

Health Research Ethics Authority

Activity Report

April 1, 2019 – March 31, 2020

Chairperson's Message

In accordance with the **Transparency and Accountability Act**, I am pleased to present the 2019-20 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 allowed the Authority to enhance recognition of ethical issues related to health research and achieve its accountability requirements to the public.

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 2019-20.

2019-20 brought extraordinary demands on the Authority both locally with the January State of Emergency, as well as globally with the progressive spread of COVID-19. 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 and the Appeal Panel 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.

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)).

Sincerely,

A handwritten signature in cursive script that reads "Regina Coady". The signature is written in black ink and is positioned above the printed name.

Ms. Regina Coady, Chairperson
Health Research Ethics Authority

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1.0 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 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 2019-20 fiscal year, the Authority had operating expenditures of approximately \$556,705. Revenue of approximately \$87,000 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 Department of Health and Community Services.

The external audit conducted on the Authority's financial statements for the 2019-20 fiscal year was completed by Ernst & Young. The audited financial statements are attached as Appendix C.

2.0 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 2019-20, 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. As well, stakeholders were invited to provide general feedback on the on the changes that had been implemented to the Authority's operations following the implementation of many of the external review recommendations.

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 for the HREB application submission to administrators, coordinators and researchers. The Authority also participated in the Canadian Association of Research Ethics Boards conference as well as the Public Responsibility in Medicine and Research conference. As well, the Authority collaborated on several local and national working groups including the Provincial Health Genetics Planning day, Sensitive Data Management, Streamlining Pediatric Research, Data Governance, the Design Jam, the Canadian Personalized Healthcare Innovation Network, and a national consent form working group.

The Authority welcomed and participated in the Government of NL review process of **the Act**.

Throughout fiscal year 2019-20, 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 192 research proposals to ensure conformity with accepted scientific and ethical standards and applicable regulations. As well, additional HREB members were recruited across the three subcommittees.

Several initiatives were undertaken in the fourth quarter of 2019-20 to deal with the publicly declared state of emergency in January, as well as the COVID-19 pandemic. The Authority partnered with MUN and Eastern Health, as well as with other stakeholders to develop an action plan in response to the public health requirements. An interim process was implemented to continue the ethical review of research unrelated to COVID-19 and to expedite the review of COVID-19 related research.

3.0 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 (2017-18, 2018-19 and 2019-20); however, the report provided for each year shows progress made in that fiscal year. The reporting below details progress in fiscal year 2019-20.

Objective: By March 31, 2020, the Authority will have promoted and provided oversight of the ethical conduct of health research within NL.

Indicators 2019-20	Progress 2019-20
<p>Implemented communication initiatives to promote the ethical conduct of health research</p>	<ul style="list-style-type: none"> ▶ During fiscal year 2019–20 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 into 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 and developed internal processes to advance the quality of reporting to the Authority and stakeholders on key metrics and research being reviewed by the HREB. • Participated in National Health Ethics Week by holding a drop-in education session for researchers at MUN, Eastern Health and the community. • Held training sessions for new HREB members and several half-day 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. Also presented related information at the Canadian Association of Research Ethics Board annual conference and the Provincial Health Genetics Planning Day.

Indicators 2019-20	Progress 2019-20
<p>Implemented initiatives towards improving the research ethics review process</p>	<ul style="list-style-type: none"> • 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., Medical Directors of the Regional Health Authorities, private industry and start-up companies) to communicate the work of the Authority. • Invited stakeholders (i.e., MUN, EH, Government) to provide general feedback on the on the changes that had been implemented to the Authority's operations following the implementation of many of the external review recommendations. • Collaborated with research ethics boards and research organizations across the country to stay abreast of processes and efficiencies in other jurisdictions. • Communicated with researchers and stakeholders to advise of all changes in processes related to accommodations for the state of emergency as COVID-19 pandemic. <ul style="list-style-type: none"> ▶ Continued the development of 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 create 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. ▶ Participated in a national consent working group to develop a common consent template for oncology clinical trials. ▶ Continued the development of by-laws and governance policies. ▶ Continued recruitment activities to strengthen the HREB membership. ▶ Evaluated and updated the Authority's administrative processes to improve the efficiency of the ethics review process.

Indicators 2019-20	Progress 2019-20
	<ul style="list-style-type: none"> ▶ Updated guidance documents for HREB applications and revised research documents to improve the processes for both the application and the ethics review. ▶ Carried out extensive recruitment activities to initiate the establishment of a Constituent Committee as mandated in Section 19 of the Act; however, the Committee had not been struck by the end of this reporting period. ▶ Developed an action plan to continue ethics review of health research in response to the declared state of emergency. ▶ Developed a prompt and robust action plan to ensure ongoing ethical review of research unrelated to COVID-19 and to expedite the review of COVID-19 related research in response to the evolving public health requirements related to COVID-19. ▶ Participated in Government of NL planning process for the amendment of the Act. ▶ Conducted a survey amongst researchers regarding changes to administrative and operational processes introduced at the end of 2018-19. Revised processes based on survey feedback.
<p>Worked to enhance the monitoring process for approved health research</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 developed an internal process to advance the quality of reporting to the Authority and stakeholders on key metrics and research being reviewed by the HREB. ▶ The Authority reviewed 2,100 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.

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 192 applications were reviewed by the three HREB

subcommittees. HREB-NCT reviewed just over 70 per cent of the applications and the remaining applications were reviewed by the HREB-CT and HREB-GG.

The Authority has been tracking the length of time for application review which progressively improved during the year to ensure compliance with 30 day decision requirement. Of the 192 studies reviewed, 188 (98%) were compliant, with the most recent non-compliant review occurring in October 2019. Table 1 outlines the amount of time for HREB application review.

Table 1

	Length of time to first decision*	Length of time to final decision**
Average	16 days	52 days
Median	16 days	38 days
Range	3-38 days	3-237 days

* Approved, Approved pending changes, Rejected

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

The Authority has continued to incorporate the recommendations of the 2018-19 external review. While the majority of the key recommendations, 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, were previously implemented, other recommendations continued throughout this fiscal year. Ongoing activities include the development of by-laws and governance policies, as well as recruitment activities to strengthen the HREB membership and to initiate the establishment of a Constituent Committee. Work to revise the policy framework was ongoing during the year but not yet completed.

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.

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.

Lastly, the Authority was represented at two conferences: the Canadian Association of Research Ethics Boards (CAREB) National Annual General Meeting and Conference and the Public Responsibility in Medicine and Research conference.

4.0 Opportunities and Challenges:

The ninth year of operation has allowed the Authority to continue to focus on its core business and to strengthen some of its developmental activities. As an evolving entity, and as guided by the 2017-20 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 faced some challenges during the fiscal year 2019-20. One significant challenge was adapting to two unanticipated public emergencies. Staff members of the Authority were required to switch to working remotely and all HREB meetings were, and continue to be, held remotely. Prompt and robust decision making and communication was required by the HREB and its stakeholders. As well, researchers were required to either halt their research activities or revise the protocol to be compliant with the public health guidelines. This resulted in the submission of numerous protocol amendments to the Authority and reviewed by the HREB.

The Authority continues to experience financial challenges in 2019-20 given its limited revenue base. The operational costs for this fiscal year were reduced from 2018-19; however, the Authority experienced a significant deficiency of revenue over expenditure. There may be opportunities to increase revenue generation from clinical trial activity as efficiencies in process continue. The Authority collaborated with funding partners MUN and Eastern Health to increase annualized funding from each party of \$21,000 and is determining requirements for fiscal stability to meet its legislative mandate.

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 retentions 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 the Department of Health and Community Services, 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. Elaine Warren, Director	Eastern Health
Dr. Ray Gosine, Director	MUN
Ms. Gerrie Smith, Director	Department of Health and Community Services
Dr. Fern Brunger, HREB Chairperson (non-voting)	HREB
Ms. Sandra Veenstra, Ethics Director (non-voting)	Authority Office

During fiscal year 2019-20 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, 2019.

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, 2020



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, 2020, 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, 2020, and its financial performance 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
June 10, 2020

Ernst & Young LLP

Chartered Professional Accountants

Health Research Ethics Authority

Statement of financial position

As at March 31

	2020	2019
	\$	\$
Assets		
Current		
Accounts receivable <i>[note 3]</i>	24,631	52,072
Prepaid expenses	12,392	12,005
Due from related party <i>[note 7]</i>	41,549	126,688
Total current assets	78,572	190,765
Tangible capital assets, net <i>[note 4]</i>	6,197	9,531
Intangible assets, net <i>[note 5]</i>	500	1,500
	85,269	201,796
Liabilities and net assets		
Current		
Accounts payable and accrued liabilities	4,752	17,318
Total current liabilities	4,752	17,318
Deferred capital contributions <i>[note 6]</i>	3,207	5,345
Total liabilities	7,959	22,663
Net assets	77,310	179,133
	85,269	201,796

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

	2020	2019
	\$	\$
Revenue		
Support-in-kind <i>[note 7]</i>	214,744	222,559
Operating grants <i>[note 7]</i>	151,000	130,000
Research project approval fees	87,000	114,000
Amortization of deferred capital contributions <i>[note 6]</i>	2,138	2,138
	<u>454,882</u>	<u>468,697</u>
Expenditures <i>[note 7]</i>		
Salaries and employee benefits	400,231	376,095
Honorariums	44,338	39,411
Rent	39,419	39,419
Professional fees (audit, legal, and consulting)	31,457	160,755
Insurance	17,334	17,183
Travel [account #s 76400, 76403, and 76425]	5,990	7,392
Conferences and seminars [accounts #s 76401 and 76501]	4,085	2,940
Amortization of tangible capital assets	3,334	3,334
Catering	3,080	4,742
Telephone	2,630	2,737
Equipment rentals	1,742	3,211
Materials and supplies	1,503	4,018
Amortization of intangible assets	1,000	1,000
Memberships	283	625
Other expenses [account #s 70700 and 75005]	279	4,797
Software maintenance and training	—	2,902
	<u>556,705</u>	<u>670,561</u>
Deficiency of revenue over expenditures prior to undernoted item	(101,823)	(201,864)
Insurance proceeds <i>[note 3]</i>	—	19,833
Deficiency of revenue over expenditures for the year	<u>(101,823)</u>	<u>(182,031)</u>

See accompanying notes

Health Research Ethics Authority

Statement of changes in net assets

Year ended March 31

	2020	2019
	\$	\$
Balance, beginning of year	179,133	361,164
Deficiency of revenue over expenditures for the year	(101,823)	(182,031)
Balance, end of year	77,310	179,133

See accompanying notes

Health Research Ethics Authority

Statement of cash flows

Year ended March 31

	2020	2019
	\$	\$
Operating activities		
Deficiency of revenue over expenditures for the year	(101,823)	(182,031)
Add (deduct) items not affecting cash		
Amortization of tangible capital assets	3,334	3,334
Amortization of intangible assets	1,000	1,000
Amortization of deferred capital contributions	(2,138)	(2,138)
	(99,627)	(179,835)
Changes in non-cash working capital balances related to operations		
Decrease (increase) in accounts receivable	27,441	(28,007)
Decrease (increase) in prepaid expenses	(387)	2,142
Decrease in accounts payable and accrued liabilities	(12,566)	(5,796)
Cash used in operating activities	(85,139)	(211,496)
Financing activities		
Decrease in due from related party	85,139	211,496
Cash provided by financing activities	85,139	211,496
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, 2020

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%. Leaseholds 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, 2020

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, 2020

3. Accounts receivable

Accounts receivable consist of the following:

	2020 \$	2019 \$
Trade accounts receivable	56,131	61,500
Less allowance for doubtful accounts	31,500	31,500
	24,631	30,000
Insurance proceeds receivable	—	22,072
	<u>24,631</u>	<u>52,072</u>

Accounts receivable at March 31, 2019 included an insurance receivable as a result of legal fees incurred between March 2018 and April 2018. The receivable is for \$22,072 for reimbursement of expenses, including HST of \$2,239, for expenses incurred to remediate legal claims. The full amount was received in the 2020 fiscal year.

4. Tangible capital assets

Tangible capital assets consist of the following:

	2020		
	Cost \$	Accumulated amortization \$	Net book value \$
Computers	6,914	6,914	—
Furniture and fixtures	10,425	6,102	4,323
Leasehold improvements	6,246	4,372	1,874
	<u>23,585</u>	<u>17,388</u>	<u>6,197</u>
	2019		
	Cost \$	Accumulated amortization \$	Net book value \$
Computers	6,914	6,914	—
Furniture and fixtures	10,425	4,017	6,408
Leasehold improvements	6,246	3,123	3,123
	<u>23,585</u>	<u>14,054</u>	<u>9,531</u>

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5. Intangible assets

Intangible assets consist of the following:

	2020		
	Cost	Accumulated amortization	Net book value
	\$	\$	\$
Software	5,000	4,500	500

	2019		
	Cost	Accumulated amortization	Net book value
	\$	\$	\$
Software	5,000	3,500	1,500

6. 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.

	2020	2019
	\$	\$
Balance, beginning of year	5,345	7,483
Less amounts amortized to revenue	2,138	2,138
Balance, end of year	3,207	5,345

7. Related party transactions

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

	2020	2019
	\$	\$
Operating grant from Memorial University of Newfoundland	65,000	65,000
Operating grant from Eastern Regional Health Authority	86,000	65,000
	151,000	130,000

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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:

	2020 \$	2019 \$
Salaries and employee benefits	151,113	148,404
Rent	39,419	39,419
Professional fees	17,194	25,136
Other	7,018	9,600
	<u>214,744</u>	<u>222,559</u>

The due from related party balance consists of the following:

	2020 \$	2019 \$
Due from Memorial University of Newfoundland	<u>41,549</u>	<u>126,688</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. The amount owing from Memorial is non-interest bearing.

8. 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 fulfil 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, 2020, 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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