Health Research Ethics Authority

Activity Report

April 1, 2013 - March 31, 2014

Chairperson's Message

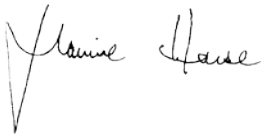
In accordance with the *Transparency and Accountability Act*, I am pleased to present the 2013-14 Activity Report for the Health Research Ethics Authority hereafter referred to as the Authority. Under the *Transparency and Accountability Act* the Authority is defined as a Category 3 entity, and as such, 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 third year of development and the extent to which planned and actual activities were met during fiscal year 2013-14.

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

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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 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 Officer 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 2013-2014fiscal year, the Authority had operating expenditures of approximately $437,121. Revenue of $198,000 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 2013-2014 fiscal year will be completed by Ernst & Young. The finalized audited financial statements, once received, will be attached as Appendix C.

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.

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 health research involving human participants and promoting the integrity of the health research environment.

6.0 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 2013-14, the Authority continued to focus on developmental activities; for example, as part of a quality assurance initiative, the HREA requested an independent peer review of the research ethics boards currently overseeing the ethics review of health research in the province. 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 health research involving human participants.

During April 1, 2013 – March 31, 2014 the HREBs reviewed and evaluated 304 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 eleven 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 remained 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, 2013 to March 31, 2014. This activity supported the strategic direction of accountability and stability of health and community services and the focus area of health research 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, 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 2013-2014	Progress 2013-2014
Provided oversight in the review and decision- making on applications for health research projects involving human subjects	• 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 the period April 1, 2013 to March 31, 2014, a total of 304 applications were reviewed by the two HREBs. • A subcommittee was formed during the period April 1, 2013 to March 31, 2014 to respond to proposed revisions to the second edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) that were open for public comment. • During the period April 1, 2013 to March 31, 2014, an appeal board rendered a final decision on an application for appeal from a decision of the research ethics board. • The Authority met monthly to discuss the operations of the organization.
Produced information for public use on the ethical review of research	• The Authority maintained a publicly accessible website with information on the ethics

	review process for researchers, HREB members and key stakeholders: www.hrea.ca • Eleven 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. • One of the above orientation sessions was video and audio recorded to create an archived webinar that will be accessible online and upon request in the future. • By end of fiscal year 2014, a new set of Guidelines had been created on behalf of the HREB in collaboration with the Labrador Health Research Advisory Committee (LAHRC) "*Guidelines for research involving Aboriginal communities in Newfoundland and Labrador*" to assist researchers with the process of engaging in research with Aboriginal communities of Newfoundland and Labrador • 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 on a national working group regarding clinical trials and participated in a roundtable discussion regarding health research in the province.
Established an inventory of all human health research conducted in Newfoundland and Labrador	• The Authority continued implementation of a 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, 2013 to March 31, 2014 the Notification Forms continued to form the basis of a communication strategy 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 a central database which functions as an inventory of all human health research conducted in Newfoundland and Labrador. The 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, 2013 to March 31, 2014. • 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 HREA hosted two external peer reviewers for a site visit in October, 2013 to conduct their review. A final report of the findings and recommendations was still pending by end of fiscal year 2014.

Discussion of Results:

The Authority has made considerable progress in its developmental activities in its third year of operation. The Authority made continued progress by contracting Grant Thornton to develop a comprehensive set of policies and procedures for the organization to enhance financial operations and other administrative responsibilities and increase transparency and accountability. These policies and procedures were under review by end of fiscal year 2014. 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.

7.0 Opportunities and Challenges:

The third 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 an evolving entity, and through the compilation of the new 2014-2017 Activity Plan, the Authority will promote the ethical conduct of health research within Newfoundland and Labrador by focusing on the development of a communications strategy to enhance public awareness of the ethical dimension of health research involving human subjects. In meeting this objective the Authority endeavours to develop and implement initiatives to improve the review process. Consideration will be given to feedback received during the first three years of operation and in consultation with stakeholders in the research community.

The finalization of the site visit report will also provide 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. To this end, the Authority aims to enhance the governance of ethics review of health research in NL.

Lastly, 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
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 Officer	HREA Ethics Office

Appendix B: Reference Documents

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

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 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 C: Audited Financial Statements

Financial Statements

Health Research Ethics Authority

March 31, 2014

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, 2014, 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, 2014 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 16, 2014.

Chartered Accountants

Health Research Ethics Authority

STATEMENT OF FINANCIAL POSITION

As at March 31

	2014 $	2013 $
ASSETS		
Current		
Accounts receivable	**98,080**	63,009
Prepaid expenses	**11,094**	10,334
Due from related parties *[note 5]*	**231,600**	145,342
Total current assets	**340,774**	218,685
Tangible capital assets, net *[note 3]*	**3,457**	4,840
	344,231	223,525
LIABILITIES AND NET ASSETS		
Current		
Accounts payable and accrued liabilities	**27,135**	15,053
Total current liabilities	**27,135**	15,053
Deferred capital contribution, net *[note 4]*	**3,457**	4,840
	30,592	19,893
Net assets	**313,639**	203,632
	344,231	223,525

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

	2014 $	2013 $
REVENUE		
Support-in-kind *[note 5]*	**217,745**	187,711
Research project approval fees	**198,000**	180,000
Operating grants *[note 5]*	**130,000**	130,000
Amortization of deferred capital contribution	**1,383**	1,383
	547,128	499,094
EXPENDITURES		
Salaries and employee benefits	**158,981**	155,935
External contracts	**115,266**	87,498
Professional fees	**39,177**	20,115
Honorariums	**33,270**	32,207
Rent	**28,502**	21,377
Insurance	**16,962**	17,528
Catering, luncheon and receptions	**4,914**	4,814
Travel	**9,353**	15,456
Bad debts	**11,250**	—
Materials and supplies	**6,163**	2,601
Equipment rentals	**3,500**	3,560
Telephone	**3,297**	3,006
Conferences and seminars	**1,883**	—
Courier, freight and postage	**1,652**	1,314
Amortization	**1,383**	1,383
Printing and photocopying	**789**	246
Advertising	**539**	579
Membership and registration fees	**240**	6,517
	437,121	374,136
Excess of revenue over expenditures	**110,007**	124,958

See accompanying notes

Health Research Ethics Authority

STATEMENT OF CHANGES IN NET ASSETS

Year ended March 31

	2014	2013
	$	$
Balance, beginning of year	**203,632**	78,674
Excess of revenue over expenditures	**110,007**	124,958
Balance, end of year	**313,639**	203,632

See accompanying notes

Health Research Ethics Authority

STATEMENT OF CASH FLOWS

Year ended March 31

	2014	2013
	$	$
OPERATING ACTIVITIES		
Excess of revenue over expenditures	**110,007**	124,958
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	**(23,749)**	(64,010)
Cash provided by operating activities	**86,258**	60,948
FINANCING ACTIVITY		
Due from related parties	**(86,258)**	(60,948)
Cash used in financing activity	**(86,258)**	(60,948)
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, 2014

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 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%.

NOTES TO FINANCIAL STATEMENTS

March 31, 2014

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, and the Board of Directors 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 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 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.

NOTES TO FINANCIAL STATEMENTS

March 31, 2014

3. TANGIBLE CAPITAL ASSETS

	2014			2013
	Cost	**Accumulated amortization**	**Net book value**	**Net book value**
	$	$	$	$
Computers	**6,914**	**3,457**	**3,457**	4,840

4. 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.

	2014	**2013**
	$	$
Balance, beginning of year	**4,840**	6,223
Less amounts amortized to revenue	**1,383**	1,383
Balance, end of year	**3,457**	4,840

5. RELATED PARTY TRANSACTIONS

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

	2014	**2013**
	$	$
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	**217,745**	187,711

NOTES TO FINANCIAL STATEMENTS

March 31, 2014

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:

	2014 $	**2013** $
Salaries and employee benefits	**155,954**	152,212
Rent	**28,502**	21,377
Professional fees	**18,950**	—
Office and administration fees	**14,339**	14,122
	217,745	187,711

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

	2014 $	**2013** $
Due from Eastern Regional Health Authority	**65,000**	54,278
Due from Memorial University of Newfoundland	**166,600**	91,064
	231,600	145,342

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.

6. 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.

NOTES TO FINANCIAL STATEMENTS

March 31, 2014

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, 2014, the Authority continues to be in a position to meet its obligations.

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

Contact Information

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