUN to replace the existing ROMEO platform with a new system called CAYUSE.</li> <li>▶ The Authority reviewed 1810 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.</li> <li>▶ 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.</li> <li>▶ Conducted Chairperson performance evaluations which is essential to build on strengths and identify areas of improvement amongst the leaders of our HREB.</li> <li>▶ Continued recruitment activities to strengthen the HREB membership.</li> </ul> |
| <p><b>Implemented a plan for sustainability of the Health Research Ethics Authority.</b></p> | <ul style="list-style-type: none"> <li>▶ The Authority is engaging with NLHS, HCS, and MUN to implement long term fiscal stability.</li> <li>▶ Continued negotiations with MUN, NLHS and HCS on the review and revision of the current MOU.</li> </ul>  |

| Indicators 2024-25 | Progress 2024-25   |
|--------------------|--|
|                    | <ul style="list-style-type: none"> <li>► Engagement with HCS on the legislative amendments passed in the House in Assembly December 2024 and scheduled to come into force July 1<sup>st</sup> 2025.</li> </ul> |

## 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 206 applications were reviewed by the three HREB subcommittees. HREB-NCT reviewed 148 applications, HREB-CT reviewed 48 applications and HREB-GG reviewed 10 applications. In addition, 1,810 events were reviewed for active studies. There was a total of 579 active studies as of fiscal year end March 31, 2025. Table 1 outlines the metrics for 2024-25.

The Interdisciplinary Committee on Ethics in Human Research (ICEHR) is an approved research ethics body under section 8 of **the Act** and may review applications of health research in accordance with **the Act**. ICEHR did not review any health research during the 2024-25 year.

Table 1

| Total Applications Reviewed |                 |                |               | TOTAL |
|-----------------------------|-----------------|----------------|---------------|-------|
|                             | HREB-NCT<br>148 | HREB-CT<br>48  | HREB-GG<br>10 | 206   |
| Total Events Reviewed       |                 |                |               |       |
|                             | HREB-NCT<br>737 | HREB-CT<br>977 | HREB-GG<br>96 | 1810  |
| Total Active Studies*       |                 |                |               |       |
|                             | HREB-NCT<br>356 | HREB-CT<br>175 | HREB-GG<br>48 | 579   |

\*Point in time measure (March 31, 2025)

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 2024-25.

Table 2

|         | Length of time to first decision | Length of time to final decision* |
|---------|----------------------------------|-----------------------------------|
| Average | 15.6 days                        | 52 days                           |
| Median  | 15.3 days                        | 44.1 days                         |
| Range   | 0-29 days                        | 0-233 days                        |

\*One study with researcher for 147 days and with HREB for 86 days

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.

There were no HREB decisions appealed in this fiscal year 2024-25.

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.

## **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 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 new HRE Act came into force July 1, 2025 and will enable several advancements including but not limited to expansion to the HREA 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 deficit for fiscal year 2025-26. The Authority is exploring further opportunities to increase revenue generation in tandem with the MOU review.

Additionally, HREA is working with key stakeholders, including MUN, HCS, 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<br>(non-voting) | HREB                  |
| Ms. Barbara Mason, Director<br>(non-voting)        | Authority Office      |

The above listing represents the composition of the Authority's Board of Directors as of March 31, 2025

## **Appendix B: Audited Financial Statements**

# Health Research Ethics Authority

Financial statements  
March 31, 2025



# 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, 2025, 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, 2025, 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  
September 9, 2025

*Ernst & Young LLP*

Chartered Professional Accountants





## Health Research Ethics Authority

### Statement of financial position

As at March 31

|  | 2025          | 2024          |
|--|---------------|---------------|
|  | \$            | \$            |
| <b>Assets</b>                            |               |               |
| <b>Current</b>                           |               |               |
| Accounts receivable <i>[note 3]</i>      | 28,000        | 53,000        |
| Prepaid expenses                         | 14,604        | 14,200        |
| <b>Total current assets</b>              | <b>42,604</b> | <b>67,200</b> |
| <b>Liabilities and net assets</b>        |               |               |
| <b>Current</b>                           |               |               |
| Accounts payable and accrued liabilities | 10,844        | 12,870        |
| Due to related party <i>[note 5]</i>     | 14,245        | 27,158        |
| <b>Total liabilities</b>                 | <b>25,089</b> | <b>40,028</b> |
| <b>Net assets</b>                        | <b>17,515</b> | <b>27,172</b> |
|  | <b>42,604</b> | <b>67,200</b> |

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

|  | 2025           | 2024           |
|--|----------------|----------------|
|  | \$             | \$             |
| <b>Revenue</b>   |                |                |
| Support-in-kind <i>[note 5]</i>                                      | 214,845        | 218,576        |
| Operating grants <i>[note 5]</i>                                     | 130,000        | 208,333        |
| Research project approval fees                                       | 129,000        | 112,500        |
|  | <b>473,845</b> | <b>539,409</b> |
| <b>Expenditures</b>  |                |                |
| Salaries and employee benefits <i>[note 5]</i>                       | 383,739        | 416,034        |
| Honorariums  | 47,589         | 41,932         |
| Professional fees <i>[note 5]</i>                                    | 25,385         | 23,625         |
| Insurance  | 19,068         | 18,497         |
| Telephone <i>[note 5]</i>  | 6,163          | 6,791          |
| Equipment rentals <i>[note 5]</i>                                    | 1,177          | 1,180          |
| Waste disposal/document storage <i>[note 5]</i>                      | 215            | 163            |
| Bank service charges   | 166            | 136            |
| Rent <i>[note 5]</i>   | —              | 3,285          |
| Bad debt expense   | —              | 500            |
| Memberships  | —              | 376            |
|  | <b>483,502</b> | <b>512,519</b> |
| <b>Excess (deficiency) of revenue over expenditures for the year</b> | <b>(9,657)</b> | <b>26,890</b>  |

See accompanying notes

## Health Research Ethics Authority

### Statement of changes in net assets

Year ended March 31

|   | 2025           | 2024          |
|---|----------------|---------------|
|   | \$             | \$            |
| <b>Balance, beginning of year</b>                             | <b>27,172</b>  | 282           |
| Excess (deficiency) of revenue over expenditures for the year | <b>(9,657)</b> | 26,890        |
| <b>Balance, end of year</b>                                   | <b>17,515</b>  | <b>27,172</b> |

*See accompanying notes*

## Health Research Ethics Authority

### Statement of cash flows

Year ended March 31

|  | 2025     | 2024     |
|--|----------|----------|
|  | \$       | \$       |
| <b>Operating activities</b>  |          |          |
| Excess (deficiency) of revenue over expenditures for the year      | (9,657)  | 26,890   |
| Changes in non-cash working capital balances related to operations |          |          |
| Decrease (increase) in accounts receivable                         | 25,000   | (19,000) |
| Increase in prepaid expenses                                       | (404)    | (436)    |
| Decrease in accounts payable and accrued liabilities               | (2,026)  | (1,987)  |
| Decrease in due to related party                                   | (12,913) | (5,467)  |
| <b>Cash provided by operating activities</b>                       | —        | —        |
| <b>Net change in cash during the year</b>                          | —        | —        |
| Cash, beginning of year  | —        | —        |
| <b>Cash, end of year</b>   | —        | —        |

*See accompanying notes*

## Health Research Ethics Authority

### Notes to financial statements

March 31, 2025

#### 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.

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 GNPOs*, 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, 2025

#### **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

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#### 3. Accounts receivable

Accounts receivable consist of the following:

|                           | 2025   | 2024   |
|---------------------------|--------|--------|
|                           | \$     | \$     |
| Trade accounts receivable | 28,000 | 53,000 |

#### 4. Tangible capital assets

Tangible capital assets consist of the following:

|                        |        | 2025         |          | 2024     |
|------------------------|--------|--------------|----------|----------|
|                        | Cost   | Accumulated  | Net book | Net book |
|                        | \$     | amortization | value    | 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:

|                               | 2025    | 2024    |
|-------------------------------|---------|---------|
|                               | \$      | \$      |
| Operating grant from Memorial | 65,000  | 140,000 |
| Operating grant from NLHS     | 65,000  | 65,000  |
|                               | 130,000 | 205,000 |

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:

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|                                | <b>2025</b>    | <b>2024</b> |
|--------------------------------|----------------|-------------|
|                                | <b>\$</b>      | <b>\$</b>   |
| Salaries and employee benefits | <b>187,528</b> | 189,457     |
| Rent                           | <b>—</b>       | 3,285       |
| Professional fees              | <b>19,762</b>  | 17,700      |
| Other expenses                 | <b>7,555</b>   | 8,134       |
|                                | <b>214,845</b> | 218,576     |

The due to related party balances consist of the following:

|  | <b>2025</b>   | <b>2024</b> |
|--|---------------|-------------|
|  | <b>\$</b>     | <b>\$</b>   |
| Due to Memorial University of Newfoundland | <b>14,245</b> | 27,158      |

The amounts due to Memorial University of Newfoundland are non-interest bearing with no set terms of repayment 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, 2025, 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 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](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**

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