

Health Research Ethics Authority

Activity Report

April 1, 2014 - March 31, 2015

Chairperson's Message

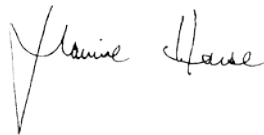
In accordance with the *Transparency and Accountability Act*, I am pleased to present the 2014-15 Activity Report for the Health Research Ethics Authority hereafter referred to as the Authority. Under the *Transparency and Accountability Act* the Authority is defined as a Category 3 entity, and as such, 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 fourth year of development and the extent to which planned and actual activities were met during fiscal year 2014-15.

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 cursive script that reads "Jeannie House". The signature is written in black ink and is positioned above a horizontal line.

Ms. Jeannie House, 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 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).

An Ethics Director is the senior employee of the Authority and reports to the Board of Directors 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 2014-2015 fiscal year, the Authority had operating expenditures of approximately \$395,747. Revenue of \$199,763 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 2014-2015 fiscal year will be completed by Ernst & Young. The finalized audited financial statements, once received, will be 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 2014-15, the Authority focused on promoting the ethical conduct of health research within NL by implementing initiatives towards improving the review process and initiating the development of a communications strategy. To this end, representatives of the Authority travelled to Labrador in June 2014 to meet with stakeholders and receive feedback on their experience with the provincial ethics review process.

In fiscal year 2014 - 2015, the Authority provided oversight of the review and decision-making on applications to conduct health research. During this time the HREBs reviewed and evaluated 283 research proposals to ensure conformity with accepted scientific and ethical standards and applicable regulations.

The Authority also held nine 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 2014-2015.

Objective: By March 31, 2015, 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 2014-2015	Progress 2014-2015
<p>Initiated the development of a communications strategy</p>	<ul style="list-style-type: none"> • During fiscal year 2014-2015, a competition was initiated to hire an Ethics Officer. The current Ethics Officer role was reclassified to be the Ethics Director. A key priority of these new roles will be to develop a formalized communication plan. Issues with recruitment have delayed achievement of this initiative in this period; however, much work has been completed to communicate with stakeholders on the work of the Authority. The development of the formal communication strategy will move into the next fiscal year's work plan as it continues to be a priority and will be actioned once the Ethics Officer position is filled. • 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. ○ Increased reporting to the Authority on key metrics and research being reviewed by both HREB subcommittees. ○ Published an article "<i>Conducting Health Research in Newfoundland and Labrador</i>" in the January edition of Connecting Voices. ○ Participated in National Health Ethics Week by developing and disseminating five research ethics bulletins to research stakeholders across the province. ○ Held 9 training and education sessions regarding the Authority, the

Indicators 2014-2015	Progress 2014-2015
	<p>HREBs and the ethics review process.</p> <ul style="list-style-type: none"> ○ Travelled to Labrador to meet with various stakeholders to discuss the current system of ethics review (and more broadly the review of health research) in the province. ○ During fiscal year 2014-2015 the Notification Forms 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.
<p>Implemented initiatives towards improving the review process</p>	<ul style="list-style-type: none"> ● Initiated the development of standard operating procedures (SOPs) to ensure consistency in handling applications at the Ethics Office and HREB review. ● Four subcommittees were formed during fiscal year 2014-2015: <ul style="list-style-type: none"> ○ Genetic Working Group tasked to outline a process for the province's genetic research for consenting family members of probands. A standardized consent process and consent template is currently being developed. ○ Working Group to develop a consent template for community-based research. The template was finalized in November 2014 and available on the Authority's website. ○ Working Group to develop a consent template for pregnancy follow-up for participants enrolled in clinical trials. This template was finalized in December 2014 and available on the Authority's website. ○ A working group looking at the review of public health research,

Indicators 2014-2015	Progress 2014-2015
	<p>registries and surveillance activities. This group is continuing to meet.</p> <ul style="list-style-type: none"> • Hired a Research Assistant for a short term contract to undertake a preliminary review of the HREB application forms and continuing review forms. Work is being finalized to streamline these forms and bring them up-to-date. • Met with stakeholders to discuss the interpretation of the definition of health research in the legislation. A formal interpretation will be prepared 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. • Provided feedback regarding the national model Clinical Trial Agreement (mCTA). • Partnered with Memorial University to develop an end-to-end research ethics review system with reporting capabilities (ROME0). The system will be used by the Ethics Office to administer the ethics review process and by the HREB for its ethics review operations. ICEHR, the only approved research ethics body under the Act will also be using ROME0 for its operations. Information collected in this system will be used for reporting to the Authority.
Clearly defined the accountability process for research ethics bodies approved under the authority of the HREA	<ul style="list-style-type: none"> • The Authority met with Grenfell's research ethics body to discuss the possibility of becoming approved under the Act to review health research. It was decided that any health research

Indicators 2014-2015	Progress 2014-2015
	<p>being conducted at Grenfell campus would continue to be reviewed by the HREB.</p> <ul style="list-style-type: none"> • The Authority met with the Interdisciplinary Committee on Ethics in Human Research (ICEHR) to clarify the expectations, relationship and responsibilities under the Act. Work is currently underway to develop a process for approval and ongoing renewal of research ethics bodies under the authority of the HREA. • Through the ROME system, the Authority will have access to all health research files that are reviewed, including files that are reviewed by approved bodies under the act. This will improve accountability and reporting processes for these approved bodies.
<p>Provided oversight of the review and decision- making on applications to conduct health research</p>	<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 283 applications were reviewed by the two HREBs. • The Authority met monthly to discuss the operations of the organization.

Indicators that the Authority will report on for fiscal year April 1, 2015 to March 31, 2016:

- 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 developmental activities during its first three years of operation. The fourth year focused on promoting and improving the ethics review process in the province.

A major initiative that contributed to identifying areas for improvement was through consultation with stakeholders in the research community. The Authority met with researchers and administrative personnel involved with health research, such as those located in Labrador. Based on the discussion, the Authority developed an action plan to address recommendations regarding the current system of ethics review and the review of health research in the province. A short term action item that was accomplished during this reporting period was the development of a community-based research consent form template.

Another major initiative that the Authority began was the collaboration with Memorial University to develop a comprehensive, end-to-end online administrative system to facilitate the review of health research in the province. The system (ROMEO) will provide researchers and administrators a web-based application process which automates the ethics review process that the Authority oversees. This will also enable the Ethics Office to move to a paperless system for administrative purposes and also for the HREB review process. The system is anticipated to go-live in October, 2015.

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

7.0 Opportunities and Challenges:

The fourth year of operation has allowed the Authority to progress from the foundational work of the organization and 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.

In 2013, the Authority, as part of a quality assurance initiative, requested an independent peer review of the research ethics boards currently overseeing the ethics review of health research in the province. The Authority hosted two external peer reviewers for a site visit in October, 2013 to conduct their review. A final report of the findings provided was pending by end of fiscal year 2014-2015. The site visit report was finalized during this reporting period which provided an opportunity for the Authority to implement recommendations and subsequently foster a stronger accountability process for other approved research ethics bodies under the Act who review health research in the province. The Authority was able to identify future collaborative projects for the various research ethics bodies, such as the development of Standard Operating Procedures (SOPs) to enhance the review and oversight of health research. The Authority is currently drafting a process for approval and ongoing renewal of research ethics bodies under the Act to enhance the governance of ethics review of health research in NL.

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. 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) in September 2014 was 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
Ms. Sandra Reid, HREA, Ethics Director	HREA Ethics Office

Appendix B: Audited Financial Statements

Financial Statements

Health Research Ethics Authority
March 31, 2015



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, 2015, 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 in our audit 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, 2015 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
September 14, 2015

Chartered Professional Accountants

Health Research Ethics Authority

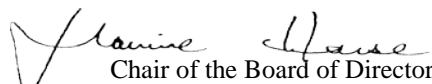
STATEMENT OF FINANCIAL POSITION

As at March 31

	2015	2014
	\$	\$
ASSETS		
Current		
Accounts receivable <i>[note 3]</i>	45,000	98,080
Prepaid expenses	10,333	11,094
Due from related parties <i>[note 6]</i>	370,164	231,600
Total current assets	425,497	340,774
Tangible capital assets, net <i>[note 4]</i>	2,074	3,457
	427,571	344,231
LIABILITIES AND NET ASSETS		
Current		
Accounts payable and accrued liabilities	25,449	27,135
Total current liabilities	25,449	27,135
Deferred capital contribution, net <i>[note 5]</i>	2,074	3,457
	27,523	30,592
Net assets	400,048	313,639
	427,571	344,231

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

	2015	2014
	\$	\$
REVENUE		
Support-in-kind <i>[note 6]</i>	195,510	217,745
Research project approval fees	144,000	198,000
Operating grants <i>[note 6]</i>	130,000	130,000
Amortization of deferred capital contribution	1,383	1,383
	470,893	547,128
EXPENDITURES		
Salaries and employee benefits	156,509	158,981
External contracts	101,899	115,266
Professional fees	16,697	39,177
Honorariums	33,688	33,270
Rent	28,502	28,502
Insurance	16,555	16,962
Travel	9,711	9,353
Catering, luncheon and receptions	5,432	4,914
Materials and supplies	5,201	6,163
Courier, freight and postage	3,666	1,652
Equipment rentals	3,496	3,500
Bad debt expense (recovery)	(3,355)	11,250
Telephone	2,668	3,297
Amortization	1,383	1,383
Conferences and seminars	1,265	1,883
Printing and photocopying	849	789
Membership and registration fees	318	240
Advertising	—	539
	384,484	437,121
Excess of revenue over expenditures	86,409	110,007

See accompanying notes

Health Research Ethics Authority

STATEMENT OF CHANGES IN NET ASSETS

Year ended March 31

	2015	2014
	\$	\$
Balance, beginning of year	313,639	203,632
Excess of revenue over expenditures	86,409	110,007
Balance, end of year	400,048	313,639

See accompanying notes

Health Research Ethics Authority

STATEMENT OF CASH FLOWS

Year ended March 31

	2015	2014
	\$	\$
OPERATING ACTIVITIES		
Excess of revenue over expenditures	86,409	110,007
Add (deduct) items not affecting cash		
Amortization of tangible capital assets	1,383	1,383
Amortization of deferred capital contributions	(1,383)	(1,383)
Net change in non-cash working capital balances		
Decrease (increase) in accounts receivable	53,080	(35,071)
Decrease (increase) in prepaid expenses	761	(760)
Increase (decrease) in accounts payable and accrued liabilities	(1,686)	12,082
Cash provided by operating activities	138,564	86,258
FINANCING ACTIVITY		
Increase in due from related parties	(138,564)	(86,258)
Cash used in financing activity	(138,564)	(86,258)
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, 2015

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 GNPO’s, 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 revenues 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 which will reduce the original cost to estimated residual value over the useful lives of the assets. Computers are amortized using a rate of 20%.

Health Research Ethics Authority

NOTES TO FINANCIAL STATEMENTS

March 31, 2015

Impairment of long-lived assets

Tangible capital 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 is 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 parties, 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.

Health Research Ethics Authority

NOTES TO FINANCIAL STATEMENTS

March 31, 2015

3. ACCOUNTS RECEIVABLE

Accounts receivable consist of the following:

	2015	2014
	\$	\$
Trade accounts receivable	61,500	109,330
Less: allowance for doubtful accounts	16,500	11,250
	<u>45,000</u>	<u>98,080</u>

4. TANGIBLE CAPITAL ASSETS

	Cost	2015 Accumulated amortization	Net book value	2014 Net book value
	\$	\$	\$	\$
Computers	<u>6,914</u>	<u>4,840</u>	<u>2,074</u>	<u>3,457</u>

5. DEFERRED CAPITAL CONTRIBUTIONS

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

	2015	2014
	\$	\$
Balance, beginning of year	3,457	4,840
Less amounts amortized to revenue	<u>1,383</u>	1,383
Balance, end of year	<u>2,074</u>	<u>3,457</u>

Health Research Ethics Authority

NOTES TO FINANCIAL STATEMENTS

March 31, 2015

6. RELATED PARTY TRANSACTIONS

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

	2015	2014
	\$	\$
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	195,510	217,745

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 the respective categories within the Statement of Operations and include the following:

	2015	2014
	\$	\$
Salaries and employee benefits	133,256	155,954
Rent	28,502	28,502
Professional fees	16,448	18,950
Office and administration fees	17,304	14,339
	195,510	217,745

The due from related parties balance is comprised of the following:

	2015	2014
	\$	\$
Due from Eastern Regional Health Authority	—	65,000
Due from Memorial University of Newfoundland	370,164	166,600
	370,164	231,600

The treasury function of the Authority is administered by Memorial and, therefore, the account with Memorial represents funds owed by Memorial. The amount owing from Eastern Health relates to the operating grant and is subject to normal trade terms. The amounts owing from Memorial and Eastern Health are non-interest bearing.

Health Research Ethics Authority

NOTES TO FINANCIAL STATEMENTS

March 31, 2015

7. FINANCIAL INSTRUMENTS AND RISK MANAGEMENT

The Authority has exposure to credit risk and liquidity risk. The Authority's Board of Directors has overall responsibility for the oversight of these risks and reviews the Authority's policies on an ongoing basis to ensure that these risks are appropriately managed. The source of risk exposure and how each is managed is outlined below.

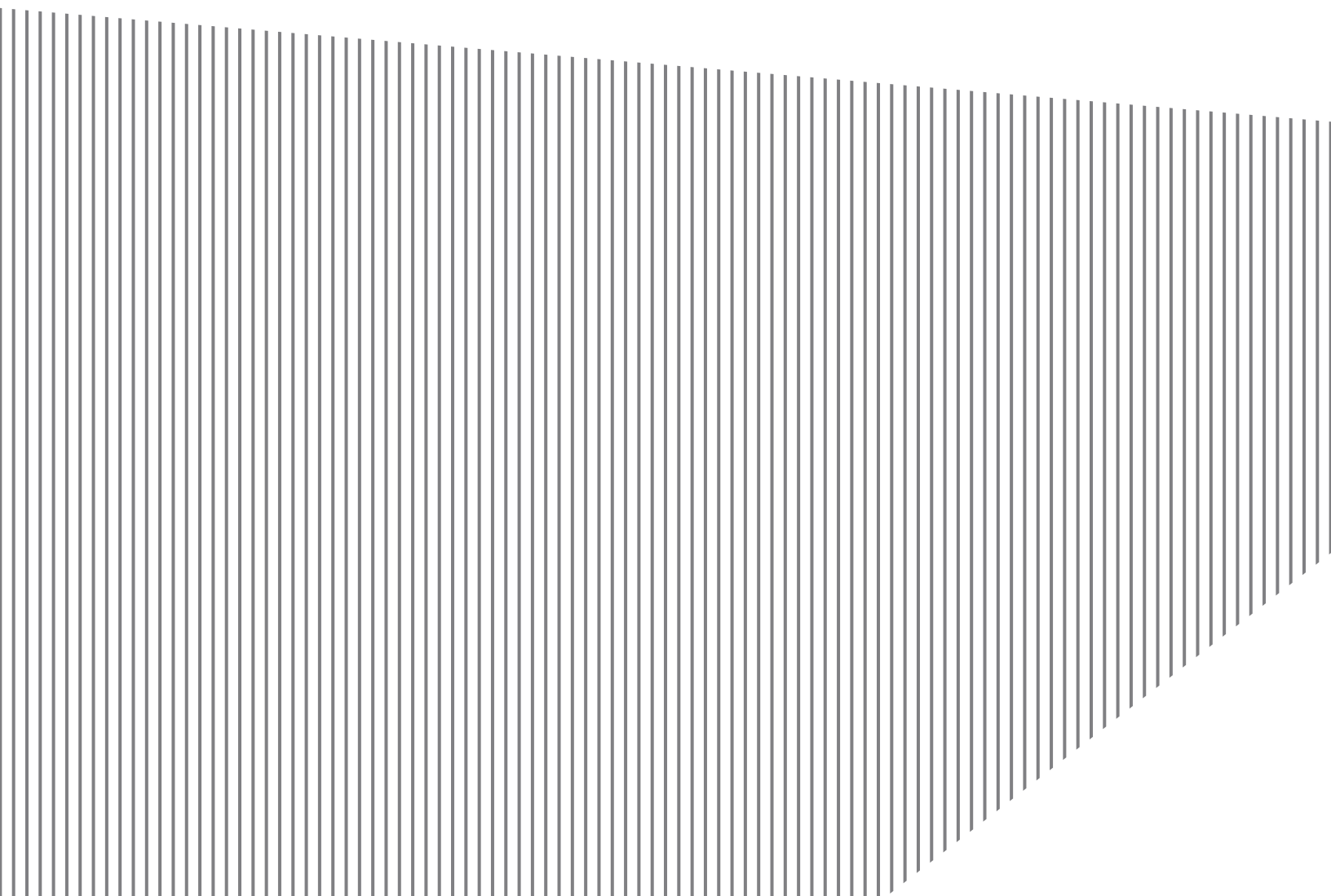
Credit risk

Credit risk is the risk of loss associated with counterparty's inability to fulfill its payment obligation. The Authority's credit risk is primarily attributed to accounts receivable and amounts due from related parties. 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, 2015, 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.



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 2010 (<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

Ethics Office

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