Health Research Ethics Authority

Activity Report

April 1, 2018 – March 31, 2019

Chairperson's Message

In accordance with the **Transparency and Accountability Act,** I am pleased to present the 2018-19 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 in its eighth year of development and the extent to which planned and actual activities were met during fiscal year 2018-19.

On behalf of the Health Research Ethics Authority 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. 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 (the Act)** (Section 2(d)).

Sincerely,

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 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.

The Authority is responsible for appointing a standing Appeal Panel. Researchers who request an appeal from a decision of the HREB or a research ethics body approved by the Authority may apply to the standing Appeal Panel of the Authority.

Membership

The Authority is an independent, not-for-profit corporation with an administrative board appointed by the Minister of Health and Community Services. The Authority has a Board with 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 2018-19 fiscal year, the Authority had operating expenditures of approximately $670,560. Revenue of approximately $114,000 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 2018-19 fiscal year was completed by Ernst & Young. The audited financial statements are attached as Appendix B.

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 2018-19, the Authority implemented several communication initiatives to promote the ethical conduct of health research and improve the research ethics review process. The Authority partnered with MUN and Eastern Health to identify opportunities to facilitate these initiatives. The Authority held 45 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 two Atlantic conferences and a conference held by the Office of the Information and Privacy Commissioner (OIPC). As well, the Authority collaborated on several national working groups including sensitive data management, streamlining pediatric research, patient engagement and ethics, and a national consent form working group.

In June 2018, the Board of Directors commissioned an external review to assess the processes and structures of the Authority and give recommendations to ensure the organization was optimally aligned with best practices. Researchers and HREB members were invited to be part of this review. Several initiatives were implemented as a result of the recommendations.

Throughout fiscal year 2018-19, 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 259 research proposals to ensure conformity with accepted scientific and ethical standards and applicable regulations. In addition, the new HREB-GG subcommittee was established and a significant number of additional HREB members were recruited across the three subcommittees.

In the fourth quarter of this fiscal year, the Authority received a court ruling from the NL Supreme court regarding the 30 day research ethics review time specified in section 9(4) of the Act. The court ruled that the HREB must consider an application and provide a decision to a research applicant within 30 days of HREB submission. Several operational improvements and procedural changes were made to advance compliance with this ruling. These included

changes to the review process that resulted in a decrease in the timeframe from application submission to HREB review and consequent decision, changes in the staffing model to streamline the review process and support the outreach and communication recommendations, and ongoing HREB recruitment and succession planning to maintain a strong HREB membership.

3.0 Mandate

In keeping with 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.

4.0 Annual Objective

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 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 (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 2018-19.

Objective: By March 31, 2019, the Authority will have promoted and provided oversight of the ethical conduct of health research within NL.

Indicators 2018-19	Progress 2018-19
Implemented communication initiatives to promote the ethical conduct of health research	► During fiscal year 2018–19 the Authority implemented 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 next fiscal year's work plan as it continues to be a priority.

Indicators 2018-19	Progress 2018-19
	► Examples of communication activities implemented this year include: – Released a redesigned publicly accessible website which provides information on the ethics review process for researchers, HREB members and key stakeholders: www.hrea.ca. This website provides a more up-to-date, comprehensive, user-friendly resource for the research community. – Worked in collaboration with MUN 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 15 training sessions for new HREB members and four 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 25 education sessions to these groups relating to the Authority, the HREB and the ethics review process. Also presented related information at two Atlantic conferences and a conference held by the OIPC. Presented to the NL Centre for Health Information regarding research conducted in Indigenous communities. – 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. – Collaborated with stakeholders at MUN and the Canadian Institutes of Health Research in the development of "Patient Engagement and Research Ethics Guidelines". – Met with key stakeholders individually (Government, MUN, and Eastern Health) to communicate the work of the Authority. Meetings also scheduled with private industry and start-up companies to continue the communications initiative. – Revised researcher feedback templates to support improved communication with research groups.

Indicators 2018-19	Progress 2018-19
	– Communicated recommendations from the external review of the Authority and the HREB directly with HREB members. Documents were made available to the research community and the public via the Authority's website. – Communicated with research ethics boards, universities and research organizations across the country to recruit new members to the HREB.
Implemented initiatives towards improving the research ethics review process	► 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. ► Commissioned an external review of the health ethics review processes and operations of the HREB, as well as the Authority structure, staffing and governance. Recommendations were adopted and the majority of the initiatives were completed or in progress by the end of the fiscal year. ► Participated in a national consent working group to develop a common consent template for oncology clinical trials. ► Participated in a national workshop to streamline ethics review of pediatric research. ► Completed an analysis of various aspects of the research ethics review process to identify areas where the review process may be improved and efficiency increased. ► Completed an examination of the Act and submitted the review to Government for consideration. ► Continued the development of by-laws and governance policies. ► Carried out extensive recruitment activities to strengthen the HREB membership. ► Established a Genetics and Genomics HREB subcommittee that is responsible for the review of genetics and genomics health research conducted in the province. ► Revised the Authority's administrative processes to improve the efficiency of the ethics review process.

Indicators 2018-19	Progress 2018-19
	► Reviewed the operations of the Authority office and revised the staffing model to be commensurate with the tasks and respond to external review recommendations. ► Created 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.
Worked to enhance the monitoring process for approved health research	► 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 1,875 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 in its eighth year 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 259 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 and has seen a marked reduction in the time it takes to render a decision to the applicant. For example, in the last quarter the average time to render a decision for clinical trials was 35 days (median 36 days) and for general research 50 days (median 38 days), which is a reduction from 140 (123) and 75 (57) days respectively in the first quarter. The Authority completed one appeal during fiscal year 2018-19 that was carried over from the previous fiscal year. The two remaining appeals that were before an appeal board at the end of the 2017-18 reporting period were withdrawn.

The Authority commissioned an external review of the health ethics review processes and operations of the HREB, as well the Authority's structure, staffing and governance. This review was conducted by Clinical Trials Ontario (CTO). The key recommendations included 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 educational resources to help research teams in the HREB application submission process. The Authority developed an action plan which included several initiatives to support the implementation of the CTO recommendations. The majority of the initiatives were completed or in progress by the end of the fiscal year.

The Authority initiated the recommended changes in human resources by hiring an additional Ethics Officer. There was also an increase in the membership on the HREB. These changes have contributed significantly 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 re-designed website also serves to provide a more 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 three conferences: the Canadian Association of Research Ethics Boards (CAREB) National Annual General Meeting and Conference, Research Atlantic 2018: Equity, Diversity, and Inclusion (CAREB East), and Naalak Gathering: Regional Dialogue on Indigenous Research Governance.

5.0 Opportunities and Challenges:

The eighth 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 2018-19. One significant challenge at the beginning of the fiscal year was the recruitment and retention of members to serve on the HREB. However, through rigorous recruitment initiatives and the strong support of its partners, MUN and Eastern Health, as well as individual commitment from its members, the membership of the HREB was robust at the end of the fiscal year.

A second challenge that impacted the operation of the Authority was an application that was filed in the NL Supreme Court in March 2018 relating to the 30 day research ethics review time specified in section 9(4) of the Act. In January 2019 the court ruled that the HREB must consider an application and provide a decision to a research applicant within 30 days of HREB submission. Operational improvements and procedural changes discussed in this report have allowed the Authority to move towards compliance in most applications; however, by fiscal year end the Authority had only been operating under this requirement for two months.

The Authority also experienced financial challenges in 2018-19 given its limited revenue base and significant accountabilities that are increasing to ensure legislative requirements are met in a timely and expert manner. Most notable cost increases in 2018/19 were associated with skill mix changes and legal costs. Future fiscal pressures are anticipated as the Authority manages rigid timeline requirements and further development of its monitoring framework for ethical health research. However, the Authority expects to observe a significant reduction in legal expenses in the upcoming year and will be vigilant in identifying opportunities for cost savings

for the organization. There may also be opportunities to increase revenue generation from clinical trial activity as efficiencies in process continue, as well as from increased funding allocations from the Authority's partners.

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
Mr. Michael Harvey, Director	Department of Health and Community Services
Dr. Fern Brunger, HREB Chairperson (non-voting)	HREB
Ms. Sharon Newman, Ethics Director (non-voting)	Authority Office

During fiscal year 2018-19 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:

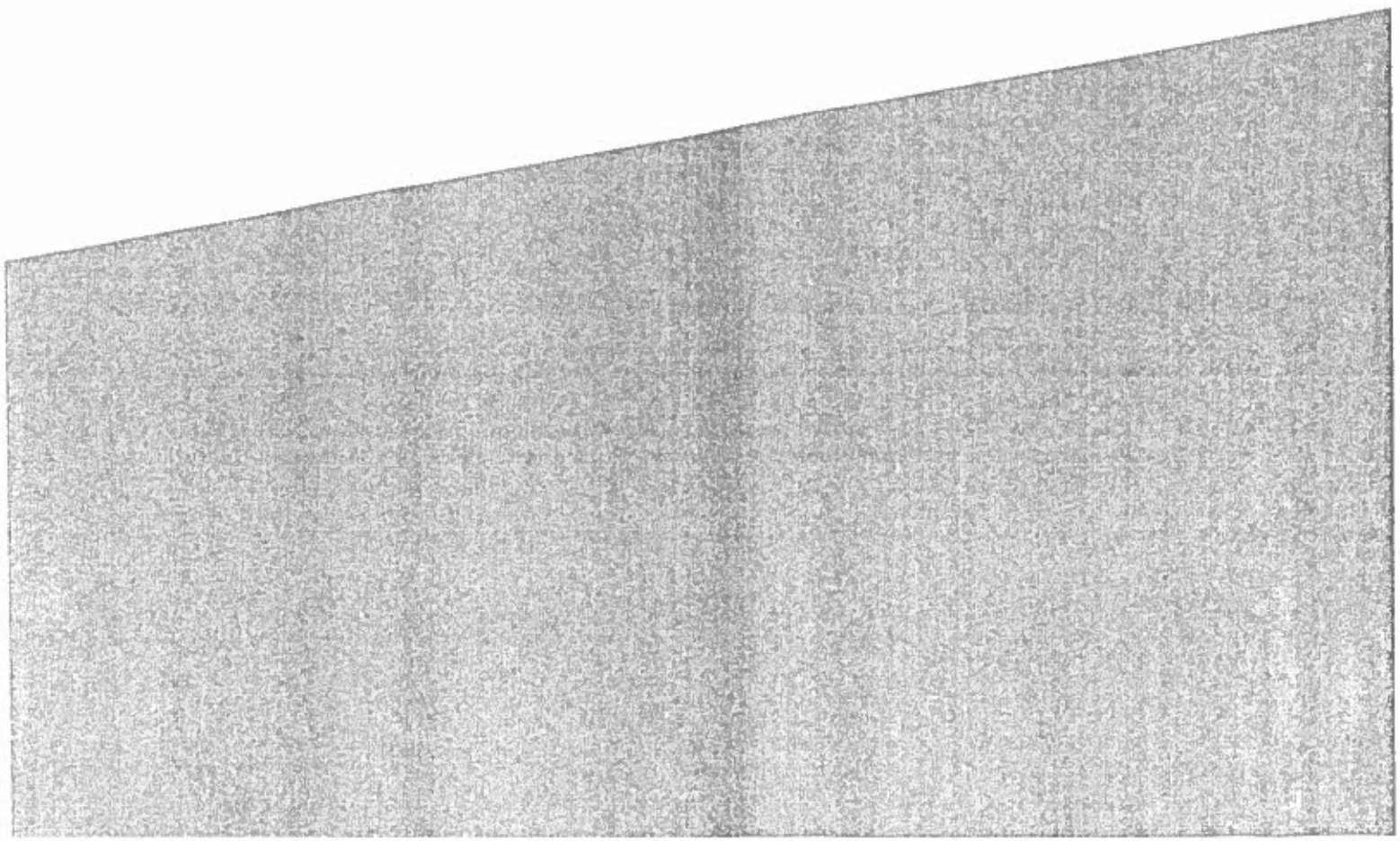
Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2014 (http://www.pre.ethics.gc.ca/default.aspx)

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, 2019



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, 2019 and the statement of operations, statement of changes in net assets and statement of and 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, 2019, 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.

Management's responsibility for the financial statements

Management is responsible for the preparation and fair presentation of these 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

St. John's, Canada
June 26, 2019

Chartered Professional Accountants

Health Research Ethics Authority

Statement of financial position

As at March 31

	2019 $	2018 $
Assets		
Current		
Accounts receivable *[note 3]*	**52,072**	24,065
Prepaid expenses	**12,005**	14,147
Due from related party *[note 7]*	**126,688**	338,184
Total current assets	**190,765**	376,396
Tangible capital assets, net *[note 4]*	**9,531**	12,865
Intangible assets, net *[note 5]*	**1,500**	2,500
	201,796	391,761
Liabilities and net assets		
Current		
Accounts payable and accrued liabilities	**17,318**	23,114
Total current liabilities	**17,318**	23,114
Deferred capital contributions, net *[note 6]*	**5,345**	7,483
Total liabilities	**22,663**	30,597
Net assets	**179,133**	361,164
	201,796	391,761

See accompanying notes

On behalf of the Board:

Regina Coady

Chair of the Board of Directors

Health Research Ethics Authority

Statement of operations

Year ended March 31

	2019 $	2018 $
Revenue		
Support-in-kind *[note 7]*	222,559	220,756
Operating grants *[note 7]*	130,000	130,000
Research project approval fees	114,000	76,500
Amortization of deferred capital contributions *[note 6]*	2,138	2,986
	468,697	430,242
Expenditures		
Salaries and employee benefits	376,095	294,541
Professional fees	160,755	86,558
Rent	39,419	36,820
Honorariums	39,411	33,060
Insurance	17,183	15,057
Travel	7,392	6,559
Other expenses	4,797	1,194
Catering	4,742	3,388
Materials and supplies	4,018	3,519
Amortization of tangible capital assets	3,334	2,189
Equipment rentals	3,211	4,276
Conferences and seminars	2,940	2,882
Software maintenance and training	2,902	—
Telephone	2,737	2,313
Amortization of intangible assets	1,000	1,000
Memberships	625	—
Bad debt (recovery)	—	(3,000)
	670,561	490,356
Deficiency of revenue over expenditures prior to undernoted item	(201,864)	(60,114)
Insurance proceeds *[note 3]*	19,833	—
Deficiency of revenue over expenditures for the year	(182,031)	(60,114)

See accompanying notes

Health Research Ethics Authority

Statement of changes in net assets

Year ended March 31

	2019 $	2018 $
Balance, beginning of year	**361,164**	421,278
Deficiency of revenue over expenditures for the year	**(182,031)**	(60,114)
Balance, end of year	**179,133**	361,164

See accompanying notes

Health Research Ethics Authority

Statement of cash flows

Year ended March 31

	2019 $	2018 $
Operating activities		
Deficiency of revenue over expenditures	(182,031)	(60,114)
Add (deduct) items not affecting cash		
Amortization of tangible capital assets	3,334	2,189
Amortization of intangible assets	1,000	1,000
Amortization of deferred capital contributions	(2,138)	(2,986)
	(179,835)	(59,911)
Changes in non-cash working capital balances related to operations		
Increase in accounts receivable	(28,007)	(19,565)
Decrease (increase) in prepaid expenses	2,142	(2,100)
Decrease in accounts payable and accrued liabilities	(5,796)	(12,661)
Cash used in operating activities	(211,496)	(94,237)
Capital activities		
Purchase of tangible capital assets	—	(5,980)
Disposal of tangible capital assets	—	19,960
Cash provided by capital activities	—	13,980
Financing activities		
Contributed capital for purchases of tangible capital assets	—	6,246
Decrease in due from related party	211,496	74,011
Cash provided by financing activities	211,496	80,257
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, 2019

1. Organization

The Health Research Ethics Authority [the "Authority"] is a non-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 Integrated 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. 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 using a rate of 20%.

Notes to financial statements

March 31, 2019

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 expenses 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.

Notes to financial statements

March 31, 2019

3. Accounts receivable

Accounts receivable consist of the following:

	2019 $	2018 $
Trade accounts receivable	61,500	55,565
Less allowance for doubtful accounts	(31,500)	(31,500)
	30,000	24,065
Insurance proceeds receivable	22,072	—
	52,072	24,065

Accounts receivable includes 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.

4. Tangible capital assets

Tangible capital assets consist of the following:

	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
	23,585	14,054	9,531

	2018		
	Cost $	Accumulated amortization $	Net book value $
Computers	6,914	6,914	—
Furniture and fixtures	10,425	1,932	8,493
Leasehold improvements	6,246	1,874	4,372
	23,585	10,720	12,865

Notes to financial statements

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5. Intangible assets

Intangible capital assets consist of the following:

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

	2018		
	Cost $	Accumulated amortization $	Net book value $
Software	5,000	2,500	2,500

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.

	2019 $	2018 $
Balance, beginning of year	7,483	4,223
Additional contributions	—	6,246
Less amounts amortized to revenue	2,138	2,986
Balance, end of year	5,345	7,483

7. Related party transactions

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

	2019 $	2018 $
Operating grant from Memorial University of Newfoundland	65,000	65,000
Operating grant from Eastern Regional Health Authority	65,000	65,000
	130,000	130,000
Support-in-kind	222,559	220,756

Notes to financial statements

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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:

	2019 $	2018 $
Salaries and employee benefits	148,404	154,521
Rent	39,419	36,820
Professional fees	25,136	21,102
Office and administration fees	9,600	8,313
	222,559	220,756

The due from related party balance consists of the following:

	2019 $	2018 $
Due from Memorial University of Newfoundland	126,688	338,184

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. Management believes that the credit risk with respect to these amounts is not material.

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, 2019, 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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