

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,

A handwritten signature in cursive script that reads "Regina Coady". The signature is written in a dark ink and is positioned below the word "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 health 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
<p>Implemented outreach and communication initiatives to support the research ethics review process.</p>	<ul style="list-style-type: none"> ▶ 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: <ul style="list-style-type: none"> • 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
	<p>opportunities for the Authority to promote and provide information related to the ethical conduct of health research and to facilitate the HREB submission process.</p> <ul style="list-style-type: none"> • 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.
<p>Strengthened the governance of health research ethics process in Newfoundland and Labrador.</p>	<ul style="list-style-type: none"> ▶ 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
	<p>medications, devices or any other products that relate to its safety including, but not limited to, side effects, adverse reactions and hospitalizations.</p> <ul style="list-style-type: none"> ▶ 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.
<p>Implemented a plan for sustainability of the Health Research Ethics Authority</p>	<ul style="list-style-type: none"> ▶ 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

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.

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 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

Health Research Ethics Authority

Financial statements
March 31, 2024



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, 2024, 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, 2024, 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
July 5, 2024

Ernst & Young LLP

Chartered Professional Accountants

Health Research Ethics Authority

Statement of financial position

As at March 31

	2024	2023
	\$	\$
Assets		
Current		
Accounts receivable <i>[note 4]</i>	53,000	34,000
Prepaid expenses	<u>14,200</u>	<u>13,764</u>
Total current assets	67,200	47,764
Tangible capital assets, net <i>[note 5]</i>		
	<u>67,200</u>	<u>47,764</u>
Liabilities and net assets		
Current		
Accounts payable and accrued liabilities	12,870	14,858
Due to related party <i>[note 6]</i>	<u>27,158</u>	<u>32,624</u>
Total liabilities	40,028	47,482
Net assets	<u>27,172</u>	<u>282</u>
	<u>67,200</u>	<u>47,764</u>

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

	2024	2023
	\$	\$
Revenue		
Support-in-kind <i>{note 6}</i>	218,576	230,978
Operating grants <i>{note 6}</i>	208,333	136,666
Research project approval fees	112,500	62,000
Amortization of deferred capital contributions		
	<u>539,409</u>	<u>429,644</u>
Expenditures <i>{note 6}</i>		
Salaries and employee benefits	416,034	379,716
Honorariums	41,932	43,104
Professional fees [audit, legal and consulting]	23,625	24,063
Insurance	18,497	18,008
Rent	3,285	39,419
Telephone	6,791	4,136
Equipment rentals	1,180	1,194
Bad Debt Expense (Recovery)	500	
Memberships	376	
Amortization of tangible capital assets		153
Materials and supplies		52
Bank service charges	136	51
Waste Disposal/Document Storage	<u>163</u>	
	<u>512,519</u>	<u>509,896</u>
Deficiency of revenue over expenditures for the year	<u>26,890</u>	<u>(80,252)</u>

See accompanying notes

Health Research Ethics Authority

Statement of changes in net assets

Year ended March 31

	2024	2023
	\$	\$
Balance, beginning of year	282	80,534
Excess (deficiency) of revenue over expenditures for the year	26,890	(80,252)
Balance, end of year	27,172	282

See accompanying notes

Health Research Ethics Authority

Statement of cash flows

Year ended March 31

	2024	2023
	\$	\$
Operating activities		
Deficiency of revenue over expenditures for the year	26,890	(80,252)
Add (deduct) items not affecting cash		
Amortization of tangible capital assets		153
Amortization of deferred capital contributions		
	<u>26,890</u>	<u>(80,099)</u>
Changes in non-cash working capital balances related to operations		
Decrease (increase) in accounts receivable	(19,000)	15,000
Decrease (increase) in prepaid expenses	(436)	(344)
Increase (decrease) in accounts payable and accrued liabilities	(1,987)	11,087
Cash used in operating activities	<u>5,467</u>	<u>(54,356)</u>
Financing activities		
Increase (decrease) in due to related party	(5,467)	54,356
Cash provided by financing activities	<u>(5,467)</u>	<u>54,356</u>
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, 2024

1. Organization

The Health Research Ethics Authority [the "Authority"] is a not-for-profit organization incorporated on July 1, 2011, without share capital under the *Health Research Ethics Authority Act* [the "Act"]. 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.

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.

The Authority is a government not-for-profit organization ["GNPO"], governed by a Board of Directors appointed by the Ministry of Health and Community Services.

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 are recognized as earned and when collection is reasonably assured.

Tangible capital assets

Purchased tangible capital assets are stated at cost. Amortization is computed on a straight-line basis at rates that will reduce the original cost to estimated residual value over the useful lives of the assets. Computers, and furniture and fixtures are amortized using a rate of 20%. Leasehold improvements are amortized on a straight-line basis using a rate of 20%.

Intangible assets

Intangible assets, which relate to purchased software, are stated at cost and are amortized over the estimated useful life of the asset on a straight-line basis using a rate of 20%.

Health Research Ethics Authority

Notes to financial statements

March 31, 2024

Impairment of long-lived assets

Tangible capital assets and intangible assets are written down when conditions indicate they no longer contribute to the Authority's ability to provide services, or when the value of the future economic benefits associated with the tangible capital assets is less than their net book value. The net write-downs are accounted for as expenditures in the statement of operations. Any associated unamortized deferred capital contributions related to the derecognized assets are recognized in income.

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 using the effective interest rate method, 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 and disclosure of contingent 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 fair values associated with support-in-kind and the allowance for doubtful accounts.

Health Research Ethics Authority

Notes to financial statements

March 31, 2024

3. Change in accounting policies

Asset retirement obligations

Effective April 1, 2022, for the fiscal year 2022-23, the Corporation adopted Section 3280 of the Public Sector Accounting Standards handbook - Asset Retirement Obligations. This new section provides guidance over the reporting of legal obligations associated with the retirement of long-lived tangible capital assets that are either currently in productive use or no longer in productive use and controlled by the Corporation, and the costs associated with the retirement of these assets. The corporation adopted the standard using the modified retroactive approach, which uses assumptions as of April 1, 2022. The asset retirement obligation liabilities and the related increase to capital assets are measured as of the date the legal obligations were incurred, and adjusted for the accumulated accretion and amortization as of that date. The Corporation completed a detailed assessment of its assets and leased assets and concluded that there were no material legal obligations to incur retirement costs in relation to these assets. As a result, there was no impact on the Corporation's financial statements as a result of adopting Section 3280.

4. Accounts receivable

Accounts receivable consist of the following:

	2024	2023
	\$	\$
Trade accounts receivable	<u>53,000</u>	<u>34,000</u>

5. Tangible capital assets

Tangible capital assets consist of the following:

	2024		
	Cost	Accumulated amortization	Net book value
	\$	\$	\$
Computers	6,914	6,914	
Furniture and fixtures	10,425	10,425	
Leasehold improvements	6,246	6,246	
	<u>23,585</u>	<u>23,585</u>	

Health Research Ethics Authority

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	2023		
	Cost	Accumulated amortization	Net book value
	\$	\$	\$
Computers	6,914	6,914	
Furniture and fixtures	10,425	10,425	
Leasehold improvements	6,246	6,246	
	<u>23,585</u>	<u>23,585</u>	

6. Related party transactions

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

	2024	2023
	\$	\$
Operating grant from Memorial University of Newfoundland	140,000	65,000
Operating grant from Newfoundland and Labrador Health Services	65,000	65,000
	<u>205,000</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:

	2024	2023
	\$	\$
Salaries and employee benefits	189,457	167,359
Rent	3,285	39,419
Professional fees	17,700	18,868
Other expenses	8,134	5,332
	<u>218,576</u>	<u>230,978</u>

The due from (to) related party balances consist of the following:

	2024	2023
	\$	\$
Due from (to) Memorial University of Newfoundland	<u>(32,624)</u>	<u>(32,624)</u>

The treasury function of the Authority is administered by Memorial, and therefore, the account with Memorial represents funds owed from (to) Memorial, and has been classified as a current asset (liability).

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7. 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 and amounts due from related party.

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, 2024, 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)

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