



Health Research Ethics Authority

Activity Report

April 1, 2021 – March 31, 2022

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1.0 Chairperson's Message

In accordance with the **Transparency and Accountability Act**, I am pleased to present the 2021-22 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** (paragraph 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 2021-22.

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 website, www.hrea.ca.

Membership

The Authority is an independent, not-for-profit corporation with an administrative board appointed by the Minister of Health and Community Services. The Authority has a Board with four directors: a representative of the Eastern Regional Health Authority (Eastern Health), a representative of Memorial University (MUN), a 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 Eastern Health and MUN. One Chairperson of the HREB and the Ethics Director sit as a non-voting members of the Board (see Appendix A).

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

Funding

During the 2021-22 fiscal year, the Authority had operating expenditures of approximately \$493,360. Revenue of approximately \$117,500 was derived from review fees levied on industry-sponsored research and other for-profit entities. Funding was also provided by MUN and Eastern Health. Additional support was provided in kind by MUN and Eastern Health as per the Memorandum of Understanding (MOU) between the Authority, MUN, Eastern Health and the HCS.

The external audit conducted on the Authority's financial statements for the 2021-22 fiscal year was completed by Ernst & Young. The audited financial statements are attached as Appendix C.

3.0 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 website, www.hrea.ca.

4.0 Vision

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.

5.0 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.

6.0 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 2021-22, 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 and faculty), 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 in the Canadian Association of Research Ethics Boards (CAREB-ACCER) annual general meeting as well as the Access, Privacy, Security and Information Management (APSIM) conference. As well, the Authority collaborated on several local and national working groups including 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, Health Canada Engagement Sessions on Clinical Trial Oversight and Implementation in the Context of COVID-19, MUN Research Strategy Framework and the Pan Canadian Research Privacy Network. Additionally, the Authority has representation on the CAREB-ACCER Board of Directors.

Throughout fiscal year 2021-22, 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 225 research proposals to ensure conformity with accepted scientific and ethical standards and applicable regulations. In addition, 2,016 events were reviewed to ensure that all stages of ongoing research projects are ethically acceptable in accordance with applicable policies and regulations. As well, additional HREB members were recruited across the three subcommittees. Revision of the policy framework, including the approval of several new standard operating procedures, 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 Authority, MUN, Eastern Health and HCS.

7.0 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 B). 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 (2020-21, 2021-22 and 2022-23); however, the report provided for each year shows progress made in that fiscal year. The reporting below details progress in fiscal year 2021-22.

Objective: By March 31, 2022, the Authority will have implemented initiatives to strengthen the ethics review process for health research and enhanced awareness of the ethical conduct of health research in Newfoundland and Labrador.

Indicators 2021-22	Progress 2021-22
<p>Implemented outreach and communication initiatives to support the research ethics review process.</p>	<ul style="list-style-type: none"> ▶ During fiscal year 2021-22 the Authority continued a robust communication strategy to communicate with stakeholders on the work of the Authority. Implementing communication initiatives to promote the ethical conduct of health research will continue throughout the 2020-2023 Activity Plan as it continues to be a priority. ▶ Examples of communication activities implemented this year 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 as well as workshops for research coordinators regarding the Authority, the HREB and the ethics review process. • Collaborated with research groups, MUN students and faculty members, Eastern Health 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. Presented several sessions to these groups relating to the Authority, the HREB and the ethics review process. • Communicated with the Regional Health Authorities 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, Eastern Health 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. • Participated in Health Canada Engagement Sessions on Clinical Trial Oversight and Implementation in the Context of COVID-19, in an effort to remain current on clinical trial practices across the country.

Indicators 2021-22	Progress 2021-22
<p>Implemented and monitored compliance with standard operating procedures (SOPs) for the research ethics review process.</p>	<ul style="list-style-type: none"> ▶ Completed new, as well as, revised policies and standard operating procedures (SOPs) to provide guidance and consistency in the research ethics review process. The SOPs will also ensure that the HREB is compliant with applicable Canadian and US regulatory and ethics guidance criteria. ▶ 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. ▶ Continued to adopt the recommendations of the 2018-19 external review of the ethics review processes and operations of the HREB, as well as the Authority structure, staffing and governance. ▶ Continued recruitment activities to strengthen the HREB membership.
<p>Developed and implemented strategies to enhance the governance of the research ethics review process.</p>	<ul style="list-style-type: none"> ▶ The Authority continues to utilize the online research application system, ROMEO, 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 reviewed 2,016 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. ▶ Continued negotiations with MUN, Eastern Health and HCS on the review and revision of the current MOU. ▶ In keeping with its fiscal management, HREA increased the fees applied to industry sponsored and for-profit research applications.

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 225 applications were reviewed by the three HREB subcommittees. HREB-NCT reviewed approximately 72 per cent of the applications and the

remaining applications were reviewed by the HREB-CT and HREB-GG. In addition, 2,016 events were reviewed for active studies.

The Authority has been 100 per cent compliant with the 30 day decision requirement. Table 1 outlines the length of time for HREB application review in 2021-22.

Table 1

	Length of time to first decision*	Length of time to final decision**
Average	12.5 days	58 days
Median	12 days	39 days
Range	1-29 days	1-524 days***

* Approved, Approved pending changes, Rejected

** Approved or Rejected. Includes the number of days the application is with the researcher/investigator, as well as HREB

*** 96 per cent of all studies received final decision in 165 days or less

The Authority has continued to incorporate the recommendations of the 2018-19 external review. A majority of the key recommendations were previously implemented, including a change in the Authority's human resource skill mix/qualifications, improved communication and engagement with the research community and primary stakeholder institutions, and the development of resources to support the HREB application submission process. Other recommendations continued throughout this fiscal year. Ongoing activities include the development of by-laws and governance policies, recruitment activities to strengthen the HREB membership as well as the revision of a policy framework to support the mandate of the HREB.

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.

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) National Annual General Meeting and the CHEER initiative.

While meetings with Government related to Legislative amendments of **the Act** occurred in the prior year, there were no meetings during this report period. The Authority remains available for further consultation related to Legislative amendments.

8.0 Opportunities and Challenges:

The Authority continues to focus on its core business and to strengthen some of its developmental activities. As an evolving entity, and as guided by the 2020-23 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 2021-22 given its limited revenue base. The Authority is exploring further opportunities to increase revenue generation in tandem with the MOU review. As well, the Authority revised the HREB review fees for clinical trials and for-profit research in April 2021 in keeping with the resources required for review and in line with its national counterparts.

The Authority is continuing to work towards maintaining, and ultimately expanding, clinical trial activity in the province. A strong clinical trial environment supports clinical services of the population of NL, supports recruitment and retention of clinicians, and supports strong economic growth. The ongoing trend of declining base clinical trial activity across the country has been experienced in NL as well and may present challenges in the future; however, there are continuing opportunities to streamline and increase efficiency of the process.

Finally, the Authority continues to strengthen its partnerships with HCS, Eastern Health 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. Judy O’Keefe, Director	Eastern Health
Dr. Ray Gosine, Director	MUN
Pending Appointment	HCS
Dr. Fern Brunger, HREB Chairperson (non-voting)	HREB
Ms. Sharon Newman, Ethics Director (non-voting)	Authority Office

During fiscal year 2021-22 the Authority had turnover in the HREB representative and Authority Office positions. The above listing represents the composition of the Authority’s Board of Directors as of March 31, 2022.

Appendix B: 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)

Appendix C: Audited Financial Statements

Health Research Ethics Authority

Financial statements

March 31, 2022



**Building a better
working world**

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.

Ernst + Young LLP

Chartered Professional Accountants

St. John's, Canada
August 8, 2022

Health Research Ethics Authority

Statement of operations

Year ended March 31

	2022	2021
	\$	\$
Revenue		
Support-in-kind <i>[note 6]</i>	221,549	235,206
Operating grants <i>[note 6]</i>	130,000	130,000
Research project approval fees	117,500	96,500
Amortization of deferred capital contributions <i>[note 5]</i>	1,069	2,138
	<u>470,118</u>	<u>463,844</u>
Expenditures <i>[note 6]</i>		
Salaries and employee benefits	362,145	306,153
Honorariums	43,015	46,252
Rent	39,419	39,419
Professional fees [audit, legal, and consulting]	22,906	21,527
Insurance	17,546	16,750
Telephone	3,388	2,638
Amortization of tangible capital assets	2,710	3,334
Equipment rentals	928	245
Memberships	550	127
Conferences and seminars	447	—
Materials and supplies	289	—
Bank service charges	17	85
Travel	—	348
Amortization of intangible assets	—	500
	<u>493,360</u>	<u>437,378</u>
Excess (deficiency) of revenue over expenditures for the year	<u>(23,242)</u>	<u>26,466</u>

See accompanying notes

Health Research Ethics Authority

Statement of cash flows

Year ended March 31

	2022	2021
	\$	\$
Operating activities		
Excess (deficiency) of revenue over expenditures for the year	(23,242)	26,466
Add (deduct) items not affecting cash		
Amortization of tangible capital assets	2,710	3,334
Amortization of intangible assets	—	500
Amortization of deferred capital contributions	(1,069)	(2,138)
	<u>(21,601)</u>	<u>28,162</u>
Changes in non-cash working capital balances related to operations		
Increase in accounts receivable	(500)	(23,869)
Increase in prepaid expenses	(347)	(681)
(Decrease) increase in accounts payable and accrued liabilities	(21,588)	20,606
Cash provided by (used in) In operating activities	<u>(44,036)</u>	<u>24,218</u>
Financing activities		
Decrease (increase) in due from related party	44,036	(24,218)
Cash provided by (used in) financing activities	<u>44,036</u>	<u>(24,218)</u>
Net change in cash during the year	—	—
Cash, beginning of year	—	—
Cash, end of year	<u>—</u>	<u>—</u>

See accompanying notes

Health Research Ethics Authority

Notes to financial statements

March 31, 2022

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 Eastern Health, 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 Eastern Health has 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, 2022

6. Related party transactions

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

	2022 \$	2021 \$
Operating grant from Memorial University of Newfoundland	65,000	65,000
Operating grant from Eastern Regional Health Authority	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:

	2022 \$	2021 \$
Salaries and employee benefits	159,883	175,263
Rent	39,419	39,419
Professional fees	17,641	17,641
Other expenses	4,606	2,883
	<u>221,549</u>	<u>235,206</u>

The due from related party balance consists of the following:

	2022 \$	2021 \$
Due from Memorial University of Newfoundland	<u>21,732</u>	<u>65,768</u>

The treasury function of the Authority is administered by Memorial, and therefore, the account with Memorial represents funds owed by Memorial, and has been classified as current.

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.

Health Research Ethics Authority

Financial statements
March 31, 2022



**Building a better
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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, 2022, 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, 2022, 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.

Ernst & Young LLP

Chartered Professional Accountants

St. John's, Canada
August 8, 2022

Health Research Ethics Authority

Statement of financial position

As at March 31

	2022	2021
	\$	\$
Assets		
Current		
Accounts receivable <i>[note 3]</i>	49,000	48,500
Prepaid expenses	13,420	13,073
Due from related party <i>[note 6]</i>	21,732	65,768
Total current assets	84,152	127,341
Tangible capital assets, net <i>[note 4]</i>	153	2,863
	84,305	130,204
Liabilities and net assets		
Current		
Accounts payable and accrued liabilities	3,771	25,359
Total current liabilities	3,771	25,359
Deferred capital contributions <i>[note 5]</i>	—	1,069
Total liabilities	3,771	26,428
Net assets	80,534	103,777
	84,305	130,204

See accompanying notes

On behalf of the Board:

Chair of the Board of Directors

Regina Coady

Health Research Ethics Authority

Statement of operations

Year ended March 31

	2022	2021
	\$	\$
Revenue		
Support-in-kind <i>[note 6]</i>	221,549	235,206
Operating grants <i>[note 6]</i>	130,000	130,000
Research project approval fees	117,500	96,500
Amortization of deferred capital contributions <i>[note 5]</i>	1,069	2,138
	<u>470,118</u>	<u>463,844</u>
Expenditures <i>[note 6]</i>		
Salaries and employee benefits	362,145	306,153
Honorariums	43,015	46,252
Rent	39,419	39,419
Professional fees (audit, legal, and consulting)	22,906	21,527
Insurance	17,546	16,750
Telephone	3,388	2,638
Amortization of tangible capital assets	2,710	3,334
Equipment rentals	928	245
Memberships	550	127
Conferences and seminars	447	—
Materials and supplies	289	—
Bank service charges	17	85
Travel	—	348
Amortization of intangible assets	—	500
	<u>493,360</u>	<u>437,378</u>
Excess (deficiency) of revenue over expenditures for the year	<u>(23,242)</u>	<u>26,466</u>

See accompanying notes

Health Research Ethics Authority

Statement of changes in net assets

Year ended March 31

	2022	2021
	\$	\$
Balance, beginning of year	103,776	77,310
Excess (deficiency) of revenue over expenditures for the year	(23,242)	26,466
Balance, end of year	80,534	103,776

See accompanying notes

Health Research Ethics Authority

Statement of cash flows

Year ended March 31

	2022	2021
	\$	\$
Operating activities		
Excess (deficiency) of revenue over expenditures for the year	(23,242)	26,466
Add (deduct) items not affecting cash		
Amortization of tangible capital assets	2,710	3,334
Amortization of intangible assets	—	500
Amortization of deferred capital contributions	(1,069)	(2,138)
	<u>(21,601)</u>	<u>28,162</u>
Changes in non-cash working capital balances related to operations		
Increase in accounts receivable	(500)	(23,869)
Increase in prepaid expenses	(347)	(681)
(Decrease) increase in accounts payable and accrued liabilities	(21,588)	20,606
Cash provided by (used in) in operating activities	<u>(44,036)</u>	<u>24,218</u>
Financing activities		
Decrease (increase) in due from related party	44,036	(24,218)
Cash provided by (used in) financing activities	<u>44,036</u>	<u>(24,218)</u>
Net change in cash during the year	—	—
Cash, beginning of year	—	—
Cash, end of year	<u>—</u>	<u>—</u>

See accompanying notes

Health Research Ethics Authority

Notes to financial statements

March 31, 2022

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 Eastern Regional Health Authority ["Eastern Health"] 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 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, 2022

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 Eastern Health, 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 Eastern Health has 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, 2022

3. Accounts receivable

Accounts receivable consist of the following:

	2022 \$	2021 \$
Trade accounts receivable	49,000	80,000
Less allowance for doubtful accounts	—	31,500
	<u>49,000</u>	<u>48,500</u>

4. Tangible capital assets

Tangible capital assets consist of the following:

	2022		
	Cost \$	Accumulated amortization \$	Net book value \$
Computers	6,914	6,914	—
Furniture and fixtures	10,425	10,272	153
Leasehold improvements	6,246	6,246	—
	<u>23,585</u>	<u>23,432</u>	<u>153</u>
	2021		
	Cost \$	Accumulated amortization \$	Net book value \$
Computers	6,914	6,914	—
Furniture and fixtures	10,425	8,187	2,238
Leasehold improvements	6,246	5,621	625
	<u>23,585</u>	<u>20,722</u>	<u>2,863</u>

5. Deferred capital contributions

Deferred capital contributions related to tangible capital assets represent the unamortized amount of donated tangible capital assets received from Memorial. The amortization of deferred capital contributions is recorded as revenue in the statement of operations.

	2022 \$	2021 \$
Balance, beginning of year	1,069	3,207
Less amounts amortized to revenue	1,069	2,138
Balance, end of year	<u>—</u>	<u>1,069</u>

Health Research Ethics Authority

Notes to financial statements

March 31, 2022

6. Related party transactions

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

	2022 \$	2021 \$
Operating grant from Memorial University of Newfoundland	65,000	65,000
Operating grant from Eastern Regional Health Authority	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:

	2022 \$	2021 \$
Salaries and employee benefits	159,883	175,263
Rent	39,419	39,419
Professional fees	17,641	17,641
Other expenses	4,606	2,883
	<u>221,549</u>	<u>235,206</u>

The due from related party balance consists of the following:

	2022 \$	2021 \$
Due from Memorial University of Newfoundland	<u>21,732</u>	<u>65,768</u>

The treasury function of the Authority is administered by Memorial, and therefore, the account with Memorial represents funds owed by Memorial, and has been classified as current.

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.

Health Research Ethics Authority

Notes to financial statements

March 31, 2022

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, 2022, 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

Contact Information

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