Health Research Ethics Authority

Activity Report

April 1, 2015 - March 31, 2016

Chairperson's Message

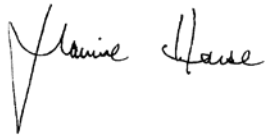
In accordance with the *Transparency and Accountability Act*, I am pleased to present the 2015-16 Activity Report for the Health Research Ethics Authority hereafter referred to as the Authority. Under the *Transparency and Accountability Act* the Authority is defined as a Category 3 entity, and as such, 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 fifth year of development and the extent to which planned and actual activities were met during fiscal year 2015-16.

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,



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Ms. Jeannie House, Chairperson
Health Research Ethics Authority

Table of Contents

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 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 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. The Chairperson of the HREB is a non-voting member of the Authority (see Appendix A).

The Ethics Director is the senior employee 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 2015-2016 fiscal year, the Authority had operating expenditures of approximately $454,466. Revenue of approximately $165,000 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 2015-2016 fiscal year was completed by Ernst & Young. The finalized audited financial statements are attached as 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 2015-16, 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. To this end, the Authority completed the development of an end-to-end online Researcher Portal to facilitate the ethics review process for health research being conducted in the province. The Researcher Portal is a highly configurable solution that can electronically route researchers' applications to various review committees for review and approval.

In fiscal year 2015 - 2016, the Authority provided oversight of the review and decision-making on applications to conduct health research. During this time the HREBs reviewed and evaluated 304 research proposals to ensure conformity with accepted scientific and ethical standards and applicable regulations.

The Authority also held eleven 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 will report on will change each fiscal year and will be identified in the relevant annual report. Thus, the reporting below details progress in fiscal year 2015-2016.

Objective: By March 31, 2016, 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 2015-2016	Progress 2015-2016
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 previous Ethics Officer role was reclassified to be the Ethics Director. 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. 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. Completing the development of a formalized communications strategy will move into the next fiscal year's work plan as it continues to be a priority. • Examples of communication activities implemented this year include: o Maintained a publicly accessible website with information on the ethics review process for researchers, HREB members and key stakeholders: www.hrea.ca.

	o Contracted an external company to re-design the HREA website to provide a more up-to-date, comprehensive, user-friendly resource for the research community. o Continued reporting to the Authority on key metrics and research being reviewed by both HREB subcommittees. o Participated in National Health Ethics Week by developing and disseminating five research ethics bulletins to research stakeholders across the province. The Authority also held two drop-in consultation sessions for researchers at Memorial University during this week. o Held 11 training and education sessions regarding the Authority, the HREBs and the ethics review process. o During fiscal year 2015-2016 the Notification Forms (one page summary of submitted application for HREB 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. With the development of a new online Researcher Portal, the information extracted from the Notification Forms was built into the application forms themselves where reports can be generated on

	key fields for reporting purposes. o Developed the 'Newfoundland and Labrador Ethics Application Screening Tool' to help guide researchers to the appropriate application for ethics review for the various REBs in the province. This tool consolidated guidance and regulations for researchers based on their project type.
Continued to enhance the review process	• Continued the development of standard operating procedures (SOPs) to ensure consistency in handling applications at the Ethics Office and HREB review. • Revised the HREB Terms of Reference to align with national guidelines and reflect current practice. • Two subcommittees met during fiscal year 2015-2016: o Genetic Working Group tasked to outline a process for the province's genetic research for consenting family members of participants in genetic research. A standardized consent process was finalized in line with national guidelines for the ethical conduct of research involving humans. This group also developed a consent template for genetic studies in

	which results will be returned and a sample newsletter template for genetic studies for research participants consented for already approved genetic projects involving results that have been/will be returned, but not specifically consented for different types of genetic analysis. This has enhanced the review process by standardizing the requirements of participant facing materials and ensuring that participant's rights are protected. o A working group was formed to review the draft 'Newfoundland and Labrador Ethics Application Screening Tool' that was developed by the Authority. The tool is publicly available via the HREA website. • Completed streamlining the HREB application forms and continuing review forms to bring them up-to-date. • Finalized the interpretation of the definition of health research in the legislation. The interpretation was incorporated into the newly developed 'Newfoundland and Labrador Ethics Application Screening Tool' and disseminated widely. The

	interpretation will ensure the scope of the HREA legislation is consistently applied and the HREBs are reviewing only health research that fits the definition. • Strengthened the review process regarding requirements for organizational approval in NL by providing guidance material on the HREA website regarding established organizational review processes in the province. • In partnership with Memorial University, completed the development of an end-to-end research ethics review system with reporting capabilities (ROMEO and Researcher Portal). The system is used by the Ethics Office to administer the ethics review process and by the HREB for its ethics review operations. The Interdisciplinary Committee on Ethics in Human Research (ICEHR), the only approved research ethics body under the Act, also uses ROMEO for its operations. Information collected in this system will be used for reporting to the Authority. All applications submitted to the HREB and ICEHR for ethics review are sent electronically via the online Researcher Portal. Any researcher submitting an application to a NL REB can create an

	account to gain access to the Researcher Portal.
Further refined and communicated the accountability process for research ethics bodies approved under the authority of the HREA	• The Authority collaborated with ICEHR in the development of the online Researcher Portal. This was an opportunity to ensure that the ethics review processes were aligned and guidelines were being applied consistently. • 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 ROMEO system, 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	• 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 304 applications were reviewed by the two HREBs. • The Authority met regularly to discuss the operations of the organization.

Indicators that the Authority will report on for fiscal year April 1, 2016 to March 31, 2017:

- Completed the development of a formalized communications strategy
- Continued to enhance the review process
- Further refined and communicated the accountability process for research ethics bodies approved under the authority of the HREA
- Provided oversight of the review and decision-making on applications to conduct health research

Discussion of Results:

The Authority made considerable progress in its fifth year by focusing on promoting and improving the ethics review process in the province.

A major initiative that contributed to significant improvement was through the development of a comprehensive, end-to-end online administrative system to facilitate the review of health research in the province. The system (ROMEO) provided researchers and administrators a web-based application process which automates the ethics review process that the Authority oversees. This enabled the Ethics Office to move to a paperless system for administrative purposes and also for the HREB review process. The corresponding Researcher Portal is aligned with ROMEO to allow researchers to submit research ethics applications online. This system went live in December 2015.

Aligned with the above initiative, and in preparation for the online submission of research ethics applications in Newfoundland and Labrador (NL), an interactive ethics application screening tool was developed to help guide researchers to the appropriate application forms for the various research ethics boards (REBs) in the province. The tool had to accommodate the various requirements for research ethics review in the province and navigate researchers to a singular end point (a specific application form inside the online Researcher Portal). Through the development of a series of yes/no questions that a researcher completes in the context of their proposed study, the tool helps researchers determine whether their research requires review (under the requirements of TCPS2), whether their research is health research (and requires review in accordance to the HREA Act) and what REB they should be applying to (either the provincial health REB (HREB) or Memorial University's two institutional REBs). Further stratification was built into the tool regarding data sources and risk level of a given study. Each question in the tool has supplementary interpretations/definitions to assist researchers in answering some of the critical questions and contact details and resources

should they still require additional information and support. This tool has succeeded in balancing the different contexts of research ethics review in the province with both institutional and provincial REBs that serve a wide variety of stakeholders that are utilizing a common platform for the online submission of ethics applications.

Lastly, the Authority was represented at three conferences: the Canadian Association of Research Ethics Boards (CAREB) National Annual General Meeting and Conference, Public Responsibility in Medicine and Research (PRIM&R) Advancing Ethical Research (AER) Conference, and the 4th World Conference on Research Integrity (WCRI).

7.0 Opportunities and Challenges:

The fifth year of operation has allowed the Authority to continue to focus more on its core business. As an evolving entity, and as guided by the 2014-2017 Activity Plan, the Authority will promote the ethical conduct of health research within Newfoundland and Labrador by developing and implementing initiatives to improve the ethics review process.

The development and implementation of an on-line system for the HREB and other approved research ethics bodies provides an opportunity to enhance governance and facilitate the review and ongoing approval of health research in the province. Developing an interpretation for the definition of health research in the Act and creating the "Newfoundland and Labrador Ethics Application Screening Tool" also provides clarity and enhances consistency for researchers who are users of the ethics review system.

As part of the communications strategy, the Authority began work on re-designing the HREA website. This is an opportunity to enhance communication 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 a challenge in the future. The current model of ethics review has removed many unnecessary barriers to start-up of clinical trials and the new online system will be a further opportunity to facilitate research activity 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. Jeannie House, Chairperson	Public
Ms. Katherine Chubbs, Director	Eastern Health
Dr. Ray Gosine, Director	MUN
Ms. Karen Stone, Director	Department of Health and Community Services
Dr. Fern Brunger, HREB Chairperson	Division of Community Health and Humanities, Faculty of Medicine, MUN
Mr. Duncan Waltrip, HREA, Ethics Officer	HREA Ethics Office
Ms. Sandra Reid, HREA, Ethics Director	HREA Ethics Office

Appendix B: Audited Financial Statements

Financial statements

Health Research Ethics Authority

March 31, 2016

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, 2016, 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, 2016 and the results of its operations and its cash flows for the year then ended in accordance with Canadian public sector accounting standards.

Ernst & Young LLP

St. John's, Canada
October 14, 2016

Chartered Professional Accountants

Health Research Ethics Authority

Statement of financial position

As at March 31

	2016 $	2015 $
Assets		
Current		
Accounts receivable *[note 3]*	**46,500**	45,000
Prepaid expenses	**10,668**	10,333
Due from related party *[note 7]*	**413,703**	370,164
Total current assets	**470,871**	425,497
Tangible capital assets, net *[note 4]*	**691**	2,074
Intangible assets, net *[note 5]*	**4,500**	—
	476,062	427,571
Liabilities and net assets		
Current		
Accounts payable and accrued liabilities	**15,546**	25,449
Total current liabilities	**15,546**	25,449
Deferred capital contributions, net *[note 6]*	**691**	2,074
	16,237	27,523
Net assets	**459,825**	400,048
	476,062	427,571

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

	2016	2015
	$	$
Revenue		
Support-in-kind *[note 7]*	**217,429**	195,510
Research project approval fees	**165,000**	144,000
Operating grants *[note 7]*	**130,000**	130,000
Amortization of deferred capital contributions	**1,383**	1,383
	513,812	470,893
Expenditures		
Salaries and employee benefits	**279,364**	258,408
Honorariums	**38,771**	33,688
Rent	**28,502**	28,502
Professional fees	**22,588**	16,697
Bad debt expense (recovery)	**16,500**	(3,355)
Insurance	**15,347**	16,555
Travel	**13,406**	9,711
Software maintenance and training	**12,500**	—
Catering, luncheons and receptions	**6,685**	5,432
Conferences and seminars	**5,381**	1,265
Courier, freight and postage	**3,606**	3,666
Equipment rentals	**3,284**	3,496
Telephone	**2,812**	2,668
Amortization of tangible capital assets	**1,383**	1,383
Materials and supplies	**1,705**	5,201
Printing and photocopying	**743**	849
Advertising	**545**	—
Amortization of intangible assets	**500**	—
Membership and registration fees	**413**	318
	454,035	384,484
Excess of revenue over expenditures for the year	**59,777**	86,409

See accompanying notes

Health Research Ethics Authority

Statement of changes in net assets

Year ended March 31

	2016	2015
	$	$
Balance, beginning of year	**400,048**	313,639
Excess of revenue over expenditures for the year	**59,777**	86,409
Balance, end of year	**459,825**	400,048

See accompanying notes

Health Research Ethics Authority

Statement of cash flows

Year ended March 31

	2016 $	2015 $
Operating activities		
Excess of revenue over expenditures	**59,777**	86,409
Add (deduct) items not affecting cash		
Amortization of tangible capital asset	**1,383**	1,383
Amortization of intangible assets	**500**	—
Amortization of deferred capital contributions	**(1,383)**	(1,383)
	60,277	86,409
Changes in non-cash working capital balances related to operations		
Decrease (increase) in accounts receivable	**(1,500)**	53,080
Decrease (increase) in prepaid expenses	**(335)**	761
Decrease in accounts payable and accrued liabilities	**(9,903)**	(1,686)
Cash provided by operating activities	**48,539**	138,564
Capital activities		
Purchase of intangible assets	**(5,000)**	—
Cash used in capital activities	**(5,000)**	—
Financing activities		
Increase in due from related party	**(43,539)**	(138,564)
Cash used in financing activities	**(43,539)**	(138,564)
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, 2016

1. Organization and basis of presentation

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

These financial statements have been prepared 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 are amortized 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%.

Notes to financial statements

March 31, 2016

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 classified 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 in the amortized cost category 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.

Notes to financial statements

March 31, 2016

3. Accounts receivable

Accounts receivable consist of the following:

	2016 $	2015 $
Trade accounts receivable	**79,500**	61,500
Less allowance for doubtful accounts	**33,000**	16,500
	46,500	45,000

4. Tangible capital assets

Tangible capital assets consist of the following:

	2016			2015
	Cost $	Accumulated amortization $	Net book value $	Net book value $
Computers	**6,914**	**6,223**	**691**	2,074

5. Intangible assets

Intangible capital assets consist of the following:

	2016			2015
	Cost $	Accumulated amortization $	Net book value $	Net book value $
Software	**5,000**	**500**	**4,500**	—

Notes to financial statements

March 31, 2016

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.

	2016 $	2015 $
Balance, beginning of year	**2,074**	3,457
Less amounts amortized to revenue	**1,383**	1,383
Balance, end of year	**691**	2,074

7. Related party transactions

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

	2016 $	2015 $
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 from Memorial University of Newfoundland	**217,429**	195,510

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:

	2016 $	2015 $
Salaries and employee benefits	**143,608**	133,256
Rent	**28,503**	28,502
Payment of prior year accounts payable	**16,448**	—
Professional fees	**16,447**	16,448
Office and administration fees	**12,423**	17,304
	217,429	195,510

Notes to financial statements

March 31, 2016

The due from related party balance consists the following:

	2016 $	2015 $
Due from Memorial University of Newfoundland	**413,703**	370,164

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 fulfill 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, 2016, 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-ld/ich/efficac/e6-eng.php#a2.0)

Contact Information

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