Activity Report

April 1, 2012 - March 31, 2013

Chairperson's Message

In accordance with the *Transparency and Accountability Act*, I am pleased to present the 2012-13 Activity Report for the Health Research Ethics Authority (HREA) hereafter referred to as the Authority. The Authority has been included under the *Transparency and Accountability Act* as a Category 3 entity and has planned and reported in keeping with these requirements. This report better enabled 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 second year of development and the extent to which planned and actual activities were met during fiscal year 2012-13.

As Chairperson of the Authority my signature below is indicative of the Authority's accountability for the results reported in this Activity Report and achievement of the objectives and any variances contained in this Activity Report.

Sincerely,

Dr. Larry Felt, Chairperson

Laure I felt

Health Research Ethics Authority

Table of Contents

1.0	Overview	.4
	Membership	.4
	Funding	.5
2.0	Primary Clients	.5
3.0	Mandate	.6
4.0	Values	.6
5.0	Vision	.7
6.0	Mission	.7
7.0	Annual Objectives	.8
8.0	Opportunities and Challenges	.14
Арр	pendix A – Authority Membership	. 15
Арр	pendix B – Strategic Directions	.16
Арр	pendix C – Reference Documents	. 17
aqA	pendix D – Audited Financial Statements	. 18

1.0 OVERVIEW

The Health Research Ethics 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 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 human 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 human health research.

The Authority is responsible for appointing the Health Research Ethics Board (HREB). The HREB has the legislated authority and responsibility for the ethical review and approval of applications for health research projects involving human subjects. By regulation, all clinical trials and genetics research conducted in Newfoundland and Labrador must be reviewed by the HREB. Other forms of human health research may be reviewed by the HREB or by other approved research ethics bodies established pursuant to section 8 of the Act.

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 Eastern Health, a representative of Memorial University of Newfoundland and Labrador (MUN), a representative employed by the Department of Health and Community Services and a public representative of the province. The Chairperson of the HREB is a member of the Authority by virtue of his or her office but does not have voting privileges. The Chairperson of the Authority is appointed by the Minister of Health and Community Services (see Appendix A).

An Ethics Officer is the senior employee of the Authority and reports to the Board of Directors of the Authority. The Ethics Officer is responsible for the operations and management of the Ethics Office and the HREB.

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 2012-2013 fiscal year, the Authority had operating expenditures of approximately \$374,000. Revenue of \$180,000 was derived from review fees levied by industry-funded contract research sponsored by pharmaceutical and other for-profit entities. The remaining funding was provided by MUN and Eastern Health.

The external audit conducted on the Authority's financial statements for the 2012-2013 fiscal year was completed by Ernst & Young. The finalized audited financial statements are attached as Appendix D.

2.0 Primary Clients

The primary clients of the Authority are the people of Newfoundland and Labrador. The Authority seeks to protect the people of Newfoundland and Labrador by ensuring that the specific stakeholders conducting health research, such as students, researchers, health professionals, health organizations, community groups, and sponsors, receive excellence in research review by members of research ethics boards (REBs). All of this activity was conducted under the Authority outlined in the HREA Act.

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;
- 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.

Concern for Welfare – Respecting and protecting research participants and assessing risks and potential benefits associated with participation in health research.

Performance Section

5.0 Vision

Excellence in Ethical Research Review

The Authority is committed to this vision by ensuring that all 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 research involving human participants and promoting the integrity of the health research environment.

6.0 Mission

The HREA chose not to include a mission as it would be redundant of the mandate, which is provided in Section 3.0: Mandate and the objective, which is in Section 7.0: Annual Objective.

7.0 Annual Objectives

As stated in the *Tri-Council Policy Statement*¹, health research may entail risks to participants and others. These risks can be trivial or profound, physical or psychological, individual or social. Ethical principles and guidelines played an important role in advancing the pursuit of knowledge while protecting and respecting research participants in order to try to prevent such occurrences. In 2012-13, the Authority continued to focus on developmental activities, such as establishing the Standing Appeal Panel to provide a second opinion on a decision of the HREB or a research ethics body approved by the Authority. During this time, the Authority also provided quality ethical review for health research conducted in Newfoundland and Labrador. The Authority required that Canadian and internationally accepted legal, ethical and regulatory principles affording protection of research participants governed the processes for HREB review and continued oversight of human health research.

During April 1, 2012 – March 31, 2013 the HREBs reviewed and evaluated 261 research proposals to ensure conformity with accepted scientific and ethical standards and applicable regulations and promoted the responsible conduct of research.

The Authority also held seven orientation and education sessions for targeted groups (HREB members, researchers and administrators) to ensure awareness of the changes to the process of ethics review in the province and provide continuing support to stakeholders.

The Authority's annual objective remains the same for the three years covered by its Activity Plan; however, the report provided for each year shows progress made in that fiscal year. Thus, the comments below are pertinent to progress in the fiscal year, April 1, 2012 to March 31, 2013. This activity supported the strategic direction of accountability and stability of health and community services and the focus area of health research (see Appendix B) by providing oversight of all health research being conducted in the province and maintaining a comprehensive inventory of all health research conducted in Newfoundland and Labrador.

_

¹ The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* is a joint policy of Canada's three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC), or "the Agencies." This Policy expresses the Agencies' continuing commitment to the people of Canada to promote the ethical conduct of research involving humans. As a condition of funding, the Agencies require that researchers and their institutions apply the ethical principles and the articles of this Policy and be guided by the application sections of the articles.

Objective: By March 31, 2013, the Authority will have provided quality ethical review of health research in Newfoundland and Labrador.

Measure: Provided quality ethical review of health research.

Indicators 2012-2013 Progress 2012-2013		
Provided oversight in the review	 The two subcommittees of 	
and decision- making on	the HREB (HREB – Clinical	
applications for health research	Trials and HREB – Non	
projects involving human subjects	Clinical Trials) continue to	
	function to review and	
	approve health research	
	involving human subjects.	
	The HREBs alternated	
	meetings on a weekly basis.	
	During the period April 1,	
	2012 to March 31, 2013, a	
	total of 261 applications were	
	reviewed by the two HREBs.	
	The Policy Advisory Group	
	(PAG) continued to respond	
	to requests from the staff of	
	the Ethics Office and the	
	Chairs of the HREBs. The	
	PAG is accountable to the	
	HREB and is appointed by	
	the HREB on the recommendation of the	
	HREB Chair and Vice-Chair	
	and the Ethics Officer (EO).	
	PAG also acts in response to	
	new legislation, regulations	
	and guidelines arising within	
	federal and provincial	
	jurisdictions, and international	
	regulatory bodies. PAG also	
	reviews previously approved	
	HREB policies. By end of	
	fiscal year 2013, a policy was	
	being developed regarding	
	the oversight and review of	
	registries of health	
	information that are compiled	

for public health mandated surveillance and research purposes. The Authority established a Standing Appeal Panel to provide a second opinion on a decision of the HREB or a research ethics body approved by the Authority. During the period April 1, 2012 - March 3, 2013, the Appeal Panel received one application for appeal which was still under deliberation by end of fiscal year 2013. • The Authority met monthly to discuss the operations of the organization. Produced information for public use The Authority maintained a on the ethical review of research publicly accessible website with information on the ethics review process for researchers, HREB members and key stakeholders: www.hrea.ca Seven orientation and education sessions were held to raise 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 was a key player in securing funding from the Panel on Research Ethics to host a regional workshop for all stakeholders in the Atlantic Provinces on the interpretation of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2).

The Authority was represented at three conferences: The Canadian Association of Research **Ethics Boards National** Annual General Meeting and Conference, The Canadian Association of Research **Ethics Boards Atlantic** Chapter and Public Responsibility in Medicine and Research Advancing Ethical Research Conference. The Authority was also represented at one workshop: The Aboriginal Health Research Ethics Workshop to discuss the new model of ethical review in the province and report on the activities of the HREBs. Established an inventory of all The Authority continued human health research conducted implementation of a in Newfoundland and Labrador standardized form (Notification Form) that all researchers must complete when submitting an ethics application. The Notification Form captures key information that will eventually be analyzed statistically to inform the Authority's work. During the period April 1, 2012 to March 31, 2013 the Notification Forms have formed the basis of a communication strategy being developed for the different Regional Health Authorities whereby the HREA is able to provide feedback on what research is being reviewed and approved for the various regions. The Authority inputs

information into two main databases which function as an inventory of all human health research conducted in Newfoundland and Labrador. The primary database was developed and launched in 2011 and is housed through MUN's Research Office. This database is linked to research funding which can only be released after appropriate ethics approval has been received. The secondary database is maintained by the Authority and is internal to the Ethics Office which captures all human health research that is being conducted in the province, irrespective of the funding source.

Rendered decisions on the establishment of other ethical review bodies in Newfoundland and Labrador

- The Authority did not receive any new requests for approval of a research ethics body during the period April 1, 2012 to March 31, 2013.
- The Authority continued planning for a site visit from appropriate external representatives to conduct a thorough evaluation to accredit both the HREBs and the Interdisciplinary Committee on Ethics in Human Research (ICEHR) which is an ethics review committee of Memorial University whose focus is on ethics review of the social sciences and humanities and studies employing qualitative methods. Two representatives have been identified to conduct the site

visit – one is a past president of the Canadian Association of Research Ethics Boards (CAREB) and the other is a previous member of the National Council on Ethics in Human Research (NCEHR) audit/evaluation team that reviewed the operations of research ethics boards across Canada.

Discussion of Results:

The Authority has made considerable progress in its developmental activities in its second year of operation. The Authority completed a lengthy negotiation with Memorial University on a Memorandum of Understanding (MOU) on administrative responsibilities and types/levels of support provided by the University to the HREA. The signing of the MOU was critical for the continuation of developmental activities such as the financial operations of the HREA's accounts. In addition to administrative progress, the ethics review of human health research by the HREBs and other approved research ethics bodies has been working well.

Annual Objective 2013 -2014:

The objectives and indicators below apply to the 2013-14 fiscal year and will be reported on in the respective annual report by the Authority.

Objective: By March 31, 2014, the Authority will have provided quality ethical review of health research in Newfoundland and Labrador.

Measure: Provided quality ethical review of health research

Indicators:

- Provided oversight in the review and decision- making on applications for health research projects involving human subjects
- Produced information for public use on the ethical review of research
- Established an inventory of all human health research conducted in Newfoundland and Labrador
- Rendered decisions on the establishment of other ethical review bodies in Newfoundland and Labrador

8.0 Opportunities and Challenges:

The second year of operation has allowed the Authority to continue to lay the foundation for many opportunities in the coming years to progress with developmental activities and core business.

As a new entity, and through the compilation of the 2011-2014 Activity Plan, the Authority identified the development of a communications strategy as a high priority. Particularly, given that the Authority is forming new partnerships with three different organisations (the Department of Health and Community Services, Eastern Regional Health Authority and Memorial University of Newfoundland), the Authority sees this as an opportunity to continue building positive working relationships with these bodies. Subsequently, one challenge the Authority will face is creating a seamless and transparent process that accommodates all three organisations. The signing of the Memorandum of Understanding (MOU) in 2012 has created a starting point for this process.

The Authority is continuously working towards maintaining, and ultimately expanding, clinical trial activity in the province. This may present a challenge in the future with the trend of declining base clinical trial activity across the country. However, the Authority sees the development of its new model of ethics review, which is more streamlined and efficient than the previous model, as an opportunity to encourage researchers to expand their clinical trial activity to the province. It is the view that the new model of ethics review will remove unnecessary barriers to start-up of clinical trials and be seen as facilitating research activity in the province.

Appendix A: Health Research Ethics Authority Membership

Position Title	Appointee/ Represents
Dr. Larry Felt, Chairperson	MUN
Ms. Katherine Chubbs, Director	Eastern Health
Ms. Jeannie House, Vice- Chairperson	Public
Ms. Tracy King, Director (resigned October 2012)	Department of Health and Community Services
Ms. Karen Stone, Director	
Dr. Fern Brunger, HREB Chairperson	Division of Community Health and Humanities, Faculty of Medicine, MUN

Appendix B: Strategic Directions

Strategic directions are the articulation of desired physical, social, or economic outcomes and normally require action by or involvement of, more than one government entity. They summarize the outcomes desired for the health sector and are communicated to entities that plan and report in collaboration with the Department.

Strategic Direction

Title: Accountability and stability of health and community services Outcome: Improved system performance and sustainability

Health is a priority of Government, such that record investments have been made for several consecutive years. In 2010, health and community services consumed approximately 42% of all government expenditures with the largest percentage allocated to regional health services (74.8 %). The ability to sustain the provision of quality services requires the coordination and integration of services, increased standardization and monitoring of clinical practice and service, and innovation. A focus on increased monitoring and evaluation, the achievement of balanced budgets, the stabilization of health human resources and increased utilization of information for evidence based practice will lead to a more sustainable health system and contribute to improved health outcomes for the people of the Province.

Focus Areas of the Strategic Direction	The Strategic Direction of Improved Accountability and Stability in the Delivery of Health and Community Services within Available Resources, is		
	Addressed by		
2011-2017	Activity Plan	Operational Plan	Work Plan
Health Research	Х		

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)

Appendix D: Audited Financial Statements

Financial Statements

Health Research Ethics Authority

March 31, 2013

INDEPENDENT AUDITORS' REPORT

To the Board of Directors of **Health Research Ethics Authority**

We have audited the accompanying financial statements of **Health Research Ethics Authority**, which comprise the statement of financial position as at March 31, 2013, 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 **Health Research Ethics Authority** as at March 31, 2013 and the results of its operations and its cash flows for the year then ended in accordance with Canadian public sector accounting standards.

Comparative information

Without modifying our opinion, we draw attention to Note 3 to the financial statements which describes that **Health Research Ethics Authority** adopted Canadian public sector accounting standards on March 31, 2012 with a transition date of April 1, 2011. These standards were applied retrospectively by management to the comparative information in these financial statements, including the balance sheet as at March 31, 2012, and the statements of operations, changes in net assets and cash flows for the year ended March 31, 2012, and related disclosures. We were not engaged to report on the restated comparative information, and as such, it is unaudited.

Ernst * young LLP

St. John's, Canada, September 27, 2013

Chartered Accountants

STATEMENT OF FINANCIAL POSITION

As at

	March 31, 2013	March 31, 2012
	2013 \$	2012 \$
		[unaudited]
ASSETS		
Current		
Accounts receivable	63,009	64,000
Prepaid expenses	10,334	10,333
Due from Eastern Regional Health Authority [note 7]	54,278	_
Due from Memorial University of Newfoundland [note 7]	91,064	30,116
Total current assets	218,685	104,449
Tangible capital assets, net [note 5]	4,840	6,223
	223,525	110,672
LIABILITIES AND NET ASSETS		
Current		
Accounts payable and accrued liabilities	15,053	15,053
Deferred revenue		10,722
Total current liabilities	15,053	25,775
Deferred capital contribution, net [note 6]	4,840	6,223
	19,893	31,998
Net assets	203,632	78,674
	223,525	110,672

See accompanying notes

On behalf of the Board:

Chair of the Board of Directors

STATEMENT OF OPERATIONS

	Year ended March 31, 2013	Nine-month period ended March 31, 2012
		[unaudited]
REVENUES		
Support-in-kind	187,711	159,408
Research project approval fees	180,000	133,000
Operating grant – Memorial University of Newfoundland	65,000	48,750
Operating grant – Eastern Regional Health Authority	65,000	48,750
Amortization of deferred capital contribution	1,383	691
•	499,094	390,599
EXPENDITURES	4	100000
Salaries and employee benefits	155,935	130,959
External contracts	119,705	70,352
Rent	21,377	21,377
Professional fees	20,115	51,922
Insurance	17,528	13,330
Travel	15,456	7,164
Membership and registration fees	6,517	775
Catering, luncheon and receptions	4,814	3,434
Equipment rentals	3,560	2,947
Telephone Materials and simplifies	3,006	2,096
Materials and supplies	2,601	1,571
Amortization	1,383	691
Courier, freight and postage	1,314 579	1,345
Advertising Printing and photocopying	246	1,324
Conferences and seminars	240	2,638
Comerciales and seminars	374,136	311,925
Excess of revenues over expenditures	124,958	78,674
LACESS OF TEVERILES OVER EXPERIENCES	127,730	70,074

See accompanying notes

STATEMENT OF CHANGES IN NET ASSETS

	Year ended March 31, 2013	Nine-month period ended March 31, 2012
		[unaudited]
Balance, beginning of period	78,674	_
Excess of revenues over expenditures	124,958	78,674
Balance, end of period	203,632	78,674

See accompanying notes

STATEMENT OF CASH FLOWS

	Year ended March 31, 2013	Nine-month period ended March 31, 2012
		[unaudited]
OPERATING ACTIVITIES		
Excess of revenues over expenditures Add (deduct) items not affecting cash	124,958	78,674
Amortization of tangible capital assets	1,383	691
Amortization of deferred capital contributions	(1,383)	(691)
Net change in non-cash working capital balances	(64,010)	(48,558)
Cash provided by operating activities	60,948	30,116
CAPITAL ACTIVITY		
Purchase of tangible capital assets	_	(6,914)
Cash used in investing activity		(6,914)
• • • • • • • • • • • • • • • • • • •		
FINANCING ACTIVITIES		
Due from Memorial University of Newfoundland	(60,948)	(30,116)
Deferred capital contributions received	_	6,914
Cash used in financing activities	(60,948)	(23,202)
Net change in cash during the period	_	_
Cash, beginning of period	<u> </u>	<u> </u>
Cash, end of period		

See accompanying notes

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 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 Eastern Health and Memorial.

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 [PSAB], 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.

Deferred revenue represents the unearned portion of the Authority's operating grant from Eastern Health.

Tangible capital assets

Purchased tangible capital assets are stated at cost. Amortization is computed on a declining balance 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%.

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 Authoroty by Memorial and Eastern Health, and the Board of Directors without charge. The costs that would otherwise associated 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 and the Board of Directors has not been recorded as the fair value is not determinable

Financial instruments

The Authority classified its financial instruments as amortized cost. This category includes accounts receivable, due from Eastern Health, due from Memorial, 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 revenues 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.

3. FIRST-TIME ADOPTION OF PUBLIC SECTOR ACCOUNTING STANDARDS

PSAB issued new standards for GNPO's for years beginning after January 1, 2012. GNPO's have a choice of:

- Public Sector Accounting Standards including PS 4200-4270 for government not-for-profit organizations; or
- Public Sector Accounting Standards without PS 4200-4270.

The Authority has chosed to follow Public Sector Accounting Stanards including PS 4200-4270 for GNPO's.

These financial statements are the first financial statements which the Authority has prepared in accordance with the Public Sector Accounting Handbook, which constitutes generally accepted accounting principles for GNPO's in Canada [GAAP]. First-time adoption of the new basis of accounting had no impact on excess of revenue over expenditures for the year ended March 31, 2012 or the net assets balance as at March 31, 2012.

4. IMPACT OF ADOPTING NEW ACCOUNTING STANDARDS

On April 1, 2012, the Authority adopted Public Sector Accounting standards *PS 3450 – Financial Instruments* ["*PS 345*"]. The standards were adopted prospectively from the date of adoption. The new standards provide comprehensive requirements for the recognition, measurement, presentation and disclosure of financial instruments.

Under PS 3450, all financial instruments, including derivatives, are included in the statement of financial position and are measured at fair value or amortized cost based on the characteristics of the instrument and the Authority's accounting policy choices [see note 2].

5. TANGIBLE CAPITAL ASSETS

Computers

		2013		2012
	Cost \$	Accumulated amortization	Net book value \$	Net book value \$
3	6,914	2,074	4,840	6,223

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.

	2013 \$	2012 \$
Balance, beginning of period	6,223	_
Contributions received	_	6,914
Less amounts amortized to revenue	1,383	691
Balance, end of period	4,840	6,223

7. RELATED PARTY TRANSACTIONS

The treasury function of the Authority is administered by Memorial and, therefore, the account with Memorial represents funds owed by Memorial. The amounts owing from Memorial and Eastern Health are non-interest bearing with no-set terms of repayment.

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 as managed by and due from Memorial. Management believes that the credit risk with respect to accounts receivable 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, 2013, the Authority continues to be in a position to meet its obligations.

To the extent that the Authority does not believe that it has sufficient liquidity to meet current obligations, consideration will be given to obtaining additional funds through related party financing, assuming this can be obtained.

Contact Information

Ethics Office

Health Research Ethics Authority Suite 200, 2nd floor, 95 Bonaventure Avenue St. John's, NL. A1B 2X5

> t: 709-777-6974 f: 709-777-8776 e: <u>info@hrea.ca</u>

web: www.hrea.ca