

Health Research Ethics Authority

Activity Report

April 1, 2016 – March 31, 2017

Chairperson's Message

In accordance with the *Transparency and Accountability Act*, I am pleased to present the 2016-17 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 sixth year of development and the extent to which planned and actual activities were met during fiscal year 2016-17.

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* (Section 2(d)).

Sincerely,

A handwritten signature in black ink that reads "Regina Coady". A short horizontal line is drawn underneath the signature.

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 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 Newfoundland and Labrador 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 health research involving human participants.

Under the Act, the Authority is responsible for appointing the Health Research Ethics Board (HREB). The HREB has two subcommittees – one that reviews clinical trials and genetic research (HREB-CT subcommittee) and one that reviews non-clinical trials research (HREB-NCT 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 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 a second opinion on a decision of the HREB or a research ethics body approved by the Authority may, after consultation with the HREB or other approved research ethics body, appeal the decision 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 representative 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 is designated as senior chair to sit as a non-voting member of the Authority (see Appendix A).

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

Funding

The Authority developed a budget for review and approval by the Minister of Health and Community Services pursuant to section 20 of the Act. During the 2016-2017 fiscal year, the Authority had operating expenditures of approximately \$454,035. Revenue of approximately \$72,000 was derived from review fees levied by 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 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 2016-2017 fiscal year was completed by Ernst & Young. The finalized audited financial statements are attached in Appendix B.

2.0 Primary Clients

The primary clients of the Authority are the people of Newfoundland and Labrador who participate in research. The Authority aims to protect the people of Newfoundland and Labrador by ensuring excellence in research ethics review within the province.

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 Values

The Authority has developed the following core values, which transcended disciplinary boundaries and supported the full range of activities under the Authority's mandate. Each member of the Authority performed their responsibilities in accordance with the following:

Quality – Valuing and promoting the pursuit of excellence in research and ethical review of all health research in Newfoundland and Labrador.

Integrity – Valuing and promoting a consistent culture of transparency and accountability in decision-making and communication to all of our stakeholders and holding ourselves to the highest ethical standards.

Collaboration – Recognizing and valuing the diversity of our stakeholders and engaging in a positive manner that is respectful of others and their different perspectives.

Responsiveness – Recognizing and adapting to the changing research and regulatory environment.

Justice – Valuing and promoting the fair and equitable distribution of benefits and burdens of research participation in such a way that no portion of the population is unduly burdened by the harms of research or denied the benefits of knowledge generated.

5.0 Vision

Excellence in Ethical Research 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 contributed 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.

6.0 Annual Objective

The Authority's mandate ensures that health research conducted in Newfoundland and Labrador (NL) is conducted in an ethical manner. One way of achieving this is by requiring ethics review by the Health Research Ethics Board (HREB) (or a research ethics body approved by the Authority) for all health research conducted in the province. Another is through the requirement that Canadian and internationally accepted legal, ethical and regulatory principles affording protection of research participants shall govern the processes for review and continued oversight of health research (see Appendix C). Ethical principles and guidelines play an important role in advancing the pursuit of knowledge while protecting and respecting research participants.

In fiscal year 2016-17, the Authority focused on promoting the ethical conduct of health research within NL by implementing initiatives towards improving the review process and streamlining existing administrative processes to increase transparency and facilitate the ethics review process. In addition, the Authority returned to focus on developmental activities; for example, amending the MOU, drafting by-laws and undergoing renovations to the existing provincial ethics office suite.

In fiscal year 2016 - 2017, the Authority provided oversight of the review and decision-making on applications to conduct health research. During this time the HREBs reviewed and evaluated 354 research proposals to ensure conformity with accepted scientific and ethical standards and applicable regulations.

The Ethics Director of the Authority also held eighteen orientation and education sessions for targeted groups (HREB members, researchers and administrators) to ensure public awareness of the process of ethics review in the province and provide continued support to administrators and researchers submitting applications to the HREB.

The Authority's annual objective is the same for the three years covered by its Activity Plan (2014-2015, 2015-2016 and 2016-2017); however, the report provided for each year shows progress made in that fiscal year. The indicators which the Authority reported on changed each fiscal year covered by the 2014-2017 Activity Plan and were identified in the relevant annual report. The reporting below details progress in fiscal year 2016-2017.

Objective: By March 31, 2017, the Authority will have promoted and provided oversight of the ethical conduct of health research within NL.

Measure: Promoted and provided oversight of the ethical conduct of health research within NL.

| Indicators 2016-2017 | Progress 2016-2017 |
|--|---|
| Completed the development of a formalized communications strategy | ► During fiscal year 2014-2015, a competition was initiated to hire an Ethics Officer. At the end of fiscal year 2015-2016 an Ethics Officer was appointed. The historical Ethics Officer role was reclassified to be the Ethics Director. During fiscal year 2015-2016 there was turnover in this position with the role unfilled for 8 months. A key priority of these two roles was to develop a formalized communication plan with the plan of completing it in fiscal year 2015-2016. As a |

| Indicators 2016-2017 | Progress 2016-2017 |
|----------------------|--|
| | <p>result of staff turnover and issues with recruitment further delayed achievement of this initiative in this period; however, much work has been done towards developing a basis for a communication strategy and work has been completed to communicate with stakeholders on the work of the Authority.</p> <p>Implementing communication initiatives to promote the ethical conduct of health research will move into the next fiscal year's work plan as it continues to be a priority.</p> <ul style="list-style-type: none"> ▶ Examples of communication activities implemented this year include: <ul style="list-style-type: none"> – Maintained a publicly accessible website with information on the ethics review process for researchers, HREB members and key stakeholders: www.hrea.ca. – Continued working with a contracted external company to re-design the HREA website to provide a more up-to-date, comprehensive, user-friendly resource for the research community. The website is currently undergoing a vulnerability assessment before going live. – Ethics Director continued reporting to the Authority on key metrics and research being reviewed by both HREB subcommittees. – Participated in National Health Ethics Week by developing and disseminating five research ethics bulletins to research stakeholders across the province. The Ethics Director of the Authority also held two drop-in consultation sessions for researchers at Memorial University during this week. – Held 18 training and education sessions regarding the Authority, the HREBs and the ethics review process. – During fiscal year 2016-2017 information collected via the online application forms for ethics review continued to form the basis of a communication strategy for the different Regional Health Authorities whereby the Authority was able to provide feedback on what research was being reviewed and approved for the various regions. |

| Indicators 2016-2017 | Progress 2016-2017 |
|--|--|
| Continued to enhance the review process | <ul style="list-style-type: none"> ▶ Continued the development of standard operating procedures (SOPs) to ensure consistency in handling applications at the Ethics Office and HREB review. ▶ A new Genetics Working Group was struck during fiscal year 2016-2017: <ul style="list-style-type: none"> – This group was tasked to make recommendations to strengthen the review process for genetic research in the province. The Genetics Working Group is continuing to meet to develop new guidance for the review of genetic research. ▶ Revised the HREB Terms of Reference to align with national guidelines and reflect current practice. ▶ Strengthened the review process regarding requirements for organizational approval in NL by providing guidance to the different organizational review committees in the province. |
| Further refined and communicated the accountability process for research ethics bodies approved under the authority of the HREA | <ul style="list-style-type: none"> ▶ Worked to develop a process for approval and ongoing renewal of research ethics bodies under the authority of the HREA. The Authority continued to clarify the expectations, relationship and responsibilities under the Act for all approved bodies. ▶ Through the online system, the staff of the Authority had access to all health research files that were reviewed, including files that were reviewed by approved bodies under the act. This improved accountability and reporting processes for these approved bodies. |
| Provided oversight of the review and decision-making on applications to conduct health research | <ul style="list-style-type: none"> ▶ The two subcommittees of the HREB (HREB – Clinical Trials and HREB – Non Clinical Trials) continue to function to review and approve health research involving human subjects. The HREBs alternated meetings on a weekly basis. During this reporting period, a total of 354 applications were reviewed by the two HREBs. ▶ A subcommittee was formed in January 2017 to respond to proposed revisions to the second edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) that were open for public comment. This document is the national ethics guideline that REBs use as a framework for ethics review. |

| Indicators 2016-2017 | Progress 2016-2017 |
|----------------------|---|
| | <ul style="list-style-type: none"> ▶ A submission was made on behalf of the HREB during the 1st and 3rd round of public consultations for the statutory review of the Provincial Health Information Act (PHIA) review. ▶ The Authority met regularly to discuss the operations of the organization. |

Indicators that the Authority will report on for fiscal year April 1, 2017 to March 31, 2018:

- ▶ Implemented communication initiatives to promote the ethical conduct of health research
- ▶ Implemented initiatives towards improving the research ethics review process
- ▶ Worked to enhance the monitoring process for approved health research

Discussion of Results:

The Authority made considerable progress in its sixth year by focusing on promoting and improving the ethics review process in the province. A major initiative contributing to this was the formation of a new Genetics Working Group to strengthen the review process for genetic research in the province. The revision to the HREB Terms of Reference and focusing on replenishing the HREB membership were two other initiatives to improve the ethics review process.

Having submissions included in the public consultation processes for the review of the proposed revisions to the TCPS2 and the statutory review of PHIA also provided opportunity to promote and strengthen the ethics review process.

Lastly, the Authority was represented at three conferences: the Canadian Association of Research Ethics Boards (CAREB) National Annual General Meeting and Conference, the CAREB Regional Conference, and

Public Responsibility in Medicine and Research (PRIM&R) Advancing Ethical Research (AER) Conference.

7.0 Opportunities and Challenges:

The sixth year of operation has allowed the Authority to continue to focus on its core business, and also return to strengthen some of its developmental activities. As an evolving entity, and as guided by the newly developed 2017-2020 Activity Plan, the Authority will promote and provide oversight of the ethical conduct of health research within NL.

The Authority faced some challenges during the fiscal year 2016-2017 with staff turnover in the Ethics Officer position. With this position vacant, progress was limited in relation to a key priority – the development of a formalized communication plan. The Authority did; however, continue work on many communications initiatives and the development of a new Activity Plan for 2017-2020 was an opportunity to re-align our strategic directions in relation to implementing communication initiatives to promote the ethical conduct of health research. The Authority did continue work on re-designing the HREA website which is an opportunity to enhance communications to various stakeholders and function as a more up-to-date, comprehensive, user-friendly resource for the research community.

The Authority is continuing to work towards maintaining, and ultimately expanding, clinical trial activity in the province. The ongoing trend of declining base clinical trial activity across the country may present challenges in the future. The current model of ethics review has removed many unnecessary barriers to start-up of clinical trials and our online system currently facilitates the research ethics process in the province.

Finally, the Authority continues to strengthen its partnerships with the Department of Health and Community Services, Eastern Regional Health Authority and Memorial University of Newfoundland. The review of the Memorandum of Understanding (MOU) began in September 2014 and was ongoing at the end of this reporting period. 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 |
| Ms. Patricia Grainger, HREB Chairperson (non-voting) | HREB |
| Ms. Sandra Veenstra, HREA, Ethics Director (non-voting) | HREA Ethics Office |

Appendix B: Audited Financial Statements

Financial statements

Health Research Ethics Authority

March 31, 2017

Independent auditors' report

To the Board of Directors of
Health Research Ethics Authority

We have audited the accompanying financial statements of the **Health Research Ethics Authority**, which comprise the statement of financial position as at March 31, 2017, and the statements of operations, changes in net assets and cash flows for the year then ended, and a summary of significant accounting policies and other explanatory information.

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.

Auditors' responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with Canadian generally accepted auditing standards. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditors consider internal control relevant to the entity's preparation and fair presentation of the financial statements 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 entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements present fairly, in all material respects, the financial position of the **Health Research Ethics Authority** as at March 31, 2017 and the results of its operations and its cash flows for the year then ended in accordance with Canadian public sector accounting standards.

The logo for Ernst & Young LLP, featuring the company name in a stylized, handwritten-style font.

St. John's, Canada
October 30, 2017

Chartered Professional Accountants

Health Research Ethics Authority
Statement of financial position

As at March 31

| | 2017 \$ | 2016 \$ |
|--|-------------------|-------------------|
| Assets | | |
| Current | | |
| Accounts receivable [note 3] | 4,500 | 46,500 |
| Prepaid expenses | 12,047 | 10,668 |
| Due from related party [note 7] | 412,195 | 413,703 |
| Total current assets | 428,742 | 470,871 |
| Tangible capital assets, net [note 4] | 29,034 | 691 |
| Intangible assets, net [note 5] | 3,500 | 4,500 |
| | 461,276 | 476,062 |
| Liabilities and net assets | | |
| Current | | |
| Accounts payable and accrued liabilities | 35,775 | 15,546 |
| Total current liabilities | 35,775 | 15,546 |
| Deferred capital contributions, net [note 6] | 4,223 | 691 |
| | 39,998 | 16,237 |
| Net assets | 421,278 | 459,825 |
| | 461,276 | 476,062 |

See accompanying notes *Regina Coady*
On behalf of the Board:

Chair of the Board of Directors
Health Research Ethics Authority

Health Research Ethics Authority
Statement of operations

Year ended March 31

| | 2017 \$ | 2016 \$ |
|--|-------------------|-------------------|
| Revenue | | |
| Support-in-kind [note 7] | 205,516 | 217,429 |
| Research project approval fees | 72,000 | 165,000 |
| Operating grants [note 7] | 130,000 | 130,000 |
| Amortization of deferred capital contributions | 913 | 1,383 |
| | 408,429 | 513,812 |
| Expenditures | | |
| Salaries and employee benefits | 298,952 | 279,364 |
| Rent | 28,948 | 28,502 |
| Professional fees | 24,868 | 22,588 |
| Honorariums | 23,552 | 38,771 |
| Software maintenance and training | 17,903 | 12,500 |
| Insurance | 14,409 | 15,347 |
| Travel | 11,980 | 13,406 |
| Conferences and seminars | 4,310 | 5,381 |
| Catering | 4,185 | 6,685 |
| Materials and supplies | 4,227 | 1,705 |
| Equipment rentals | 3,198 | 3,284 |
| Telephone | 2,995 | 2,812 |
| Amortization of tangible capital assets | 2,308 | 1,383 |
| Other expense | 2,641 | 5,307 |
| Bad debt expense | 1,500 | 16,500 |
| Amortization of intangible assets | 1,000 | 500 |
| | 446,976 | 454,035 |
| Excess (deficiency) of revenue over expenditures for the year | (38,547) | 59,777 |

See accompanying notes

Health Research Ethics Authority
Statement of changes in net assets

Year ended March 31

| | 2017 | 2016 |
|---|----------------|-------------|
| | \$ | \$ |
| Balance, beginning of year | 459,825 | 400,048 |
| Excess (deficiency) of revenue over expenditures for the year | (38,547) | 59,777 |
| Balance, end of year | 421,278 | 459,825 |

See accompanying notes

Health Research Ethics Authority

Statement of cash flows

Year ended March 31

| | 2017 \$ | 2016 \$ |
|--|-----------------|-----------------|
| Operating activities | | |
| Excess (deficiency) of revenue over expenditures | (38,547) | 59,777 |
| Add (deduct) items not affecting cash | | |
| Amortization of tangible capital asset | 2,308 | 1,383 |
| Amortization of intangible assets | 1,000 | 500 |
| Amortization of deferred capital contributions | (913) | (1,383) |
| | <u>(36,152)</u> | <u>60,277</u> |
| Changes in non-cash working capital balances related to operations | | |
| Decrease (increase) in accounts receivable | 42,000 | (1,500) |
| Decrease in prepaid expenses | (1,379) | (335) |
| Decrease (increase) in accounts payable and accrued liabilities | 20,229 | (9,903) |
| Cash provided by operating activities | <u>24,698</u> | <u>48,539</u> |
| Capital activities | | |
| Purchase of intangible assets | — | (5,000) |
| Purchase of tangible capital assets | <u>(30,651)</u> | — |
| Increase in deferred capital contributions | 4,445 | — |
| Cash used in capital activities | <u>(26,206)</u> | <u>(5,000)</u> |
| Financing activities | | |
| Decrease (increase) in due from related party | 1,508 | (43,539) |
| Cash provided by (used in) financing activities | <u>1,508</u> | <u>(43,539)</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 the financial statements

March 31, 2017

1. Organization

The Health Research Ethics Authority [the “Authority”] is a non-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 include 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 amortized over the estimated useful life of the asset using a rate of 20%.

Health Research Ethics Authority

Notes to the financial statements

March 31, 2017

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 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 the determination of fair values associated with support-in-kind and the allowance for doubtful accounts.

Health Research Ethics Authority

Notes to the financial statements

March 31, 2017

3. Accounts receivable

Accounts receivable consist of the following:

| | 2017 \$ | 2016 \$ |
|--------------------------------------|--------------|---------------|
| Trade accounts receivable | 39,000 | 79,500 |
| Less allowance for doubtful accounts | 34,500 | 33,000 |
| | <u>4,500</u> | <u>46,500</u> |

4. Tangible capital assets

Tangible capital assets consist of the following:

| | 2017 Cost \$ | 2017 Accumulated amortization \$ | 2016 Net book value \$ | 2016 Net book value \$ |
|------------------------|--------------------|---|---------------------------------|---------------------------------|
| Computers | 6,941 | 6,941 | — | 691 |
| Furniture and fixtures | 4,445 | 307 | 4,138 | — |
| Leasehold improvements | 26,206 | 1,310 | 24,896 | — |
| | <u>37,592</u> | <u>8,558</u> | <u>29,034</u> | <u>691</u> |

5. Intangible assets

Intangible capital assets consist of the following:

| | 2017 Cost \$ | 2017 Accumulated amortization \$ | 2016 Net book value \$ | 2016 Net book value \$ |
|----------|--------------------|---|---------------------------------|---------------------------------|
| Software | 5,000 | 1,500 | 3,500 | 4,500 |

Health Research Ethics Authority

Notes to the financial statements

March 31, 2017

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.

| | 2017 \$ | 2016 \$ |
|-----------------------------------|--------------|------------|
| Balance, beginning of year | 691 | 2,074 |
| Additional contributions | 4,445 | — |
| Less amounts amortized to revenue | 913 | 1,383 |
| Balance, end of year | 4,223 | 691 |

7. Related party transactions

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

| | 2017 \$ | 2016 \$ |
|--|----------------|------------|
| Operating grant from Memorial University of Newfoundland | 65,000 | 65,000 |
| Operating grant from Eastern Regional Health Authority | 65,000 | 65,000 |
| Support-in-kind | 130,000 | 130,000 |
| | 205,516 | 217,429 |

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:

| | 2017 \$ | 2016 \$ |
|--|----------------|------------|
| Salaries and employee benefits | 146,505 | 143,608 |
| Rent | 28,892 | 28,503 |
| Payment of prior year accounts payable | — | 16,448 |
| Professional fees | 20,343 | 16,447 |
| Office and administration fees | 9,776 | 12,423 |
| | 205,516 | 217,429 |

Health Research Ethics Authority

Notes to the financial statements

March 31, 2017

The due from related party balance consists of the following:

| | 2017 \$ | 2016 \$ |
|--|-------------------|-------------------|
| Due from Memorial University of Newfoundland | 412,195 | 413,703 |

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, 2017, 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.

9. Comparative figures

Certain figures from the prior year have been reclassified to conform to the presentation adopted for the current year.

Appendix C: Reference Documents

The following reference documents support the work of the Authority and can be accessed at:

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

Guidelines for Good Clinical Practice of the International Committee on Harmonization
(<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-lid/ich/efficac/e6-eng.php#a2.0>)

Contact Information

Ethics Office

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